OSIRIS THERAPEUTICS, INC.
Form PRER14A
July 01, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A

(Rule 14a-101)
Information Required in Proxy Statement
Schedule 14A Information

Proxy Statement Pursuant to Section 14(a) of
the Securities Exchange Act of 1934 (Amendment No.)

Filed by the Registrant x

Filed by a Party other than the Registrant o

Check the appropriate box:
x Preliminary Proxy Statement

o **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

o Definitive Proxy Statement
o Definitive Additional Materials
o Soliciting Material Pursuant to §240.14a-12

OSIRIS THERAPEUTICS, INC.
(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):
o No fee required.

o Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

x Fee paid previously with preliminary materials.

o Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

7015 Albert Einstein Drive
Columbia, Maryland 21046
Phone: 443.545.1800
Fax: 443.545.1701

www.Osiris.com

, 2008

Dear Stockholder,

You are cordially invited to attend a special meeting of stockholders of Osiris Therapeutics, Inc. to be held at 2:00 p.m. Eastern Daylight Time (EDT), on , , 2008, at the principal executive offices of Osiris Therapeutics, Inc., located at 7015 Albert Einstein Drive, Columbia, Maryland 21046. At this meeting, we will seek stockholder approval of an asset purchase agreement with NuVasive, Inc. and the transactions contemplated thereby, including the sale by us to NuVasive of our Osteocel product line, including Osteocel® and Osteocel® XO, and related business assets.

On May 8, 2008, we entered into the asset purchase agreement with NuVasive, Inc., a medical device company headquartered in San Diego, California and focused on the design, development and marketing of products for the surgical treatment of spine disorders. The business assets to be sold pursuant to the asset purchase agreement involve the processing, manufacturing, marketing and selling of Osteocel, and a similar formulation in development, Osteocel XO. Osteocel is an allograft material containing cancellous bone, used in spinal fusion and other surgical procedures. Subject to the terms of the asset purchase agreement, the sale will be effected at two closings a technology assets closing which is expected to occur as soon as practicable following the satisfaction of various conditions precedent; and a manufacturing assets closing which is expected to occur within approximately eighteen months following the technology assets closing. During the period between the technology assets closing and the manufacturing assets closing, we will continue to manufacture or have manufactured, and supply, Osteocel pursuant to a manufacturing agreement to be entered into by us and NuVasive at the time of the technology assets closing. At the manufacturing assets closing we will transfer to NuVasive specified manufacturing equipment and facilities currently employed by us in the manufacture of Osteocel. Our business related to Osteocel and Osteocel XO will then terminate.

Enclosed with this letter is a Notice of Special Meeting, a Proxy Statement, and a Proxy Card and return envelope. Before deciding how to vote, you should review in detail the attached proxy statement for a more detailed explanation of the proposal to approve the sale, a description of the asset purchase agreement and the related manufacturing agreement, the background of the decision to enter into the asset purchase agreement, the reasons that our Board of Directors has decided to recommend that you approve the asset purchase agreement and the transactions contemplated thereby and a discussion of risk factors and other considerations, which appear in the sections of the proxy statement entitled Risk Factors and Other Considerations.

Our Board of Directors has unanimously approved and recommends that you vote FOR approval of the asset purchase agreement and the transactions contemplated thereby, all as further described in the accompanying proxy statement.

We hope you will be able to attend the special meeting. Your vote is important. Whether or not you plan to attend the special meeting, we urge you to vote. You are urged to vote by signing, dating and promptly returning the proxy card in the enclosed prepaid return envelope. Your proxy will be voted at the special meeting in accordance with your instructions. Failure to return a properly executed proxy card or to vote at the special meeting will have the same effect as a vote AGAINST approval of the asset purchase agreement and the transactions contemplated thereby. If you do not specify a choice on the proposal described in this proxy statement, your proxy will be voted as recommended by our Board of Directors. If you hold your shares through an account with a brokerage firm or other nominee or fiduciary such as a bank, please follow the instructions you receive from such brokerage firm or other nominee or fiduciary to vote your shares. Of course, if you attend the special meeting you may revoke your proxy and vote in person if you wish, even if you have previously returned your proxy card.

You may be asked to present valid picture identification at the special meeting, such as a driver s license or passport. Cameras, recording devices and other electronic devices will not be permitted at the meeting.

Sincerely,

C. Randal Mills, Ph.D.
President and Chief Executive Officer

YOUR VOTE IS IMPORTANT.

PLEASE RETURN YOUR PROXY CARD PROMPTLY.

OSIRIS THERAPEUTICS, INC.

7015 ALBERT EINSTEIN DRIVE

COLUMBIA, MARYLAND 21046

NOTICE OF SPECIAL MEETING OF STOCKHOLDERS
TO BE HELD ON , 2008

DATE: , 2008
TIME: 2:00 p.m. EDT
PLACE: The offices of Osiris Therapeutics, Inc., 7015 Albert Einstein Drive, Columbia, Maryland 21046

PURPOSES:

1. To approve the asset purchase agreement by and between Osiris Therapeutics, Inc. and NuVasive, Inc. (a copy of which is attached as Appendix A to the proxy statement accompanying this Notice of Special Meeting), and the transactions contemplated thereby, including the sale to NuVasive of our Osteocel product line, including Osteocel® and Osteocel® XO, and related business assets; and

2. To transact such other business as may properly come before the meeting or any postponements or adjournments thereof.

Our Board of Directors has unanimously approved and recommends that you vote FOR approval of the asset purchase agreement and the transactions contemplated thereby, all as further described in the accompanying proxy statement.

WHO MAY VOTE:

You may vote if you were the record owner of Osiris Therapeutics, Inc. common stock at the close of business on , 2008. A list of stockholders of record will be available at the special meeting and during the 10 days prior to the meeting, at the office of the Corporate Secretary at the above address. This notice and proxy are first being mailed to stockholders on or about , 2008.

Stockholders are urged to carefully review the information contained in the accompanying proxy statement prior to deciding how to vote their shares at the special meeting.

All stockholders are cordially invited to attend the special meeting. Your participation in the special meeting, in person or by proxy, is important. Whether you plan to attend the special meeting or not, you are requested to complete, sign, date and return the enclosed proxy card as soon as possible in accordance with the instructions on the proxy card. A pre-addressed, postage prepaid return envelope is enclosed for your convenience. Your prompt cooperation will be greatly appreciated.

BY ORDER OF THE BOARD OF DIRECTORS

Philip R. Jacoby, Jr.
Corporate Secretary

, 2008

7015 Albert Einstein Drive
Columbia, Maryland 21046
Phone: 443.545.1800
Fax: 443.545.1701

www.Osiris.com

, 2008

PROXY STATEMENT FOR SPECIAL MEETING OF STOCKHOLDERS

This proxy statement provides information that you should read before you vote on the proposal that will be presented at the special meeting of stockholders of Osiris Therapeutics, Inc. The special meeting will be held on , 2008, at 2:00 p.m., EDT, at Osiris Therapeutics, Inc. s principal executive offices, located at 7015 Albert Einstein Drive, Columbia, Maryland 21046.

On or about , 2008, we began mailing this proxy statement and the accompanying proxy card to stockholders who according to our records owned shares of our common stock at the close of business on , 2008.

This proxy statement is available electronically at *http://www.osiris.com*.

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SUMMARY TERM SHEET

This summary term sheet highlights material terms of the asset purchase agreement and related documents, and the proposed sale by us to NuVasive of our Osteocel product line, including Osteocel® and Osteocel® XO, and related business assets, and also highlights selected information described in greater detail elsewhere in this proxy statement. This summary term sheet does not contain all of the information that may be important to you in evaluating the asset purchase agreement and proposed sale. To understand fully the terms of the asset purchase agreement and proposed sale, we strongly encourage you to read this proxy statement in its entirety, including the information incorporated by reference and the appendices. We have included page references in this summary term sheet to direct you to a more complete discussion of certain topics in the proxy statement.

NuVasive, Inc. (see page 21)	NuVasive, Inc., a Delaware corporation, is the proposed purchaser under the Asset Purchase Agreement, dated May 8, 2008. NuVasive is a medical device company focused on the design, development and marketing of products for the surgical treatment of spine disorders. NuVasive s product portfolio is focused on applications in the over $4.2 billion U.S. spine fusion market. NuVasive s current principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS®, as well as a growing offering of cervical and motion preservation products.
Osiris Therapeutics, Inc. (see page 21)	Osiris Therapeutics, Inc., a Delaware corporation, is a stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. We currently manufacture, market and sell Osteocel, an allograft material containing cancellous bone for regenerating bone in orthopedic indications. Osteocel XO is a similar formulation under development, also using cancellous bone. Our core business, however, is the development of biologic drug candidates containing mesenchymal stem cells, including Prochymal , which is being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease and also Crohn s disease. Prochymal is the only stem cell therapeutic currently designated by the FDA as both an Orphan Drug and Fast Track product. We have also partnered with Genzyme Corporation to develop Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies. Additionally, Prochymal is being developed for the repair of heart tissue following a heart attack, for the protection of pancreatic islet cells in patients with type 1 diabetes and for the treatment of moderate to severe chronic obstructive pulmonary disease. Our pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen for osteoarthritis in the knee.
Osteocel Asset Sale (see page 21)	We are selling our Osteocel product line, including Osteocel and Osteocel XO, and related business assets.
	The sale will be effected at two closings a technology assets closing which is expected to occur as soon as practicable following the satisfaction of various conditions precedent; and a manufacturing assets closing which is expected to occur within approximately eighteen months following the technology assets closing. During the period between the technology assets closing and the manufacturing assets closing, we will continue to manufacture or have manufactured, and supply, Osteocel, pursuant to a manufacturing agreement to be entered into between us and NuVasive at the time of the technology assets closing. At the technology assets closing, we will transfer to NuVasive technology and other business assets related to the first generation Osteocel product line including intellectual property, permits, data and records, and contract rights related to the development, manufacturing and sale of Osteocel and Osteocel XO. At the manufacturing assets closing, we will transfer specified Osteocel manufacturing equipment and facilities to NuVasive, including the leasehold interest in our Columbia, Maryland administrative offices and Osteocel processing facility. Our business related to Osteocel and Osteocel XO will then

terminate.

Manufacturing Agreement (see page 22 and 34)	In connection with the sale of the technology assets of the Osteocel business pursuant to the asset purchase agreement, we and NuVasive agreed to enter into a manufacturing agreement under which we will continue to process Osteocel and supply Osteocel to NuVasive for a period of eighteen months after the technology assets closing. During the term of the manufacturing agreement, NuVasive is responsible for submitting binding purchase orders to us, for stated minimum quantities of Osteocel over certain stated periods. Assuming that we can produce sufficient quantities in a timely manner, we estimate that we will have the opportunity to generate in excess of $50.0 million in revenue related to the manufacture and supply of Osteocel pursuant to the manufacturing agreement over a period of approximately eighteen months following the technology assets closing.
Osteocel XC (see page 28)	Osteocel XC is the name we use to refer to our second generation mesenchymal stem cell product candidate for bone repair, which would utilize culture expanded mesenchymal stem cells to create a synthetic version of Osteocel. We are not currently selling Osteocel XC to NuVasive pursuant to the asset purchase agreement, and we are not currently engaged in an active product development program focused specifically on Osteocel XC. We have, however, granted NuVasive a right pursuant to the asset purchase agreement to acquire exclusive rights to Osteocel XC through December 31, 2009 on generally predefined terms subject, in part, to final negotiation. Through that same date, NuVasive is also afforded a right of first negotiation prior to any other transaction involving the transfer of Osteocel XC by us to a third party.
Reasons for the Sale (see page 12)	While the assets to be transferred represent a profitable product line for us, our Board of Directors believes they are not core to our business. Our Board of Directors believes it is appropriate and in our best interest and the best interest of our stockholders to sell these non-core assets and to invest the proceeds from the sale in our core research and development activities. In deciding to authorize the sale, our Board of Directors considered a number of positive and negative factors, discussed in more detail later in this proxy statement under the heading Sale of Osteocel Business.
Purchase Price (see page 23)	The initial purchase price to be paid to us at the technology assets closing will be $35.0 million in cash. The milestone payment to be paid to us at the manufacturing assets closing will be $12.5 million, payable either in cash or in shares of NuVasive common stock having then equivalent market value. In addition, during the interim period between the technology assets closing and the manufacturing assets closing and, if applicable, after the manufacturing assets closing, we have the ability to earn additional milestone payments not to exceed approximately $37.5 million in the aggregate. Receipt of each of the milestone payments is conditioned upon the satisfaction of certain conditions, including conditions relating to the production and delivery by us of agreed upon quantities of Osteocel on or before certain agreed upon dates, and completion of the transfer of the manufacturing assets in accordance with agreed upon terms. These milestone payments may be paid, at the discretion of NuVasive, in cash or in shares of NuVasive common stock having then equivalent market value. We have the opportunity to derive additional fee revenue during this interim period of in excess of $50.0 million from the manufacture and supply of Osteocel product under the manufacturing agreement, which imposes minimum purchase order obligations on NuVasive during the term of the agreement.

Assumed and Excluded Liabilities (see page 22)	NuVasive has not agreed to assume any of our current liabilities. NuVasive has, however, agreed to assume the obligations to perform arising in the ordinary course of the Osteocel business after the technology assets closing date with respect to certain contracts to be assumed by NuVasive which constitute a portion of the technology assets, and after the manufacturing assets closing date with respect to certain contracts to be assumed by NuVasive which constitute a portion of the manufacturing assets. Additionally, NuVasive has agreed to assume all expenses and liabilities relating to the Osteocel business that arise in the ordinary course of the Osteocel business consistent with past practice after the technology assets closing.
Conditions to the Technology Assets Closing (see page 30)	The obligation of each party to complete the purchase and sale of the assets to be transferred at the technology assets closing is subject to the satisfaction or waiver of the following conditions:

- receipt of all authorizations, consents, approvals and permits of governmental authorities specified in the asset purchase agreement, including the expiration or termination of any waiting period (including any extensions thereof) under the Hart-Scott-Rodino Act (which has now been satisfied);

- absence of any change in law or regulation or the presence of any injunction or other judgment or order that would restrain or otherwise prevent the proposed sale;

- absence of any action, suit, proceeding, claim, arbitration or investigation pending that is reasonably expected to result in an unfavorable judgment, order, decree, stipulation or injunction that would prohibit the transfer of the technology assets or cause such transfer to be rescinded;

- approval of the asset purchase agreement and the transactions contemplated thereby, by our stockholders;

- execution and delivery by us and NuVasive of the manufacturing agreement and a license agreement;

- execution and delivery of the other specified ancillary agreements and documents by us, NuVasive and/or each of our representatives; and

- other customary closing conditions.

Our obligation to complete the sale of the assets at the technology assets closing is subject to the satisfaction or waiver of the following conditions:

- the representations and warranties of NuVasive in the asset purchase agreement must be true and correct in all material respects (except those qualified by materiality or relating to the corporate status, organizational and governing documents, authorization of the transaction and corporate authority, which must be true and correct in all respects);

- NuVasive having performed in all material respects its pre-closing obligations and covenants; and

- other customary closing conditions.

NuVasive s obligation to complete the purchase of the assets at the technology assets closing is subject to the satisfaction or waiver of the following conditions:

- the representations and warranties by us in the asset purchase agreement must be true and correct in all material respects (except those qualified by materiality or relating to the corporate status, organizational and governing documents, authorization of the transaction and corporate authority, and the title to and sufficiency of the transferred assets, which must be true and correct in all respects);

- our having performed in all material respects our pre-closing obligations and covenants;

- the absence of any material adverse event or development related to the Osteocel business;

- the absence of any liens, other than permitted liens, on the technology assets;

- we shall have received the required consents and delivered the required notices with respect to the sale of the assets; and

- other customary closing conditions.

Conditions to the Manufacturing Assets Closing
(see page 24)

NuVasive s obligation to pay the third milestone payment of approximately $12.5 million at the time of the manufacturing assets closing is subject to satisfaction or waiver of the following conditions:

- our representations and warranties in the asset purchase agreement must be true and correct in all material respects (except those qualified by materiality or relating to the corporate status, organizational and governing documents, authorization of the transaction and corporate authority, and the title and sufficiency of the transferred assets which must be true and correct in all respects);

- our having performed in all material respects our obligations and covenants with respect to the manufacturing assets and the transfer thereof;

- the absence of any action, suit, proceeding, claim, arbitration or investigation pending that is reasonably expected to result in an unfavorable judgment, order, decree, stipulation or injunction that would prevent the transfer of the manufacturing assets or cause such transfer to be rescinded;

- the absence of any liens, other than permitted liens, on the manufacturing assets;

- delivery of certain ancillary agreements, documents and certificates;

- the absence of any material adverse event or development related to the manufacturing assets;

- the absence of any change in law or regulation or the presence of any injunction or order that would restrain or otherwise prevent the proposed sale of the manufacturing assets; and

- other customary closing conditions.

No Bids
(see page 27)

We have agreed that, after execution of the asset purchase agreement and prior to the earlier of the manufacturing assets closing or the termination of the asset purchase agreement, we will not directly or indirectly, initiate, solicit, entertain or encourage any other entity or person to make a proposal to us to acquire any of the assets to be transferred pursuant to the asset purchase agreement or negotiate, discuss, or enter into an agreement related to such a proposal.

If, however, if at any time prior to obtaining stockholder approval for the asset sale, we receive an unsolicited proposal that our Board of Directors determines in good faith to be superior to NuVasive s proposal and determines in good faith and after consultation with outside counsel that it must take action with respect to such proposal to avoid a breach of its fiduciary duties under Delaware law, and notifies NuVasive of such proposal and after good faith negotiations with NuVasive, our Board of Directors determines that such proposal remains superior to NuVasive s proposal, we may furnish nonpublic information to, and negotiate with, the party making the superior proposal. After compliance with notice and negotiation provisions of the asset purchase agreement, our Board of Directors may withdraw, modify or qualify its recommendation that our stockholders approve the asset purchase agreement and the transactions contemplated thereby, and recommend the superior proposal. Notwithstanding such superior proposal or change in the recommendation of our Board of Directors, we are obligated to hold the stockholder meeting for purposes of approving the asset purchase agreement and the transactions contemplated thereby.

Non-Compete
(see page 27)

We have agreed, for a period beginning with the technology assets closing and ending eighteen months after the manufacturing assets closing, not to engage in any business or activities, either directly or indirectly, that compete with the Osteocel business (other than our activities with respect to Osteocel XC), or solicit or encourage any employee, consultant or customer of NuVasive to leave the employ of, or cease doing business with, NuVasive.

Indemnification
(see page 32)

The parties have agreed to indemnify one another for any fraud, misrepresentations or breaches of representations, warranties and covenants contained in the asset purchase agreement. In addition, we have agreed to indemnify NuVasive for any retained liabilities and NuVasive has agreed to indemnify us for any assumed liabilities. With respect to the indemnification related to breach of representations, warranties and covenants, each party s right to indemnification will generally arise after its losses reach $250,000, with limited exceptions, and then it will receive payments for all losses, with the maximum indemnity payments for such losses equal to $15 million, except in the case of any breach by us of representations related to certain specified matters, as respects which the overall liability cap is increased to $20 million plus the amount of any milestone payment(s) earned by us, up to an aggregate total of $35 million. The obligations of each party to make any payment in respect of losses arising from fraud, intentional misrepresentation or intentional breach of a transaction document, and with respect to the assumed and excluded liabilities, is unlimited.

Termination
(see page 31)

The asset purchase agreement may be terminated at any time prior to the technology assets closing:

- by mutual consent of the parties;

- by either party, if, without the fault of the terminating party, the technology assets closing does not take place before September 8, 2008, subject to certain extensions;

- by either party, if a court or governmental entity permanently enjoins, restrains or prohibits the sale;

- by either party, if the asset purchase agreement is not approved by our stockholders provided that we may not terminate the agreement if failure to receive approval is caused by our action or failure to act and such action or failure to act constitutes a breach by us of the agreement;

- by either party, if the non-terminating party has breached any representation, warranty, covenant or agreement in any material respect, if such breach is not cured within 10 days; and

- by NuVasive if our Board of Directors changes its recommendation with respect to the sale.

We have agreed to pay NuVasive a $350,000 fee to cover negotiation expenses if the closing does not take place before September 8, 2008 and at the time of such termination stockholder approval has not been obtained and/or if our stockholders do not approve the asset purchase agreement and the transactions contemplated thereby.

If, however, the agreement is terminated after our Board of Directors changes its recommendation with respect to the asset sale, we are required to pay NuVasive a $2 million fee.

Closings
(see page 22)

The technology assets closing will take place promptly after the receipt of all necessary consents and approvals. The manufacturing assets closing will take place promptly after the earlier to occur of (i) the termination of the manufacturing agreement by NuVasive, or (ii) the expiration of the stated term of the manufacturing agreement, which is eighteen months.

Risk Factors
(see page 15)

There are risks and uncertainties related to the proposed sale, and risks to and uncertainties for us if the proposed sale is completed. You should carefully consider all of these risks and uncertainties in deciding how to vote on the proposal to approve the asset purchase agreement and the transactions contemplated thereby. If any of these risks occur, the business, financial condition or results of operation of our could be materially adversely affected, the value of its common stock could decline and you may lose all or part of your investment.

Accounting Treatment
(see page 19)

The sale of our Osteocel business will be accounted for as a sale of net assets. We believe that upon the technology assets closing we will recognize a gain on the sale of the assets.

Tax Consequences
(see page 20)

The proposed sale will be a taxable sale of assets. We anticipate that we will be able to offset substantially all of the taxable gain to be recognized for United States federal income tax purposes against our current operating and capital losses and net operating and capital loss carryforwards.

The sale of assets contemplated by the asset purchase agreement will not be a taxable event for our stockholders under applicable United States federal income tax laws.

Required Approvals
(see page 19)

The ability of the parties to consummate the sale is subject to the expiration of the applicable waiting period (including any extensions) under the U.S. Hart-Scott-Rodino Act (which waiting period has now been satisfied), and satisfaction of certain requirements of the U.S. Securities and Exchange Commission in connection with this proxy statement. We are also seeking stockholder approval pursuant to this proxy statement to satisfy any approvals which may be required in respect of the asset purchase agreement and the transactions contemplated thereby under the Delaware General Corporation Law.

Company Voting and Support Agreements (see page 19)	Officers and directors of ours, and certain of their affiliates, holding approximately 47% of our outstanding voting stock, have executed voting agreements committing to vote for the approval of the asset purchase agreement and the transactions contemplated thereby, subject in some cases to certain exceptions typical in voting agreements of this type, which allow for a reduction of the committed shares to 38%. Included among those who have executed voting agreements are Peter Friedli, the Chairman of the Board of Directors and our single largest stockholder, and certain of his affiliates, including Venturetec, Inc. and U.S. Venture 05, Inc., and C. Randal Mills, our President and CEO and a member of our Board of Directors.
Appraisal Rights (see page 19)	Under Delaware law and our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, our stockholders do not have appraisal rights as a result of the proposed sale.
Fees and Expenses (see page 21)	Except as described above in certain termination events, each of the parties has paid and will pay its own expenses in connection with the asset purchase agreement and the transactions contemplated thereby.
No Payments to Stockholders (see page 11)	All of the consideration received in the proposed sale will be paid to us. No payments will be made to any of our stockholders.

QUESTIONS AND ANSWERS REGARDING THE SPECIAL MEETING

Set forth below are some key questions and answers to provide you with more information about the special meeting. These questions and answers are qualified in their entirety by reference to the more detailed information appearing elsewhere in or accompanying this proxy statement. We urge you to review the entire proxy statement and accompanying materials carefully.

SPECIAL MEETING AND VOTING

Q: Why am I receiving this proxy statement?

A: You have received this proxy statement and the enclosed proxy card from us because you held shares of our common stock on , 2008, the record date for the special meeting of stockholders.

Q: What is the proposal I will be voting on at the special meeting?

A: As a stockholder, you are requested to approve the asset purchase agreement with NuVasive, Inc., dated May 8, 2008, and the transactions contemplated thereby, including the sale by us to NuVasive of our Osteocel product line, including Osteocel® and Osteocel® XO, and related business assets. Our Board of Directors is not aware of any other matters to be presented at the special meeting. If any other matters should properly come before the special meeting, the persons named as proxies in the enclosed proxy card will vote the proxies in accordance with their best judgment.

Q: Who is entitled to vote?

A: Only holders of record of shares of our common stock on the close of business on , 2008 will be entitled to vote at the special meeting. Each share of our common stock issued and outstanding on the record date will be entitled to one vote. On , 2008, we began mailing this proxy statement to all persons entitled to vote at the special meeting. At the close of business on , 2008, there were shares of common stock outstanding, which constitute all of our voting shares.

Q: When and where is the special meeting being held?

A: The special meeting is being held on , 2008 at our principal executive offices located at 7015 Albert Einstein Drive, Columbia, Maryland 21046, at 2:00 P.M., EDT.

Q: What vote is required to approve the asset purchase agreement?

A: Under Delaware law and our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, the affirmative vote of the holders of a majority of our outstanding shares of common stock is required for stockholder approval of the asset purchase agreement and the transactions contemplated thereby.

Q: Who is soliciting my proxy?

A: Our Board of Directors is soliciting your proxy. We are paying the cost of requesting these proxies. Our directors, officers and employees may request proxies in person or by telephone, mail, facsimile or otherwise, but they will not receive additional compensation for their services. We have not retained any third parties to assist us in soliciting proxies for the special meeting.

Q: How does the Board of Directors recommend that I vote at the special meeting?

A: The Board of Directors unanimously recommends that you vote FOR proposal No. 1, including the approval of the asset purchase agreement and the transactions contemplated thereby.

Q: How is my vote counted if I vote by proxy?

A: If you decide to vote by proxy, your proxy card will be valid only if you sign, date and return it before the special meeting to be held on , 2008. You may vote FOR, AGAINST or ABSTAIN. If you fail to vote FOR the sale or you ABSTAIN, it has the same effect as a vote AGAINST the proposal.

Q: What if my shares are held in street name, will my broker be able to vote my shares?

A: Yes, but only if you provide instructions to your broker on how to vote.

Q: Can I change my vote after I have mailed my signed proxy card?

A: Yes, you may change your vote at any time before your shares are voted at the special meeting. You may change your vote in one of three ways:

1. You may notify the Corporate Secretary of Osiris in writing before the special meeting that you wish to revoke your proxy. In this case, please contact Osiris Therapeutics, Inc., 7015 Albert Einstein Avenue, Columbia, Maryland 21046, Attention: Philip R. Jacoby, Jr., Corporate Secretary.

2. You may submit a signed and dated proxy that is dated later than your original proxy.

3. You may attend the special meeting and vote. Merely attending the special meeting will not by itself revoke a proxy; you must obtain a ballot and vote your shares to revoke the previously submitted proxy.

PROPOSED SALE OF ASSETS

Q: What assets are being sold?

A: We are selling our Osteocel product line, including Osteocel and Osteocel XO, and related business assets. Osteocel is currently available and is used for regenerating bone in orthopedic indications. The sale will be effected at two closings a technology assets closing and a manufacturing assets closing. The assets to be transferred at the technology assets closing include intellectual property, permits, data and records, and contract rights related to the development, manufacturing, marketing and sale of Osteocel and Osteocel XO. The assets to be transferred at the manufacturing closing include specified Osteocel manufacturing equipment and facilities, including the leasehold interest in our Columbia, Maryland administrative offices and processing facility. Following the manufacturing assets closing, our business related to Osteocel and Osteocel XO will terminate. We have also granted NuVasive the right to acquire exclusive rights to Osteocel XC, (which is how we refer to a second generation mesenchymal stem cell product candidate for bone repair, which would utilize culture expanded mesenchymal stem cells to create a synthetic

version of Osteocel) through December 31, 2009 on generally predefined terms subject, in part, to final negotiation, and have provided NuVasive with a right of first negotiation prior to any other transaction involving the transfer by us of Osteocel XC to a third party through that same date.

Q: What is the purchase price for the assets?

A: The initial purchase price to be paid to us by NuVasive at the technology assets closing is $35.0 million in cash.

During the interim period between the technology assets closing and the manufacturing assets closing, and, if applicable, after the manufacturing assets closing, NuVasive will pay us certain milestone payments, not to exceed approximately $50.0 million in the aggregate, including $12.5 million to be paid upon the manufacturing asset closing. Receipt of each of the milestone payments is conditioned upon the satisfaction of certain conditions, including conditions relating to the production and delivery by us of agreed upon quantities of product on or before certain agreed upon dates, and completion of the transfer of the manufacturing assets in accordance with agreed upon terms. These milestone payments may be paid, at the discretion of NuVasive, in cash or in freely transferable shares of NuVasive common stock having then equivalent market value.

Q: Why are we selling these assets?

A: While the assets to be transferred represent a profitable product line for us, our Board of Directors does not believe they are core to our business. Our Board of Directors believes it is appropriate and in our best interest and the best interest of our stockholders to sell these non-core assets and to invest the proceeds from the sale in our core research and development activities.

In deciding to authorize the sale, our Board of Directors considered a number of positive and negative factors, discussed in more detail later in this proxy statement.

Q: Did the Board of Directors receive a fairness opinion on the sale of the assets?

A: No. The Board of Directors does not believe it was necessary to obtain a fairness opinion to assist it in its review of the proposed transaction and the negotiated purchase price.

Q: What if we receive another offer for the assets?

A: We have agreed that after execution of the asset purchase agreement and prior to the earlier of the manufacturing assets closing or the termination of the asset purchase agreement, we will not, directly or indirectly, initiate, solicit, entertain or encourage any other entity or person to make a proposal to us to acquire the assets to be transferred.

If, however, at any time prior to obtaining stockholder approval for the asset sale, we receive an unsolicited proposal that our Board of Directors determines in good faith to be superior to NuVasive s proposal and it determines in good faith after consultation with outside counsel that it must take action with respect to such proposal to avoid a breach of its fiduciary duties under Delaware law, and notifies NuVasive of such proposal and after good faith negotiations with NuVasive, our Board of Directors determines that such proposal remains superior to NuVasive s proposal, we may furnish nonpublic information to, and negotiate with, the party making the superior proposal. After compliance with the notice and negotiation provisions of the asset purchase agreement, our Board of Directors may withdraw, modify or qualify its recommendation that the stockholders approve the asset purchase agreement and the transactions contemplated thereby, and recommend the superior proposal. Notwithstanding such superior proposal or change in the recommendation of our Board of Directors, we are obligated to hold the stockholder meeting for purposes of approving the asset purchase agreement and the transactions contemplated thereby.

Q: Have any of our stockholders agreed to vote in favor of the proposal to approve the asset purchase agreement, and, if so, are there any material conditions to that agreement?

A: Officers and directors of ours, and certain of their affiliates, holding approximately 47% of our outstanding voting stock, have executed voting agreements committing to vote for the approval of the asset purchase agreement and related transactions, subject in some cases to certain exceptions typical in voting agreements of this type, which allow for a reduction of the committed shares to 38%. Included among those who have executed voting agreements are Peter Friedli, the Chairman of the Board of Directors and our single largest stockholder, and certain of his affiliates, including Venturetec, Inc. and U.S. Venture 05, Inc., and C. Randal Mills, our President and CEO and a member of our Board of Directors.

Q: What happens if the asset purchase agreement and the transactions contemplated thereby are not approved by holders of a majority of our outstanding shares?

A: The asset purchase agreement may be terminated by either us or NuVasive, in which case we will generally pay a termination fee to NuVasive in the amount of $350,000. If, however, the agreement is terminated after our Board of Directors changes its recommendation with respect to the asset sale, we are required to pay NuVasive a $2.0 million fee.

Q: Will I owe any federal income tax as a result of the asset sale?

A: No. You will not owe any federal income tax as a result of the asset sale.

Q: Will any of the proceeds from the sale be distributed to me as a stockholder?

A: No. We intend to retain the proceeds and use them to further our future business plans.

Q: Can I still sell my shares?

A: Yes. The sale will not affect your right to sell or otherwise transfer your shares of common stock.

Q: Who can I contact with questions about the proposal?

A: If you have more questions about the sale of assets or would like additional copies of this proxy statement, you should contact Osiris Investor Relations, at 443-545-1800.

In addition, we are a public reporting company and are required to file reports and other information with the SEC. You may read and copy this information at the SEC s public reference facilities. You may call the SEC at 1-800-SEC-0330 for information about these facilities. This information is also available at the SEC s Internet site at http://www.sec.gov and you can also request copies of these documents from us.

BACKGROUND OF THE TRANSACTION

In the Fall of 2007, we began to actively search for a potential acquirer of our Osteocel business and related assets. This initiative was commenced in anticipation of possible commercialization of our lead biologic drug product candidate, Prochymal, and after a determination that the divestiture of Osteocel, a human cell and tissue based product, would facilitate, both financially and operationally, our transition to a biologic drug company. We are not an orthopedics company, and it was determined that the effort involved in developing an adequate sales force to market and distribute Osteocel as an orthopedic product could be detrimental to our focus on becoming a biologic drug company.

In December 2007, while our search continued, we entered into a financial advisory agreement with Robin Young Consulting Group (RYCG), whereby RYCG agreed to provide services to us in connection with the potential sale by us of our Osteocel business to a select potential purchaser. As part of its services, RYCG agreed to introduce us to NuVasive, to explain Osteocel to NuVasive and to help NuVasive appreciate the value of incorporating Osteocel into their existing business model, and to assist us in structuring, negotiating and closing a transaction involving the sale to NuVasive of our Osteocel business. Pursuant to the arrangements entered into between us and RYCG, RYCG is entitled to a success fee, contingent upon the transaction closing and our receipt of the proceeds, of $600,000 plus one percent (1%) of the transaction value in excess of $70.0 million. These amounts are to be paid by us as and when we receive payments under the terms of the asset purchase agreement. In addition, we agreed to reimburse RYCG for reasonable out-of-pocket expenses incurred by RYCG in connection with its acting for us pursuant to the financial advisory agreement, and we agreed to indemnify RYCG in a manner typical for agreements of this type.

Beginning in the Fall of 2007 and continuing into the first quarter of 2008, we evaluated and considered three proposals for the purchase of our Osteocel business. Two of these proposals, including the NuVasive proposal, were given serious consideration by us and discussions or negotiations ensued by and between us and the prospective acquirers over the course of a number of months. After considering these proposals carefully, in light of our business objectives, we determined that the proposal for the sale of our Osteocel business to NuVasive was the more favorable of the available alternatives and we are determined to pursue that alternative.

Over the course of five months, discussions and due diligence ensued and negotiations took place with regard to the transaction with NuVasive, in various locations throughout the country. Our Board of Directors met on several occasions during this period to discuss with management the terms of the prospective transaction, the status of the negotiations and the prospect for the successful completion of the NuVasive transaction and possibly other transactions, and to evaluate the potential risks and benefits of the NuVasive transaction and possible other transactions.

On May 2, 2008, our Board of Directors met once again to consider and vote upon the approval of the asset purchase agreement with NuVasive and the transactions contemplated thereby, including the sale of Osteocel and Osteocel XO and the related business assets. After careful consideration, these matters were then approved by unanimous vote of our Board of Directors. The asset purchase agreement between us and NuVasive for the sale of our Osteocel business and related assets was then executed as of May 8, 2008.

SALE OF OSTEOCEL BUSINESS

Reasons for the Sale of our Osteocel Business

We are proposing to sell our Osteocel business to NuVasive because we believe that the sale and the transactions contemplated thereby are in the best interest of our company, and you.

While the business assets to be transferred represent a profitable product line for us, and represent a substantial portion of our revenue, our Board of Directors does not believe that this product line is core to our business. Our Board of Directors determined that the divestiture of our Osteocel product line will facilitate our transition to a biologic drug company and is the preferred course of action as we prepare for commercialization of Prochymal. Moreover, our Board of Directors believes that the divestiture of these non-core assets will allow us to invest the sale proceeds in our core research and development activities, and will facilitate our efforts to bring our biologic drug product candidates to market, and our objective of turning the promise of stem cells into a reality.

Benefits of the Sale

The sale of our Osteocel business will:

- provide us with a minimum of $47.5 million in non-dilutive financing, including $35.0 million at the technology assets closing and $12.5 million at the manufacturing assets closing;

- provide us with the opportunity to earn up to an additional $37.5 million in milestone payments, if earned and received;

- provide us with the opportunity to derive additional fee revenue during the eighteen month period following the technology assets closing and prior to the manufacturing assets closing, from the manufacture and supply by us to NuVasive of Osteocel product under the manufacturing agreement, which imposes minimum purchase order obligations on NuVasive over this period; and

- allow us to direct substantially all of our research and development resources to our core business of commercializing biologic drug candidates containing culture expanded mesenchymal stem cells.

In arriving at a determination that the sale of our Osteocel business to NuVasive is in the best interest of our company and our stockholders, our Board of Directors carefully considered the terms of the asset purchase agreement, as well as the potential impact of the proposed sale on our company. As part of this process, the Board of Directors considered the advice of our advisors, including our legal and accounting advisors. In determining to authorize the proposed sale, our Board of Directors considered the benefits and factors set forth above, as well as the terms and conditions of the asset purchase agreement, including a provision which allows our Board to consider unsolicited offers to purchase our Osteocel business that are superior to NuVasive s offer, and to recommend a superior offer to our stockholders, subject to certain conditions, including NuVasive s right to match any superior offer and our obligation to pay NuVasive a termination fee in the amount of $2.0 million if we decide to pursue a transaction with a party other than NuVasive. In addition, our Board of Directors considered the fact that the asset purchase agreement did not contain any financing contingency or material due diligence conditions not satisfied at the time which the asset purchase agreement was entered into.

Risks of the Sale

Our Board of Directors also considered numerous potential risks associated with engaging in a proposed transaction, as well as failing to engage in the proposed transaction, as further described below under the heading Rick Factors which begins on page 15. You should carefully consider all of these risks before deciding how to vote on the proposed asset purchase agreement and the transactions contemplated thereby.

As discussed more fully beginning on page 15, these risks include the following:

- The proposed sale may not be completed or may be delayed if the conditions to closing are not satisfied or waived in a timely manner or ever.

- We may not receive all of the payments available to us under the terms of the asset purchase agreement, and accordingly, we may have less cash available to us to fund our remaining operations.

- The asset purchase agreement will expose us to contingent liabilities which could adversely affect our ability to pursue our core business focused on the development and marketing and obtaining of FDA approval for our biologic drug candidates, including Prochymal .

- If the proposed sale is not completed, we may explore other potential transactions, but alternatives may be less favorable to us.

- The failure to complete the proposed sale may result in a decrease in the market value of our common stock and may impair our ability to achieve our objectives of developing, obtaining FDA approval and marketing our biologic drug candidates, including Prochymal.

- By completing the proposed sale, we will be selling the assets that have historically generated substantially all of our revenue.

- Our business following the sale will depend primarily on the success of our biologic drug candidates business.

- If the risks associated with the Osteocel business as previously disclosed by us occur and affect either NuVasive or us, and correspondingly our ability to earn milestones payments under the asset purchase agreement or to generate revenues under the manufacturing agreement, then we may not realize the full benefit of the proposed sale and related transactions, and our business, financial condition and results of operations could be materially adversely affected.

The foregoing discussion of the information and factors considered by our Board of Directors is not intended to be exhaustive, but does include material factors considered. In view of the complexity and wide variety of information and factors, both positive and negative, considered by our Board of Directors, it is not practical to quantify, rank or otherwise assign relative or specific weights to the factors considered. In addition, the Board did not reach any specific conclusion with respect to each of the factors considered, or any aspect of any particular factor. Instead, the Board conducted an overall analysis of the factors described above, including discussions with management and advisors. In considering the factors described above, individual members of the Board may have given different weights to different factors. The Board considered all of these factors in totality and concluded, on the whole, that such factors supported its determination to approve the proposed sale of our Osteocel business pursuant to the asset purchase agreement. After taking into consideration all of the factors set forth above, our Board of Directors, following consultations with its advisors, concluded that the proposed sale is fair to, and in the best interest of, our company and our stockholders, and that we should proceed with the sale.

Recommendation of our Board of Directors

Our Board of Directors has determined that the proposed sale of our Osteocel business is fair to, and in the best interest of, our company and our stockholders. Our Board of Directors unanimously approved the asset purchase agreement and the transactions contemplated thereby, and recommends that the stockholders vote in favor of the proposal to approve the asset purchase agreement and the transactions contemplated thereby, including the sale to NuVasive of our Osteocel product line, including Osteocel and Osteocel XO, and related business assets.

RISK FACTORS

You should carefully consider the risk factors described below as well as other information provided to you in this proxy statement in deciding how to vote on the proposal to approve the asset purchase agreement, the related transaction documents, and the consummation of the transactions contemplated thereby. If any of the following risk factors actually occur, our business, financial condition or results of operations could be materially adversely affected.

Risk Factors Regarding the Proposal to Approve the Asset Purchase Agreement and the Transactions Contemplated Thereby.

The proposed sale may not be completed or may be delayed if the conditions to closing are not satisfied or waived in a timely manner or ever.

The proposed sale may not be completed or may be delayed because the conditions to closing may not be satisfied or waived. Conditions which must be satisfied or waived prior to the technology assets closing include obtaining stockholder approval and required consents from third parties such as tissue suppliers and parties to important contracts. If the transaction is not completed, it is possible that we will have difficulty recouping the costs incurred in connection with negotiating the proposed transaction, our relationships with our customers, suppliers and employees may be damaged and our business may be seriously harmed. In addition, depending upon the reason for the termination, pursuant to the asset purchase agreement, we may become obligated upon termination to pay NuVasive a termination fee of up to $2.0 million.

We may not receive all of the payments available to us under the terms of the asset purchase agreement, and accordingly, we may have less cash available to us to fund our remaining operations.

The terms of the asset purchase agreement provide for an initial payment to us of $35.0 million in cash and allow for the prospect of additional milestone payments to us, of up to approximately an additional $50.0 million in the aggregate. In addition, pursuant to the terms of the manufacturing agreement, we will have the ability to earn fee revenues related to the production of Osteocel® that we supply to NuVasive following the technology assets closing and prior to the manufacturing assets closing. These potential fee revenues could exceed $50.0 million. Our ability to earn these milestone payments, or to earn fee revenues from the supply of Osteocel to NuVasive, is subject to a number of conditions and uncertainties, including raw material availability, and we have no assurances that any of these amounts will, in fact, be paid to or be received by us. Although there are certain minimum purchase order obligations under the manufacturing agreement, we may be limited or experience difficulty in our ability to fulfill those purchase orders. In addition, NuVasive has disclaimed any obligation under the asset purchase agreement to operate the purchased business to allow for or permit the achievement of any milestones. If we do not receive these payments, we will have less cash available to fund our remaining operations and to support the continued development and pursuit of FDA approval for our biologic drug candidates, including Prochymal.

The asset purchase agreement will expose us to contingent liabilities which could adversely affect our ability to pursue our core business focused on the development and marketing and obtaining of FDA approval for our biologic drug candidates, including Prochymal .

In the asset purchase agreement we have made customary representations and warranties, which are described below under the heading Summary of Material Terms of the Asset Purchase Agreement Representation and Warranties . We agreed to indemnify NuVasive for any losses from breaches of our representations and warranties that occur within specified periods following the technology assets closing. Our

indemnification obligation for breach of representation and warranties under the asset purchase agreement relating to:

- disposition of certain contracts;
- intellectual property;
- authorizations and regulatory compliance;
- environmental matters;
- taxes; and
- brokers.

survive until sixty days after the expiration of the applicable statutes of limitations.

Our representations and warranties under the asset purchase agreement relating to:

- organization, good standing and authority;
- organizational and governing documents, and approval;
- due execution and delivery;
- title to and sufficiency of transferred assets;
- consents and absence of conflicts;
- financial information;
- litigation and claims;
- compliance with laws;
- employees, independent contractors, labor matters and employee benefits;
- insurance;
- fair consideration and absence of fraudulent conveyance;

- product warranties and product liabilities;
- customers and suppliers;
- real property and leases;
- capital expenditures;
- absence of changes and complete disclosure since December 31, 2007; and
- obsolete items and inventory.

survive the technology assets closing and continue until eighteen months after the manufacturing assets closing.

The parties have agreed to indemnify each other for breaches of representations, warranties and covenants contained in the asset purchase agreement, and we have agreed to indemnify NuVasive for any excluded liabilities. With respect to the indemnification related to breach of representations, warranties and covenants, each party s right to indemnification will generally arise after its losses reach $250,000, and then it will receive payments for all losses, with the maximum indemnity payments for such losses equal to $15.0 million, except in the case of any breach by us of representations related to certain specified matters, as respects to which the overall liability cap is increased to $20.0 million plus the amount of any milestone payment(s) earned, up to an aggregate of $35.0 million. Should we incur liability for breach of these representations or warranties, our ability to pursue our core business focused on the development and marketing approval for our biologic drug candidates, including Prochymal, could be materially and adversely affected.

If the proposed sale is not completed, we may explore other potential transactions, but alternatives may be less favorable to us.

If the proposed sale is not completed, we may explore other strategic alternatives, including a sale of our Osteocel business assets to another party. An alternative transaction may have terms that are less favorable to us than the terms of the proposed sale, or we may be unable to reach agreement with any third party on an alternate transaction that we would consider to be reasonable.

The failure to complete the proposed sale may result in a decrease in the market value of our common stock and may impair our ability to achieve our objectives of developing, obtaining FDA approval and marketing our biologic drug candidates, including Prochymal.

The failure to complete the proposed sale may result in a decrease in the market value of our common stock and may impair our ability to achieve our objectives of becoming profitable as quickly as possible and enhancing the value of our assets to our stockholders.

If our stockholders fail to approve the proposed sale, or if the proposed sale is not completed for any other reason, the market price of our common stock may decline. In addition, failure to complete the proposed sale will result in a reduction in the amount of cash otherwise available to us and may substantially limit our ability to implement our strategy of pursuing the continued development, FDA approval and marketing of our biologic drug candidates, including Prochymal.

Risk Factors Relating to Our Company if the Sale is Completed

By completing the proposed sale, we will be selling the assets that have historically generated substantially all of our revenue.

We will be selling our entire product line relating to the processing, manufacturing, marketing and selling of Osteocel. This business has historically been the source of substantially all of our revenue. Although we expect to receive continued revenues for the supply of product pursuant to the manufacturing agreement, these revenues will not be long term, will have substantially reduced margins and will likely cease concurrent with the manufacturing assets closing, anticipated to occur within eighteen months after the technology assets closing. Although our business related to the development, obtaining FDA approval and marketing of our biologic drug candidates, including Prochymal, will remain, this business has generated no appreciable revenue and has caused us to incur significant operating expenses and resulted in the incurrence of substantial losses in each year since our inception. We expect to continue to incur operating expenses and anticipate our expenses and losses will increase in the foreseeable future as we continue our efforts to develop, obtain FDA approval and market our biologic drug candidates, including Prochymal. Even in the event that all milestone payments are received by us under the asset purchase agreement, these funds and the funds available under the manufacturing agreement may not collectively be sufficient to fund our anticipated losses and expenses. Accordingly, we may need to seek additional funding prior to our becoming cash flow positive on an operational basis. We would likely seek such funding through public or private financing or some combination thereof. Additional funding may not be available to us on acceptable terms, or at all.

Our business following the sale will depend primarily on the success of our biologic drug candidates business.

Our biologic drug candidate business will be the primary focus of our business after the sale. We will, however, continue to manufacture Osteocel under the manufacturing agreement which should result in revenues related to the manufacture and supply of Osteocel to NuVasive until the manufacturing assets closing date, anticipated to occur approximately eighteen months after the technology assets closing date. Our long term business prospects will, however, be dependent almost solely on the success of our biologic drug candidate business. This business is based on novel technologies and involves significant risks and challenges in regards to product development and optimization, manufacturing, government regulation, intellectual property, third-party reimbursement and market acceptance, among other risks previously disclosed by us.

If the risks associated with the Osteocel business as previously disclosed by us occur and affect either NuVasive or us, and correspondingly our ability to earn milestones payments under the asset purchase agreement or to generate revenues under the manufacturing agreement, then we may not realize the full benefit of the proposed sale and related transactions, and our business, financial condition and results of operations could be materially adversely affected.

On March 17, 2008, we filed our Annual Report on Form 10-K with the SEC that discussed various risks associated with our business generally, as well as risks specific to our Osteocel business. These risks include risks related to

- our dependence upon a limited supply of adult marrow-rich bone necessary to produce Osteocel;
- the potential for disease transmission from Osteocel and our biologic drug candidates, which are derived from human tissue and bone marrow sources;
- our limited experience manufacturing Osteocel and our ability to manufacture Osteocel in sufficient quantities;
- product liability claims;
- risks related to intellectual property including the patent position for Osteocel; and
- risks related to regulatory approval and other government regulations, including the risk that the FDA decides that Osteocel does not meet the appropriate regulatory requirements to allow for its continued sale.

If any of these risks (or the additional risks referred to in our Form 10-K filing referenced above) occur, and correspondingly our ability to earn milestone payments under the asset purchase agreement and/or generate revenues under the manufacturing agreement, then we may not realize the full benefit of the sale and the related transactions, and our business, financial condition and results of operations could be materially adversely affected.

OTHER CONSIDERATIONS

Company Voting and Support Agreements

Peter Friedli, the Chairman of our Board of Directors and our single largest stockholder, and certain entities with which he is affiliated, including Venturetec, Inc. and US Venture 05, Inc., together with C. Randal Mills, our President and Chief Executive Officer and a member of our Board of Directors, have entered into voting agreements with NuVasive simultaneously with the execution and delivery of the asset purchase agreement. As of June 1, 2008, the shares covered by the voting agreements represented in the aggregate approximately 47% of our outstanding common stock. Pursuant to the voting agreements, the stockholder parties thereto have agreed to vote in favor of the asset purchase agreement and the transactions contemplated thereby, subject in some cases to an exception typical in voting agreements of this type, which allows for reduction of the shares covered by the voting agreements to 38%, in the event that our Board of Directors, in the exercise of its fiduciary duties, changes its recommendation to the stockholders in respect of approval of the asset purchase agreement and the transactions contemplated thereby.

The above description summarizes select provisions of the voting agreements and is qualified in its entirety by reference to the complete text of the form of company voting and support agreement attached as Appendix C to this proxy statement. We urge you to read carefully the entire form of company voting and support agreement for its terms and other information that may be important to you.

Interest of Directors and Executive Officers in the Sale of Assets

In considering the recommendation of our Board of Directors with respect to the asset purchase agreement and the transactions contemplated thereby, you should be aware that certain of our directors and executive officers have interests in the sale of assets that are in addition to, or different from the interests of our stockholders generally and that create potential conflicts of interest. These interests are described below:

- Mr. Friedli, Chairman of our Board of Directors and our single largest stockholder, and certain entities with which he is affiliated, have entered into voting agreements as discussed above; and

- C. Randall Mills, our President and Chief Executive Officer and a member of our Board of Directors, has entered into a voting agreement as discussed above.

As of June 1, 2008, our directors and executive officers beneficially owned 16,974,973 shares of our outstanding common stock, representing approximately 51.6% of the outstanding shares of common stock. For additional information regarding the beneficial ownership of our common stock see the section of this proxy under the heading Security Ownership of Certain Beneficial Owners and Management. The vote of holders of a majority of the shares of our common stock outstanding on the record date is required to approve the asset purchase agreement and the transactions contemplated thereby.

Appraisal Rights

Neither Delaware law, nor our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws provide for appraisal rights or other similar rights for stockholders who do not vote in favor of, or vote against, the sale.

Accounting Treatment

The proposed sale of our Osteocel business assets will be accounted for as a sale of net assets. Upon the closing of the transaction, we will recognize a gain and the historical and future financial results of the Osteocel business will be reported as results of discontinued operations in our statements of operations.

Required Approvals

Neither we nor NuVasive are aware of any regulatory requirements or governmental approvals or actions that may be required to consummate the transactions contemplated by the asset purchase agreement, except for expiration of the applicable waiting period (including any extensions thereof) under the U.S. Hart-Scott-Rodino Act (which has now occurred), compliance with the applicable regulations of the Securities and Exchange Commission in connection with this proxy statement, and compliance with the Delaware General Corporation Law in connection with the stockholder approval being requested at the special meeting for which this proxy statement has been prepared.

Tax Consequences

The following is a summary of the principal material United States federal income tax consequences relating to the proposed sale of assets. The proposed sale of assets will be a transaction taxable to us for United States federal income tax purposes. We will recognize taxable income equal to the amount realized on the sale in excess of our tax basis in the assets sold. The amount realized on the sale will consist of the cash we receive in exchange for the assets sold, plus the amount of related liabilities assumed by NuVasive. Although the sale of the assets will result in a taxable gain to us, substantially all of the taxable gain will be offset against our current year losses from operations plus available net operating loss carry forwards, as currently reflected on our consolidated federal income tax returns.

The proposed sale of the assets will not be a taxable event for our stockholders under applicable United States federal income tax laws.

This summary does not consider the effect of any applicable foreign, state, local or other tax laws nor does it address tax consequences applicable to stockholders that may be subject to special federal income tax rules. This summary is based on the current provisions of the Internal Revenue Code, existing, temporary, and proposed Treasury regulations thereunder, and current administrative rulings and court decisions. Future legislative, judicial or administrative actions or decisions, which may be retroactive in effect, may affect the accuracy of any statements in this summary with respect to the transactions entered into or contemplated prior to the effective date of those changes.

SUMMARY OF MATERIAL TERMS OF THE ASSET PURCHASE AGREEMENT

The following is a summary of the material provisions of the asset purchase agreement, a copy of which is attached as Appendix A to this proxy statement, and is incorporated by reference into this summary. While we believe this summary covers the material terms of the asset purchase agreement, this summary may not contain all of the information that is important to you, and we urge you to read the asset purchase agreement in its entirety.

The Parties

Osiris Therapeutics, Inc.

We are a stem cell therapeutic company headquartered in Columbia, Maryland, focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic, and cardiovascular areas. We were incorporated in Delaware in April 2002. Our predecessor company was organized in 1992. We currently manufacture, market and sell Osteocel® for regenerating bone in orthopedic indications. It is the only commercially available product in the U.S. containing viable stem cells. Our lead biologic drug candidate, Prochymal™, is being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease and Crohn s disease, and is the only stem cell therapeutic currently granted both Orphan Drug and Fast Track status by the Food and Drug Administration (FDA). Prochymal is also being developed for the repair of heart tissue following a heart attack and for protection of pancreatic islet cells in patients with type 1 diabetes. Our pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen™ for osteoarthritis in the knee. We have also partnered with Genzyme Corporation to develop Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies.

We are a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. We have developed an extensive intellectual property portfolio to protect our technology in the United States and a number of foreign countries including 47 U.S. and 253 foreign patents owned or licensed.

NuVasive, Inc.

NuVasive, Inc., a Delaware corporation, is a medical device company headquartered in San Diego, California, focused on the design, development and marketing of products for the surgical treatment of spine disorders. NuVasive s currently-marketed product portfolio is focused on applications for spine fusion surgery, a market estimated to exceed $4.2 billion in the United States in 2008. NuVasive s principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS™, as well as a growing offering of cervical and motion preservation products. NuVasive s currently-marketed products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. NuVasive focuses significant research and development efforts on both MAS and motion preservation products in the areas of (i) fusion procedures in the lumbar and thoracic spine, (ii) cervical fixation products, and (iii) motion preservation initiatives such as total disc replacement and nucleus-like cervical disc replacement.

Asset Sale

On May 2, 2008, our Board of Directors unanimously approved the asset purchase agreement and the transactions contemplated thereby pursuant to which we agreed, among other things, to sell our Osteocel product line, including Osteocel and Osteocel® XO, and related business assets to NuVasive for an initial payment of $35.0 million in cash. In addition, we have the ability to earn certain milestone payments not to exceed approximately $50.0 million in the aggregate. Receipt of each of the milestone payments is conditioned upon the satisfaction of certain conditions, including conditions relating to the production and delivery by us of agreed upon quantities of Osteocel on or before certain agreed upon dates and completion of the transfer of certain manufacturing assets in accordance with agreed upon terms. The assets consist of our business (which we refer to herein collectively as our Osteocel business) involving the development, processing, manufacturing, marketing and selling of an osteobiologic allograft material containing cancellous bone (which contains intrinsic viable mesenchymal stem cells) used in spinal fusion and other surgical procedures and commonly known as Osteocel and Osteocel XO, including current formulation and all development projects related to Osteocel and Osteocel XO (which we sometimes refer to herein collectively as Osteocel). Upon completion of the sale, our business related to Osteocel and Osteocel XO will then terminate.

Manufacturing Agreement

In connection with the transactions contemplated by the asset purchase agreement, we agreed to enter into a manufacturing agreement with NuVasive to continue to manufacture and supply Osteocel for a period of eighteen months after the technology assets closing. For a summary of the material terms of the manufacturing agreement see the discussion in this proxy statement under the heading Summary of the Material Terms of the Manufacturing Agreement in this proxy statement.

Closings

Pursuant to the terms of the asset purchase agreement and to facilitate our continuing to manufacture and supply Osteocel pursuant to the manufacturing agreement, we will transfer all of the assets to be transferred with respect to the Osteocel business in two phases.

Technology Assets Closing

The consummation of the technology assets transfer, at which the technology assets related to the Osteocel business will be transferred (including intellectual property, permits, data and records, and contract rights related to the development, manufacturing and sale of Osteocel and Osteocel XO), will be held as soon as reasonably practicable after the special meeting of stockholders, if the asset purchase agreement and transactions contemplated thereby are approved by our stockholders and all other conditions to closing have been satisfied or waived.

Manufacturing Assets Closing

The consummation of the manufacturing assets transfer, at which the manufacturing assets related to the Osteocel business (including our leasehold interest in our Columbia, Maryland administrative offices and Osteocel processing facility and specified equipment now employed by us in the manufacture of Osteocel) will be transferred, will be held at the manufacturing assets closing, to be held as soon as reasonably practicable following the earlier to occur of the termination of the manufacturing agreement by NuVasive, and the expiration of the stated term of the manufacturing agreement, which is eighteen months from the date of the technology assets closing. Our business related to Osteocel and Osteocel XO will then terminate.

Purchased Assets, Excluded Assets and Assumed Liabilities

The assets to be sold pursuant to the asset purchase agreement consist of all of our operating assets, tangible property and intellectual property with respect to the Osteocel business and include the following:

- certain intellectual property including patents, trademarks, and copyrights and other intangible rights and property used in, held for use in, intended for use in, related to or necessary for the operation of the Osteocel business;

- all inventory and work in process existing as of the manufacturing closing date relating to the Osteocel business;

- certain rights related to the development of Osteocel, including all clinical trails and related clinical trial data;

- all data and records related to the operation of the Osteocel business, including client and customer lists;

- the tangible personal property used in or necessary for the operation of the Osteocel business;

- certain permits, licenses, franchises, consents, authorizations, registrations and other approvals and operating rights relating to the Osteocel business;

- all claims against third parties related to the operation of the Osteocel business;

- all rights related to deposits and prepaid expenses, claims for refunds and rights to offset in respect thereof relating to the assets and/or assets transferred pursuant to the agreement;

- all rights in and to certain contracts used in, related to or necessary for the operation of the Osteocel business; and

- all goodwill relating to the foregoing assets.

Except for the foregoing assets, NuVasive will not acquire and will have no right, title or interest in any of our assets, and such assets will remain our property. Furthermore, we have specifically excluded from the assets to be initially transferred to NuVasive all of our right, title and interest in and to any second generation mesenchymal stem cell product for bone repair utilizing culture-expanded mesenchymal stem cells to create a synthetic version of Osteocel. We call this second generation mesenchymal stem cell product candidate Osteocel® XC. Although we are not currently engaged in an active product development program focused specifically on Osteocel XC, we have granted to NuVasive pursuant to the asset purchase agreement a right to acquire exclusive rights to Osteocel XC on generally predefined terms subject, in part, to final negotiation, through December 31, 2009. Through that same date, NuVasive is also afforded a right of first negotiation prior to any other transaction involving Osteocel XC.

NuVasive is assuming liabilities including:

- the obligations to perform arising in the ordinary course of business under any contracts assumed by NuVasive after the technology assets closing, if such contract constitutes a portion of the technology assets, and after the manufacturing assets closing, if such contract constitutes a portion of the manufacturing assets; and

- the expenses and liabilities relating to the Osteocel business which are incurred or accrued in the ordinary course of business after the technology assets closing (excluding our liabilities under the manufacturing agreement).

NuVasive is not assuming any liabilities other than as described above. Specifically, NuVasive is not assuming:

- any trade accounts payable of the Osteocel business;

- any of our liabilities or obligations in respect of any kind of our indebtedness;

- any of our liabilities or obligations related to the employment, termination or compensation of any of our employees, consultants or service providers, including any and all liabilities or obligations to any employees transferred from us to NuVasive incurred prior to the time such employees are employed by NuVasive;

- any of our liabilities or obligations relating to any product warranty or product liability claims owing, accrued or the underlying facts with respect to which arise out of our operation of the Osteocel business;

- any of our liabilities or obligations for any taxes relating to the Osteocel business for any period

(or portion thereof) ending on or prior to the date of the technology assets closing and any taxes of the Osteocel business related to the manufacturing assets for any period (or portion thereof) ending on or prior to the manufacturing assets closing;

- any of our liabilities or obligations under any contract assumed by NuVasive prior to the date on which any such contract is transferred by us to NuVasive;

- any environmental liabilities or obligations to the extent arising out of the operation of the Osteocel business prior to the technology assets closing with respect to the technology assets and prior to the manufacturing assets closing with respect to the manufacturing assets; and

- any of our liabilities or obligations incurred, arising from or out of or in connection with the asset purchase agreement and the related agreements.

Purchase Price

Initial Purchase Price

At the technology assets closing, NuVasive will make payment to us of $35.0 million in cash, pursuant to the terms of the asset purchase agreement and assume certain liabilities related to the technology assets.

Additional Purchase Price

In addition to the initial purchase price, NuVasive is obligated, subject to and contingent upon our achievement of the performance milestones described below not later than the applicable date for satisfaction of each such milestone, to pay us an amount of cash or, subject to certain restrictions, shares of common stock of NuVasive having then equivalent market value (the form of payment of which is to be determined in the sole discretion of NuVasive), equal to the sum of the milestone(s) achieved by us.

Each milestone is independent of each other milestone and may be satisfied and payment due therefor regardless of non-satisfaction of any other milestone.

Pursuant to the asset purchase agreement, NuVasive may not issue shares of NuVasive common stock in respect of any milestone payment, and will instead be obligated to deliver cash, unless such shares of NuVasive common stock may be re-sold by us pursuant to Rule 144 of the rules and regulations promulgated under the Securities Act of 1933, as amended, on the date of such issuance.

The milestones are as follows:

- if at any time prior to April 15, 2009, we have delivered to NuVasive an aggregate of 125,000 cubic centimeters of Osteocel in accordance with the terms of the manufacturing agreement, NuVasive shall pay to us $5.0 million;

- if at any time prior to the manufacturing assets closing, we have delivered to NuVasive an aggregate of 250,000 cubic centimeters of Osteocel, including any Osteocel delivered in satisfaction of any prior milestone in accordance with the terms of the manufacturing agreement, NuVasive shall pay to us an additional $5.0 million;

- subject to the prior satisfaction of the conditions described below, at the manufacturing assets closing, NuVasive shall pay to us $12.5 million plus or minus, an adjustment for certain then existing work in progress;

- if prior to the manufacturing assets closing, we have delivered to NuVasive an aggregate of 275,000 cubic centimeters of Osteocel in accordance with the terms of the manufacturing agreement, including the Osteocel delivered pursuant to any prior milestone, then NuVasive shall pay an additional $5.0 million to us at the manufacturing assets closing;

- at the manufacturing assets closing, NuVasive shall pay to us an amount equal to the product of (i) (A) the excess delivery amount divided by (B) 58,300, rounded down to the nearest whole number multiplied by (ii) $2.5 million; provided, however, that in no event shall the payment exceed $7.5 million. Excess delivery amount means the number by which the total number of cubic centimeters of Osteocel delivered to NuVasive prior to the manufacturing assets closing in accordance with the terms of the manufacturing agreement exceeds 250,000 cubic centimeters; and

- if at any time following the technology assets closing the Osteocel business generates $35.0 million in cumulative net sales NuVasive shall pay to us an additional $15.0 million.

In no event, however, shall the sum of all of the milestone payments made by NuVasive to us exceed $50.0 million plus or minus an adjustment for certain work in progress at the date of the manufacturing assets closing. NuVasive s obligation to make the $12.5 million milestone payment at the manufacturing assets closing is subject to the satisfaction (or waiver by NuVasive) of the following conditions:

- the representations and warranties by us in the asset purchase agreement must be true and correct in all material respects with respect to the manufacturing assets at and as of the date of the manufacturing assets closing (except those qualified by materiality or relating to the corporate status, organizational documents and good standing, authorization of the transaction and corporate authority, and the title and sufficiency of the transferred assets, which must be true and correct in all respects);

- we must have performed and complied in all material respects with all our obligations and covenants with respect to the manufacturing assets and the transfer thereof;

- absence of any event, circumstance, development with respect to, change in or effect on the manufacturing assets that is, or could reasonably be expected to be, materially adverse to such manufacturing assets, taken as a whole;

- absence of any action, suit, proceeding claim, arbitration or investigation before any governmental entity or before any arbitrator pending that is reasonably expected to result in an unfavorable judgment, order, decree, stipulation or injunction that would either prevent the transfer of the manufacturing assets or cause such transfer to be rescinded;

- none of the work in process shall be held under a consignment or similar arrangement or be in transit and all such work in process shall have been manufactured in accordance with then current Good Tissue Practices (cGTP);

- delivery to NuVasive of all certificates and bill of sale and assignment and assumption agreements in accordance with the asset purchase agreement;

- absence of any liens, other than permitted liens, on the manufacturing assets; and

- delivery to NuVasive of a good standing certificate from the Secretary of State of the State of Delaware.

Representations and Warranties

We have made a number of representations and warranties, subject to qualification in some cases, in the asset purchase agreement relating to:

- our corporate organization, good standing, organizational and governing documents and authority to enter into, execute and deliver and the enforceability of, the asset purchase agreement and the related transaction documents;

- title and sufficiency of the transferred assets;

- consents and absence of conflicts;

- tax matters;

- financial information;

- contracts to be assumed by NuVasive;

- litigation and claims;

- compliance with laws;
- employees, independent contractors, labor matters and employee benefits;
- intellectual property;
- insurance;
- fair consideration and absence of fraudulent conveyances;
- authorizations and regulatory compliance;
- product warranties and product liabilities;
- environmental matters;
- real property and leases;
- use of brokers or other representatives in connection with the asset sale;
- capital expenditures relating to the Osteocel business;
- absence of certain changes or events since December 31, 2007;
- obsolete items and inventory;

- customers and suppliers of the Osteocel business; and

- accuracy and adequacy of our disclosures to NuVasive relating to the Osteocel business.

NuVasive has represented and warranted to us, among other things, that is an organization duly formed, validity existing and in good standing under the laws of the State of Delaware and has full corporate power and authority to execute and deliver and to perform its obligations under the asset purchase agreement and the related transaction documents. NuVasive has also represented that no further consents or approvals are required for it to consummate the purchase of the Osteocel business and that no broker or other representative acted on its behalf in connection with the transactions contemplated by the asset purchase agreement in such manner as to give rise to any valid claim by any person against us for any fees or other payment.

For purposes of claims for indemnification, all of the representations and warranties made by us and NuVasive will survive for eighteen months after the manufacturing assets closing except for those representations and warranties we made relating to taxes, disposition of certain contracts, intellectual property, authorizations and regulatory compliance, environmental matters and brokers which survive for sixty days after the expiration of the applicable statutes of limitations.

Further Assurances

Each party agreed with the other that at any time and from time to time following the date of the asset purchase agreement, and without further consideration, each will promptly execute and deliver to the other such further assurances, instruments and documents and take such further action as the other may reasonably request in order to carry out the full intent and purpose of the agreement and to consummate the transactions contemplated thereby. We have also agreed to take such further action as may be necessary to remedy a breach by us of the representations and warranties made by us in the asset purchase agreement concerning the title to and sufficiency of the transferred assets.

Covenants

The asset purchase agreement contains customary covenants on our operation and use of the assets related to the Osteocel business. We have agreed to conduct our activities associated with the transferred assets in their ordinary and usual course, consistent with past practice, and will use commercially reasonable efforts to preserve intact all rights, privileges, franchises and other authority related to the activities associated with the transferred assets, and maintain in their current, or currently-planned, condition its current relationships with licensors, licensees, suppliers, contractors, distributors, customers, and others having relationships related to the activities associated with the transferred assets. We have also agreed that, except as expressly contemplated by the asset purchase agreement or approved in writing by NuVasive, prior to the technology assets closing with respect to all technology assets and the manufacturing assets closing with respect to the manufacturing assets, we will not:

- create, incur or assume any obligation which would materially and adversely affect the transferred assets or NuVasive s ability to operate the Osteocel business in substantially the same manner and condition as currently conducted by us;

- enter into certain contracts or violate, terminate, amend or otherwise modify or waive any of the terms of any contract to be assumed by NuVasive;

- sell, lease, license, transfer or dispose of any of the transferred assets (except for sales of Osteocel in the ordinary course of business consistent with our past practices);

- change any of our accounting methods with respect to the Osteocel business;

- terminate, waive or release any material right or material claim with respect to the Osteocel business or any of the transferred assets;

- license any of the technology to be transferred to NuVasive (except for licenses under our standard customer agreement made in the ordinary course of business consistent with our past practices);

- initiate, settle or agree to settle any litigation, action, suit, proceeding, claim or arbitration relating to the Osteocel business;

- change the manner in which we extend warranties, discounts or credits to customers with respect to Osteocel;

- modify or fail to maintain our current insurance coverage with respect to the transferred assets;

- sell, dispose of or encumber any of the transferred assets or license any transferred assets;

- enter into any agreements or commitments relating to the transferred assets;

- fail to comply in all material respects with all laws and regulations applicable to the activities associated with the transferred assets;

- change or announce any change to the Osteocel business or the transferred assets; or

- agree to take any of the foregoing actions or take any action which would reasonably be expected to prevent us from performing or cause us not to perform one or more covenants required to be performed by us.

Financial Statements

We have agreed to provide NuVasive with certain historical financial statements and information related to the Osteocel business.

Confidentiality

We have agreed to maintain the confidentiality of all information related to the Osteocel business and the transferred assets. Our confidentiality obligations do not apply to the portion of any confidential information that we can demonstrate is in the public domain or enters the public domain without the wrongful act or breach of the asset purchase agreement by us, approved in advance by NuVasive for release, or subject to certain limited exceptions, disclosed by a court of competent jurisdiction.

Non-Solicitation/No-Bids

We have agreed that, until the earlier to occur of the manufacturing assets closing, or the termination of the asset purchase agreement, neither we nor any of our representatives will, directly or indirectly, initiate, solicit, entertain or encourage any proposal, inquiry or offer from any person (other than NuVasive) concerning the acquisition or license of all or any portion of the transferred assets, or make any statements to third parties which may reasonably be expected to lead to any such proposal, or negotiate, engage in any substantive discussions, or enter into any agreement, with any person concerning any such proposal.

If, however, at any time prior to obtaining stockholder approval we receive an unsolicited bona fide written proposal that did not result from any breach of our representations of warranties, our Board of Directors has determined in good faith that such proposal constitutes a superior proposal, our Board of Directors has determined in good faith, after consultation with outside counsel, that failure to take action with respect to such superior proposal would result in a breach of its fiduciary duties under Delaware law, then we must notify NuVasive of such determination

and offer to discuss in good faith with NuVasive (and, if NuVasive accepts, thereafter negotiate in good faith), for a period of no less than five business days, any adjustments in the terms and conditions of the asset purchase agreement proposed by NuVasive. If, following such notice and discussions, our Board of Directors has determined that such proposal remains superior to NuVasive s proposal, then we may furnish non-public information with respect to us to the person or group making such proposal pursuant to a customary confidentiality agreement, and participate in discussions or negotiations with such person or group regarding such proposal, and our Board of Director may withdraw, modify or qualify its recommendation that our stockholders approve the asset purchase agreement and the transactions contemplated thereby, and may recommend the superior proposal. We must, however, provide or make available to NuVasive any material non-public information concerning us, that is provided to the person making such proposal which was not previously provided or made available to NuVasive. Notwithstanding any such superior proposal or any change in the recommendation of our Board of Directors, we are obligated to hold the stockholder meeting for purposes of approving the asset purchase agreement and the transactions contemplated thereby.

Non-Competition and Non-Solicitation of Employees

From the date of the technology assets closing until eighteen months following the manufacturing assets closing, we have agreed to not:

- engage in any business or activities that compete with the Osteocel business;

- enter the employ of, or render services to, any person (or any affiliate of any person) who or which is engaged in a competitive business with respect to such competitive business;

- acquire a financial interest in, or otherwise become actively involved with, any competitive business;

- solicit, encourage or attempt to solicit or encourage any employee of NuVasive or any of its affiliates who was immediately prior to the technology assets closing or manufacturing assets closing (as applicable), an active employee of ours to leave the employment of NuVasive or its affiliates;

- hire any of our former employees who left our employment in connection with the technology assets closing or the manufacturing assets closing;

- hire any of our former employees who terminates employment with NuVasive or its affiliates in the one year period following the manufacturing assets closing;

- solicit, encourage or attempt to solicit or encourage to cease to work with NuVasive or its affiliates any employee of, or consultant then under contract with, NuVasive or its affiliates who is or has been engaged in the Osteocel business;

- solicit, induce or attempt to induce any customer to cease doing business in whole or in part with NuVasive or its affiliates with respect to the Osteocel business;

- attempt to limit or interfere with any business agreement existing between the NuVasive and/or its affiliates and any third party; or

- disparage the business reputation or employees of NuVasive, or any of its affiliates, or take any actions, knowingly, willfully or, recklessly, that are harmful to the NuVasive s or its affiliates goodwill with certain third parties or the public.

Notwithstanding the foregoing, we are not prohibited or restricted from:

- engaging in or operating the business of any second generation mesenchymal stem cell product for bone repair utilizing culturally-expanded mesenchymal stem cells to create a synthetic version of Osteocel, including, without limitation, Osteocel XC; or

- consummating a transaction with a third party, through stock or asset acquisition, merger, consolidation or otherwise, where any such third party acquires all or a portion of our outstanding common stock or assets, provided that any such third party agrees to be bound by the non-competition provisions of the asset purchase agreement.

Employee Matters

We have agreed to provide NuVasive with reasonable access to our active employees performing services with respect to the Osteocel business to enable NuVasive to discuss compensation terms and present offers of employment to such employees. NuVasive may, in its sole discretion, offer employment to these employees commencing as of the manufacturing assets closing. NuVasive has agreed to recognize each of our employees that it hires original hire date with us and prior service with us as service with NuVasive for purposes of eligibility to participate in, and determining vesting and any accrued benefits based on length of service under, NuVasive s employee benefit plans, policies, arrangements and payroll policies. At NuVasive s request, we have agreed to accelerate the vesting of any options to purchase our common stock, held by one or more of our former employees at or following the technology assets closing on the terms and subject to the conditions as NuVasive shall reasonably request and which are in accordance with the applicable option agreements and related documents.

Osteocel XC: Negotiation; Purchase Option

Purchase Option

For a period commencing on the date of the technology assets closing and ending on December 31, 2009, we have granted NuVasive the right to acquire from us the exclusive rights to any second generation mesenchymal stem cell product for bone repair utilizing culture expanded mesenchymal stem cells to create a synthetic version of Osteocel (i.e. Osteocel XC) at certain generally pre-defined terms, including a minimum cash price, an agreement to fund development efforts, an exclusive product supply agreement with an agreed gross margin and on non-monetary terms and conditions substantially similar to the terms and conditions on which the Osteocel business is being acquired by NuVasive pursuant to the asset purchase agreement. Consummation of any such transaction is in any event subject, in part, to final negotiation between the parties of the terms of the transaction.

Right of First Negotiation

We have also agreed that until December 31, 2009, if we desire to enter into a transaction or accept a third-party proposal for the sale, license, joint-venture arrangement, transfer or partial transfer of Osteocel XC, we will first provide NuVasive with a notice of such desired transaction. If, within five business days of the receipt of such notice, NuVasive gives us written notice of its interest to negotiate a transaction on the terms contained in the notice, then we and NuVasive have agreed, to exclusively negotiate an agreement to carry out such transaction with NuVasive. If NuVasive fails to timely respond to the notice, or if we enter into an agreement for such transaction with NuVasive within thirty days, then neither we nor NuVasive shall have a right or be under any obligation to enter into such transaction, and we may, subject to NuVasive s purchase option, consummate with a third-party a transaction on terms not materially less favorable to us than the terms contained in the notice.

Consents and Termination of Certain Contracts

We have agreed prior to the technology assets closing to obtain at our expense, consents and waivers for certain of the contracts being assumed by NuVasive. We have also agreed prior to the technology assets closing to terminate contracts relating to the Osteocel business.

Regulatory and Other Authorizations

We have agreed, that prior to the technology assets closing, we will use our commercially reasonable efforts to obtain in writing and at our own expense all consents and waivers related to certain contracts to be assumed by NuVasive. If the assignment or transfer of any assumed contract would constitute a breach thereof, we have agreed to establish with NuVasive any back-to-back arrangement reasonably requested by NuVasive in order to provide for NuVasive the benefits intended to be assigned under any such assumed contract (subject to the right of any third party thereunder to terminate such assumed contract), including, without limitation, the enforcement by us for the benefit of NuVasive, at NuVasive s sole cost and expense, of any and all of our rights against a third party to such assumed contract arising out of the breach by such third party or otherwise.

Hart-Scott-Rodino Act Notification

We have agreed with NuVasive to promptly prepare, execute and file a notification with the United States Justice Department and the Federal Trade Commission as required by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Pursuant to the terms of the asset purchase agreement, the technology assets closing is subject to and conditioned upon the receipt of requisite approvals or the expiration of the applicable waiting period (including any extensions thereof) under the Hart-Scott-Rodino Act (which has now been obtained).

Public Announcements

Except as required by law, neither party s representatives can make any public announcement concerning the asset purchase agreement without the prior written consent of the other party.

Transfer Taxes

All taxes arising out of the consummation of the transactions contemplated by the asset purchase agreement imposed on us shall be paid by us and promptly discharged by us when due and all such taxes imposed on NuVasive shall be paid by NuVasive and promptly discharged by NuVasive when due.

Stockholder Meeting and Proxy

We have agreed to promptly prepare and file with the SEC a proxy statement relating to the approval of the asset purchase agreement and the transactions contemplated thereby by our stockholders, and to use our reasonable best efforts to promptly respond to any comments of the SEC with respect thereto, and to cause such proxy statement to be promptly mailed to our stockholders.

We have also agreed to promptly establish a record date for, duly call, give notice of, convene and hold a meeting of our stockholders for the purpose of obtaining the affirmative vote of the holders of a majority of our outstanding shares of common stock in favor of the approval of the asset purchase agreement and the transactions contemplated thereby. We have further agreed that the proxy statement will include a statement that our Board of Directors recommends to our stockholders that they approve the asset purchase agreement and the transactions contemplated thereby.

Additionally, we have agreed that our Board of Directors will not modify or withdraw its recommendation or take any action with respect to the sale of the transferred assets to any party other than NuVasive unless, prior to the receipt of stockholder approval for the sale of the transferred assets to NuVasive, our Board of Directions determines in good faith that an unsolicited bona fide written alternative proposal received by us concerning the transferred assets constitutes a superior proposal (after compliance with the notification and negotiation provisions set forth in the asset purchase agreement), in which case, our Board of Directors may withdraw, modify or qualify its recommendation concerning the sale of the assets to NuVasive and may recommend such superior proposal; however, notwithstanding such superior proposal or change in recommendation of our Board of Directors, we are still obligated to hold the stockholder meeting.

Closing Conditions

The obligation of each party to consummate the transactions contemplated by the asset purchase agreement are subject to the satisfaction of the following conditions:

- all applicable waiting periods (including any extensions thereof) under the Hart-Scott-Rodino Act shall have expired or otherwise been terminated (which condition has now been satisfied);

- no law or regulation shall have been adopted or promulgated, and no temporary restraining order, preliminary or permanent injunction or other judgment or order issued by any governmental entity shall be in effect, which has the effect of making the transactions contemplated by the asset purchase agreement illegal, or otherwise enjoining or prohibiting the consummation of the transactions contemplated by the agreement; and

- our stockholders shall have approved the asset purchase agreement and the transactions contemplated thereby.

The obligation of NuVasive to consummate the transactions contemplated by the asset purchase agreement are subject to the satisfaction (or waiver by NuVasive) of the following conditions:

- our representations and warranties must be true and correct in all material respects (except those qualified by materiality or those relating to the corporate status, organizational and governing documents, authorization of the transaction and corporate authority and the title to and sufficiency of the transferred assets, which shall be true and correct in all respects) at and as of the technology assets closing as if then made (other than representations and warranties made as of a specified date, which need be true and correct only as of the specified date);

- we must have performed and complied in all material respects with all of our agreements and covenants required to be performed or complied with under the agreement including the delivery of the required

financial statements;

- there must not have occurred, from the date of the agreement through the date of the technology assets closing, any material adverse effect on the Osteocel business or any event or development which, individually or in the aggregate, would have a material adverse effect on the Osteocel business;

- no action suit, proceeding claim, arbitration or investigation before any governmental entity or before any arbitrator shall be pending that would reasonably be expected to result in an unfavorable judgment, order, decree, stipulation or injunction that would either prevent consummation of the transactions contemplated by the agreement or cause such transactions to be rescinded;

- delivery of all required notices, consents and waivers by us;

- delivery by us to NuVasive of each intellectual property agreement, manufacturing agreement, bill of sale and assignment and assumption agreement, license agreement, certificate, certificate of good standing and opinion, required to be delivered to NuVasive pursuant to the agreement; and

- absence of any liens, other than permitted liens, on the transferred assets.

Our obligation to consummate the transactions contemplated by the asset purchase agreement are subject to the satisfaction (or waiver by us) of the following conditions:

- the representations and warranties of NuVasive must be true and correct in all material respects (except for those that are qualified by materiality or those relating to the corporate status, organizational and governing documents, authorization of the transaction and corporate authority, which shall be true and correct in all respects) at and as of the date of the technology assets closing as if then made (other than representations and warranties made as of a specified date, which need be true and correct only as of the specified date);

- NuVasive must have performed and complied in all material respects with all of its agreement and covenants required to be performed or complied with under the agreement as of the technology assets closing;

- no action suit, proceeding claim, arbitration or investigation before any governmental entity or before any arbitrator shall be pending that would reasonably be expected to result in an unfavorable judgment, order, decree, stipulation or injunction that would either prevent consummation of the transactions contemplated by the agreement or cause such transactions to be rescinded; and

- delivery by NuVasive to us of each intellectual property agreement, manufacturing agreement, bill of sale and assignment and assumption agreement, license agreement, certificate, certificate of good standing, and opinion, required to be delivered to us pursuant to the asset purchase agreement.

Termination

The asset purchase agreement may be terminated at any time prior to the technology assets closing:

- by mutual written consent of NuVasive and us;

- by NuVasive or us if, without the fault of the terminating party, the technology assets closing has not occurred on of before September 8, 2008, subject to certain extensions;

- by NuVasive, if we are in material breach of any of our representations, warranties, covenants or agreements, which breach is not cured by us within ten calendar days following receipt of written notice of such

breach or failure to perform, provided that NuVasive is not in material breach of any of its representations, warranties, covenants or agreements at the time such notice is delivered;

- by us, if NuVasive is in material breach of any of its representations, warranties, covenants or agreements, which breach is not cured by NuVasive within ten calendar days following receipt of written notice of such breach or failure to perform, provided that we are not in material breach of any of its representations, warranties, covenants or agreements at the time such notice is delivered;

- by NuVasive or us if any governmental entity has entered a final, non-appealable order or injunction restraining, enjoining or otherwise prohibiting the transactions contemplated by the agreement, provided that such right of termination is not available to any party if such party failed to take reasonable efforts to prevent or contest the imposition of such order or injunction;

- by NuVasive or us if our stockholders do not approve the agreement and the transactions contemplated thereby at the stockholders meeting or at any adjournment or postponement thereof, provided that we do not have the right to terminate the agreement if such failure to obtain stockholder approval is the result of our action or failure to act and such action or failure to act constitutes a breach of the agreement by us; or

- by NuVasive if our Board of Directors changes its recommendation that our stockholders approve the agreement and the transactions contemplated thereby.

In the event of termination of the agreement by NuVasive or us pursuant to the provisions set forth above, all obligations of the parties under the agreement terminate without any liability of any party to the other party, except for any liability of a party for breaches of agreement prior to such termination. Certain sections of the agreement survive any termination thereof.

If we or NuVasive terminate the agreement because the technology assets closing has not occurred on or before September 8, 2008 (or any extension thereof) and at the time of such termination stockholder approval has not been obtained or the agreement is terminated as a result of our stockholders not approving the agreement, then we have agreed to promptly pay to NuVasive $350,000.

Additionally, if we or NuVasive terminate the agreement after our Board of Directors changed its recommendation with respect to the asset sale, then we are required to promptly pay to NuVasive $2.0 million.

Indemnification

We have agreed to indemnify, defend and save harmless NuVasive and its directors, officers, employees, affiliates, agents, advisors, representatives, stockholders and assigns from, against and in respect of any and all losses incurred or suffered by any such party arising out of, or related to, the following:

- any misrepresentation or breach of warranty made by us in any transaction document or in any other document, certificate or other instrument required to be delivered by us under any transaction document;

- any breach or non fulfillment of any covenant or agreement made or to be performed by us in any transaction document or in any agreement or instrument entered in connection with any transaction document;

- any fraud or intentional misrepresentation with respect to, or intentional breach of, any transaction document by us; and

- any of our liabilities not assumed by NuVasive under the asset purchase agreement.

NuVasive has agreed to indemnify, defend and save harmless us and our directors, officers, employees, affiliates, agents, advisors, representatives, stockholders and assigns from, against and in respect of any and all losses incurred or suffered by any such party arising out of, or related to, the following:

- any misrepresentation or breach of warranty made by NuVasive in any transaction document or in any document, certificate or other instrument required to be delivered by NuVasive under any transaction document;

- any breach or non fulfillment of any covenant or agreement made or to be performed by NuVasive in any transaction document or in any agreement or instrument entered in connection with any transaction document;

- any fraud or intentional misrepresentation with respect to, or intentional breach of, any transaction document by NuVasive; and

- any of our liabilities assumed by NuVasive under the asset purchase agreement.

Pursuant to the asset purchase agreement the parties have agreed that neither party shall be liable or be obligated to make any payment in respect of losses suffered by an any indemnified party for a misrepresentation, breach of warranty, or breach or non fulfillment of any covenant by a party (other than with respect to our representations about the title to and sufficiency of the transferred assets) under any transaction document, certificate or other instrument, until the aggregate of all losses suffered by such indemnified party under the asset purchase agreement exceeds $250,000, after which such other party shall be entitled to recover all such losses. In no event, however, can the aggregate indemnity amount payable by any indemnifying party for a misrepresentation, breach of warranty or breach or non fulfillment of any covenant by a party other than with respect to certain specified representations and warranties made with respect to taxes, disposition of certain contracts, intellectual property, authorizations and regulatory compliance, environmental matters and brokers, exceed $15.0 million.

Additionally, neither party shall be liable or be obligated to make any payment in respect of losses suffered by an indemnified party for any misrepresentation or breach of warranty with respect to any of the specified representations or warranties other than with respect to representations and warranties relating to the disposition of certain assumed contracts or losses by us resulting from NuVasive s breach or non-fulfillment of any covenant or agreement under any transaction document or other instrument, or document, required to be delivered under the asset purchase agreement until the aggregate of all losses suffered by such indemnified party exceeds $250,000, after which such party shall be entitled to recover all such losses. In no event, however, shall the aggregate indemnity amount payable by us with respect to such liabilities and all other liabilities of ours with respect to our breach of a warranty with respect to the disposition of certain contracts, when taken together with all other losses paid or payable to an indemnified party, exceed $20.0 million plus any milestone payment(s) that become payable pursuant to the asset purchase agreement. Additionally, absent fraud, intentional misrepresentation or intentional breach of agreement, in no event shall the aggregate indemnity amount for losses payable by any indemnifying party pursuant to the asset purchase agreement, exceed an aggregate total of $35.0 million.

Each party s liability and obligation to make any payment in respect of losses suffered by an indemnified party resulting from fraud, intentional misrepresentation or intentional breach of the agreement, or related to the liabilities retained by Osiris or assumed by NuVasive under the asset purchase agreement shall be unlimited.

For purposes of claims for indemnification, the representations and warranties set forth in the asset purchase agreement survive for eighteen months after the manufacturing assets closing except for those representations we made relating to taxes, disposition of certain contracts, intellectual property, authorization and regulatory compliance, environmental, and brokers which survive for sixty days after the expiration of the applicable statutes of limitations.

Amendment and Waivers

No amendment to, or any waiver with respect to any provision of, the asset purchase agreement will be effective unless in writing and executed, in the case of an amendment, by each party to the agreement or, in the case of a waiver by each party against whom the waiver is to be effective.

SUMMARY OF MATERIAL TERMS OF THE MANUFACTURING AGREEMENT

The following is a summary of the material provisions of the manufacturing agreement, a form of which is attached as Appendix B to this proxy statement, and is incorporated by reference into this summary. While we believe this summary covers the material terms of the manufacturing agreement, this summary may not contain all of the information that is important to you and we urge you to read the form of manufacturing agreement in its entirety.

Overview

In connection with the sale of the technology assets of the Osteocel business under the asset purchase agreement, we and NuVasive agreed to enter into the manufacturing agreement under which we will continue to process Osteocel and supply Osteocel to NuVasive for a period of eighteen months after the technology assets closing.

Manufacturing Obligations

During the term of the manufacturing agreement, we will manufacture and supply Osteocel to NuVasive in accordance with agreed upon manufacturing specifications and all applicable laws. NuVasive is responsible for submitting binding purchase orders to us, for stated minimum quantities of Osteocel over certain stated periods during the term of the manufacturing agreement. We are obligated to use our commercially reasonable efforts to procure donor tissue and to manufacture Osteocel as necessary to meet this minimum performance levels. We can, in our discretion, manufacture and deliver Osteocel to NuVasive in quantities that exceed the ordered quantities, but NuVasive is not obligated to purchase such excess product in amounts over a designated excess product level.

Assuming that we can produce sufficient quantities in a timely manner, we estimate that we will have the opportunity to generate in excess of $50.0 million in revenue related to the manufacture and supply of Osteocel pursuant to the manufacturing agreement over a period of approximately eighteen months following the technology assets closing. There can be no assurance, however, that we will be able to supply sufficient quantities or that we will otherwise be successful in this regard.

We have the ability to subcontract or delegate some or all of our manufacturing obligations to subcontractors approved by NuVasive.

Obligations of Osiris

In addition to its manufacturing obligations, we are responsible for:

- performing all quality control, release testing and documentation preparation and retention with respect to manufacturing lots;

- replacing product rejected by NuVasive;

- providing a limited warranty with respect to the product;

- complying with all packaging and labeling requirements;

- maintaining all manufacturing records and safety records;

- continuing its pursuit of accreditation from the American Association of Tissue Banks, and maintaining such accreditation once received; and

- notifying NuVasive of any customer complaints relating to the product, and assisting NuVasive with any complaint investigations.

Obligations of NuVasive

NuVasive has the following additional obligations under the manufacturing agreement:

- granting a non-exclusive and non-transferable license to us for the term of the manufacturing agreement under the technology assets, to fulfill our obligations under the manufacturing agreement; and

- obtaining, at its own expense, all required regulatory approvals to distribute, sell and market Osteocel.

Indemnification

Each of the parties have provided the other with indemnification with respect to losses and damages arising out of a breach of its responsibilities under the manufacturing agreement.

Term and Termination

The manufacturing agreement will begin on the date of the technology assets closing and extend for eighteen months thereafter. The manufacturing agreement may be terminated early as a result of an uncured breach by the non-terminating party, the bankruptcy or insolvency of a party, or if prior to the expiration of the agreement we have delivered to NuVasive an agreed upon number of cubic centimeters of Osteocel.

UNAUDITED PRO FORMA FINANCIAL INFORMATION

The following unaudited pro forma financial statements give effect to the sale of assets contemplated by the asset purchase agreement and the related transaction documents. The unaudited pro forma balance sheet and statements of operations filed with this report are presented for illustrative purposes only. The pro forma balance sheet as of March 31, 2008 has been prepared to reflect the sale if it had taken place on such date, and is not necessarily indicative of our financial position had such sale occurred on that date. The unaudited pro forma financial statements, including notes thereto, should be read in conjunction with our historical financial statements included in our Form 10-K for the year ended December 31, 2007, including portions thereof reproduced below under the heading Selected Financial Data, the unaudited financial statements filed in our Form 10-Q for the quarter ended March 31, 2008, and the unaudited financial statements for the business to be transferred to NuVasive, included as Appendix D to this proxy statement.

Costs and expenses attributed to the business to be transferred include direct costs primarily associated with the business, as well as corporate expenses, including accounting, legal and human resources expenses. The corporate expenses were allocated to the business based upon estimated relative time and resources dedicated to the business. Management believes the basis of the allocations is reasonable. Certain corporate non-operating transactions of ours have not been allocated to the transferred business. These items include interest income and expense.

Statement of Operations Data:

	Three Months Ended March 31, 2008		
	Historical	Pro Forma Adjustments	Pro Forma As Adjusted
	(In thousands, except per share data)		
Product sales	$ 7,511	$ (7,511)	$
Cost of goods sold	3,781	(3,781)	
Gross profit	3,730	(3,730)	
Revenue from collaborative research licenses, royalties and grants	362		362
Operating expenses:			
Research and development	16,875	(99)	16,776
General and administrative	2,608	(82)	2,526
Total operating expenses	19,483	(181)	19,302
Loss from operations	(15,391)	(3,549)	(18,940)
Interest income (expense):			
Interest income	145		145
Interest expense	(354)		(354)
Total interest expense, net	(209)		(209)
Net loss	$ (15,600)	$ (3,549)	$ (19,149)
Basic and diluted net loss per share	$ (0.49)		$ (0.60)
Weighted Average Common Stock outstanding, in thousands (basic and diluted)	31,741		31,741

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	Year Ended December 31, 2007		
	Historical	Pro Forma Adjustments	Pro Forma As Adjusted
	(In thousands, except per share data)		
Product sales	$ 15,240	$ (15,240)	$
Cost of goods sold	6,955	(6,955)	
Gross profit	8,285	(8,285)	
Revenue from collaborative research licenses and grants	2,048		2,048
Operating expenses:			
Research and development	50,851	(4,142)	46,709
General and administrative	6,708	(206)	6,502
Total operating expenses	57,559	(4,348)	53,211
Loss from operations	(47,226)	(3,937)	(51,163)
Interest income (expense):			
Interest income	1,321		1,321
Interest expense	(8,016)		(8,016)
Total interest expense, net	(6,695)		(6,695)
Net loss	$ (53,921)	$ (3,937)	$ (57,858)
Basic and diluted net loss per share	$ (1.89)		$ (2.03)
Weighted Average Common Stock outstanding, in thousands (basic and diluted)	28,489		28,489

Balance Sheet Data:

	As of March 31, 2008			
		Pro Forma Adjustments		Pro Forma
	Historical	Net Asset to be Sold	Proceeds of Sale	As Adjusted
	(In thousands)			
Assets				
Current assets:				
Cash	$ 4,719	$	$	$ 4,719
Short-term investments	7,280		43,171	50,451
Accounts receivable	4,315	(3,955)		360
Inventory	4,622	(4,622)		
Prepaid expenses and other current assets	1,406	(72)		1,334
Total current assets	22,342	(8,649)	43,171	56,864
Property and equipment, net	7,168	(8,283)	2,744	1,629
Restricted cash	280			280
Other assets	1,106			1,106
Total assets	$ 30,896	$ (16,932)	$ 45,915	$ 59,879
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable and accrued expenses	$ 16,498	$ (3,068)	$	$ 13,430
Notes payable, current portion	12,891			12,891
Capital lease obligations, current portion	587			587
Total current liabilities	29,976	(3,068)		26,908
Capital lease obligations, net of current portion	8			8
Total liabilities	29,984	(3,068)		26,916
Stockholders equity	912	(13,864)	45,915	32,963
Total liabilities and stockholders equity	$ 30,896	$ (16,932)	$ 45,915	$ 59,879

The unaudited pro forma financial information as of and for the three month period ended March 31, 2008 and for the year ended December 31, 2007, gives effect to the following pro forma adjustments:

Statement of Operations Data:

- To give retroactive effect to the decrease in net sales, cost of goods sold and operating expenses estimated to be attributable to our Osteocel business, including Osteocel and Osteocel XO and related business assets.

Balance Sheet Data:

- Represents assets to be sold to and liabilities to be assumed by NuVasive, Inc. related to our Osteocel business.

- Represents the gross cash sales price to be received at the technology assets closing of $35.0 million, plus the $12.5 million to be received upon the transfer of the manufacturing assets at the manufacturing assets closing.

- The asset purchase agreement provides us with opportunities to receive milestone payments in the maximum aggregate amount of $37.5 million, related to Osteocel sales and production goals. Such milestone payments have not been reflected in the pro forma balance sheet data, since their receipt cannot be assured until earned.

SELECTED FINANCIAL DATA

We derived the selected financial data presented below for the periods or dates indicated from the financial statements of Osiris Therapeutics, Inc.. Our financial statements for these periods were audited by Stegman & Company, an independent registered public accounting firm. You should read the data below in conjunction with our financial statements, related notes and other financial information appearing in Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data of our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

	Year Ended December 31,				
	2007	2006	2005	2004	2003
	(in thousands, except per share data)				
Statement of Operations Data:					
Product sales	$ 15,240	$ 8,291	$ 957	$	$
Cost of goods sold	6,955	3,697	444		
Gross profit	8,285	4,594	513		
Revenue from collaborative research licenses and grants	2,048	1,181	3,013	3,911	3,981
Operating expenses:					
Research and development	50,851	37,590	16,927	11,888	18,639
General and administrative and other expenses	6,708	8,459	2,294	1,704	4,467
Total operating expenses	57,559	46,049	19,221	13,592	23,106
Loss from operations	(47,226)	(40,274)	(15,695)	(9,681)	(19,125)
Interest expense, net	(6,695)	(4,685)	(4,300)	(847)	(605)
Net loss	$ (53,921)	$ (44,959)	$ (19,995)	$ (10,528)	$ (19,730)
Basic and diluted net loss per share	$ (1.89)	$ (2.70)	$ (2.23)	$ (1.19)	$ (3.60)
Weighted average shares of common stock used in computing basic and diluted net loss per share	28,489	16,663	8,959	8,814	5,475

	At December 31,				
	2007	2006	2005	2004	2003
Balance Sheet Data:					
Cash and short-term investments	$ 18,164	$ 39,181	$ 43,471	$ 488	$ 1,339
Working capital	7,247	33,166	38,103	(5,459)	(5,314)
Total assets	37,041	49,168	51,014	5,972	9,748
Notes payable, less current portion	1,200	25,000	47,411	7,519	179
Mandatorily redeemable convertible preferred stock			64,267		
Convertible preferred stock			32,746	15,243	13,000
Accumulated deficit	(241,424)	(187,503)	(142,544)	(122,549)	(112,021)
Total stockholders equity (deficit)	14,336	11,287	(73,662)	(13,004)	(5,563)

QUARTERLY FINANCIAL DATA (UNAUDITED)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2007				
Total revenues	$ 2,279	$ 3,547	$ 4,297	$ 7,165
Product sales	2,000	3,252	4,003	5,985
Cost of goods sold	901	1503	1,826	2,725
Research and development expenses	11,030	10,583	10,842	18,396
General and administrative expenses and fees	1,506	1,501	1,689	2,012
Net loss	(11,501)	(10,458)	(10,390)	(21,572)
**Net loss per common share, basic and diluted	(0.42)	(0.37)	(0.36)	(0.73)
2006				
Total revenues	$ 1,400	$ 1,987	$ 2,841	$ 3,244
Product sales	1,105	1,689	2,539	2,958
Cost of goods sold	489	762	1,113	1,333
Research and development expenses	4,368	10,922	9,242	13,058
General and administrative expenses and fees	1,138	1,209	5,300	812
Net loss	(5,121)	(11,605)	(15,565)	(12,668)
**Net loss per common share, basic and diluted	(0.56)	(1.27)	(0.75)	(0.46)
2005				
Total revenues	$ 385	$ 1,339	$ 1,285	$ 961
Product sales			284	673
Cost of goods sold			220	224
Research and development expenses	2,657	3,592	3,464	7,214
General and administrative expenses and fees	752	487	554	501
Net loss	(3,868)	(3,394)	(4,678)	(8,055)
**Net loss per common share, basic and diluted	(0.43)	(0.38)	(0.52)	(0.88)

**

Earning per share are calculated on a quarterly basis and may not be additive to year-to-date amounts.

ADDITIONAL INFORMATION REGARDING

OSIRIS AND NUVASIVE

Each of Osiris and NuVasive is a public company and files annual, quarterly and current reports, proxy statements and other information with the United States Securities and Exchange Commission, or SEC. These reports contain significant information about us and NuVasive, our respective businesses, products and finances. Any statement included in any of these reports is automatically updated and superseded if information subsequently filed modifies or replaces that information.

Copies of each of the following reports (without exhibits) previously filed with the SEC by us or by NuVasive, as the case may be, are attached to this proxy statement as Appendix E and F, respectively:

Reports filed by Osiris (Appendix E)

- Annual Report on Form 10-K for the fiscal year ended December 31, 2007
- Quarterly Report on Form 10-Q (as modified by Form 10-Q/A) for the quarterly period ended March 31, 2008
- Current Report on Form 8-K filed with the SEC on June 10, 2008
- Current Report on Form 8-K filed with the SEC on June 17, 2008

Reports filed by NuVasive (Appendix F)

- Annual Report on Form 10-K for the fiscal year ended December 31, 2007
- Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2008

These reports, without exhibits and without the documents incorporated therein by reference, are incorporated fully into this proxy statement by this reference.

You are urged to carefully review and analyze these reports before submitting a proxy card in respect of the matters to be submitted for a vote at the special meeting.

You may also read any document that we or NuVasive file with the SEC at the SEC s Public Reference Section or through the SEC s website as further described below under the heading Available Information. In addition, we maintain a website that contains information about us at http://www.osiris.com; and NuVasive maintains a website that contains information about it at http://www.nuvasive.com. The information found on or accessible through either our or NuVasive s website is not incorporated into and does not form a part of this proxy statement or any other report or document that we or NuVasive file or furnish with the SEC.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of June 1, 2008 for (a) each of our executive officers and directors, (b) all of our current directors and executive officers as a group and (c) each stockholder that we know to be the beneficial owner of more than 5% of our common stock. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of June 1, 2008 pursuant to the exercise of options or warrants to be outstanding for the purpose of computing the percentage ownership of such individual or group, but those shares are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders. Percentage of ownership is based on 31,771,667 shares of common stock outstanding on June 1, 2008.

Name and Address of Beneficial Owners	Number	Percent
Executive Officers and Directors		
Gregory H. Barnhill	12,421	
Harry E. Carmitchel, Jr. (1)	88,250	
Cary J. Claiborne (2)	75,000	
Lode Debrabandere (3)	41,250	
Earl R. Fender (4)	42,500	
Peter Friedli (5)	16,239,720	49.3%
Felix Gutzwiller	49,500	
Philip R. Jacoby, Jr. (6)	7,750	
C. Randal Mills (7)	400,000	1.2%
Jay M. Moyes	4,500	
Michelle LeRoux Williams (8)	14,082	
All directors and executive officers as a group (11 persons)	16,974,973	51.6%
Other 5% Stockholders		
Venturetec, Inc. (9)	4,153,310	13.0%
c/o Osiris Therapeutics, Inc. 7015 Albert Einstein Drive Columbia, Maryland 21046		
Thomas Schmidheiny (10)	3,053,267	9.5%
23 Fraubourg de Hopital 2000 Neuchatel, Switzerland		
BIH SA (10)	2,658,113	8.3%
23 Fraubourg de Hopital 2000 Neuchatel, Switzerland		

(1) Includes 82,000 shares owned directly by Mr. Carmitchel and 6,250 shares issuable upon the exercise of options.
(2) Mr. Claiborne s employment terminated in November 2007.
(3) Includes 41,500 shares issuable upon exercise of options.
(4) Includes 42,500 shares issuable upon exercise of options. Mr. Fender s employment terminated in April 2008.
(5) Includes 9,880,371 shares owned directly by Mr. Friedli; 1,000,000 shares issuable upon the exercise of outstanding warrants; assuming the warrants are exercised in full for cash; 205,423 shares issuable upon the conversion of a certain convertible promissory note, which may be converted at the discretion of the holder; 625 shares owned by Margrit Friedli, Mr. Friedli s mother; 3,963,629 shares owned by Venturetec, Inc., 189,681 shares issuable to Venturetec, Inc. upon the conversion of a certain convertible promissory note, which may be converted at the discretion of the holder and 1,000,000 shares owned by US Venture 05, Inc. Mr. Friedli is the President of Venturetec, Inc. and US Ventures 05, Inc.
(6) Includes 5,625 shares owned directly by Mr. Jacoby and 2,175 shares issuable upon the exercise of options.
(7) Includes 123,000 shares owned directly by Dr. Mills; 2,000 shares owned in custodial accounts where Dr. Mills is the custodian; and 275,000 shares issuable upon the exercise of options.

(8) Includes 14,082 shares issuable upon the exercise of options.
(9) Included 3,963,629 shares owned directly by Venturetec, Inc. and 189,681 shares issuable upon the conversion of a certain convertible promissory note owned by Venturetec, Inc., which may be converted at the discretion of the holder.
(10) Includes 395,154 shares owned directly by Mr. Schmidheiny; 2,408,944 shares owned by BIH SA; and 249,169 shares issuable upon the conversion of a certain convertible promissory note owned by BIH SA, which may be converted at the discretion of the holder. Mr. Schmidheiny is the Chairman and controlling shareholder of BIH SA.

OTHER MATTERS FOR ACTION AT THE SPECIAL MEETING

Our Board of Directors knows of no other business which will be presented at the special meeting. However, if any other business is properly brought before the special meeting or any postponement or adjournment thereof, which may properly be acted upon, the proxies solicited hereby will be voted on such matter in accordance with the best judgment of the proxy holders named therein.

AVAILABLE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and, in accordance therewith, file reports, proxy statements and other information with the U.S. Securities and Exchange Commission. Reports, proxy statements and other information filed by us may be inspected without charge and copies obtained upon payment of prescribed fees from the Public Reference Section of the U.S. Securities and Exchange Commission at 100 F Street, NE, Washington, D.C. 20549, or by way of the U.S. Securities and Exchange Commission s website, http://www.sec.gov.

FORWARD LOOKING STATEMENTS

This proxy statement includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Forward-looking statements include statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, compensation arrangements, financing needs, plans or intentions relating to collaborations or business combinations, business trends and other information that is not historical information.

When used in this proxy statement, the words *estimates, expects, anticipates, projects, plans, intends, believes, forecasts* and variations of such words or similar expressions are intended to identify forward-looking statements. All forward-looking statements, including, without limitation, are based upon our current expectations and various assumptions. Our expectations, beliefs and projections are expressed in good faith and we believe there is a reasonable basis for them. However, there can be no assurance that management s expectations, beliefs and projections will result or be achieved.

There are a number of risks and uncertainties that could cause our actual results to differ materially from the forward-looking statements contained in this proxy statement. Important factors that could cause our actual results to differ materially from the forward-looking statements we make in this proxy statement are set forth in this proxy statement, including Risk Factors. There may be other factors that may cause our actual results to differ materially from the forward-looking statements.

All forward-looking statements attributable to us or persons acting on our behalf apply only as of the date of this proxy statement and are expressly qualified in their entirety by the cautionary statements included herein. We undertake no obligation to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances and do not intend to do so.

WHETHER OR NOT YOU INTEND TO BE PRESENT AT THE MEETING, YOU ARE URGED TO FILL OUT, SIGN, DATE AND RETURN THE ENCLOSED PROXY AT YOUR EARLIEST CONVENIENCE.

By order of the Board of Directors:

Philip R. Jacoby, Jr.
Corporate Secretary

Columbia, Maryland

, 2008

Appendix A

ASSET PURCHASE AGREEMENT

by and between

OSIRIS THERAPEUTICS, INC.

and

NUVASIVE, INC.

Dated as of May 8, 2008

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ASSET PURCHASE AGREEMENT

This **ASSET PURCHASE AGREEMENT** (this "Agreement") dated as of the 8th day of May, 2008, is by and between **OSIRIS THERAPEUTICS, INC.**, a Delaware corporation ("Seller"), and **NUVASIVE, INC.**, a Delaware corporation ("Purchaser").

RECITALS:

A. Seller is engaged in the business of processing, manufacturing, marketing and selling an osteobiologic allograft material containing cancellous bone (which contains intrinsic viable mesenchymal stem cells) used in spinal fusion and other surgical procedures and commonly known as Osteocel® and Osteocel® XO including current formulation and all development projects related to Osteocel® and Osteocel® XO (collectively, the Product) (the development, manufacturing, marketing and sale of the Product shall be referred to herein as the Business).

B. Pursuant to this Agreement, Seller and Purchaser intend that (i) Seller sell and transfer to Purchaser all of Seller s right, title and interest in and to all of Seller s property and assets set forth in Section 1.1(a) hereof, and (ii) Purchaser assume certain specified obligations of Seller, contractual and otherwise, set forth in Section 1.2(a), all on the terms and conditions contained in, and as more fully set forth in, this Agreement.

C. Simultaneously with the execution and delivery of this Agreement and as a condition and material inducement to the willingness of Purchaser to enter into this Agreement, Purchaser and certain stockholders of Seller are entering into voting agreements pursuant to which, among other things, such stockholders have agreed to vote in favor of approval of the transactions contemplated by this Agreement and the other Transaction Documents and to take certain other actions in furtherance of the transactions contemplated hereby, in each case upon the terms and subject to the conditions set forth herein.

Accordingly, in consideration of the premises and the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

ARTICLE I.

PURCHASE AND SALE OF ASSETS

Section 1.1 Transferred Assets; Excluded Assets; Time of Transfer.

(a) Transferred Assets. On the terms and subject to the conditions set forth in this Agreement and in reliance upon the representations and warranties contained herein, at the times set forth in Section 1.1(c) below, Seller shall sell, transfer, assign, set over, convey and deliver to Purchaser, and Purchaser shall purchase, acquire, accept, assume and receive from Seller, free and clear of any Liens (other than Permitted Liens), all right, title and interest of Seller in, to and under the following assets and property, real, personal or mixed, tangible or intangible, of Seller with respect to the Business (other than the Excluded Assets) (the Transferred Assets):

(a) Transferred Assets. On the terms and subject to the conditions set forth in this Agreement and in reliance

(i) All Patent Rights, Trademark Rights and Copyright Rights set forth on Schedule 1.1(a)(i) hereto (the Transferred Technology);

(ii) All inventory (other than Finished Inventory) and work in process existing as of the Manufacturing Closing Date, which includes any and all goods, raw materials and work in process used or consumed in the Business, together with all rights of Seller relating to such inventory against suppliers thereof (the Work in Process);

(iii) [Intentionally omitted.];

(iv) The rights of Seller related to the development of the Product, including all clinical trials, and related clinical trial data, which rights are identified on Schedule 1.1(a)(iv) (the Product Development);

(v) All data and records related to the operation of the Business, which data and records include (without limitation) client and customer lists, research and development reports, financial and billing records (including routing and billing information), creative materials, advertising materials, marketing materials, promotional materials, studies, reports, correspondence and other similar documents (the Records), which Records are identified on Schedule 1.1(a)(v); provided that all such data and records provided pursuant to this Section 1.1(a)(v) may in Seller s sole discretion, have redacted therefrom all data unrelated to the Business;

(vi) The tangible personal property of Seller used in or necessary for the operation of the Business identified on Schedule 1.1(a)(vi);

(vii) The permits, licenses, franchises, consents, authorizations, registrations and other approvals and operating rights relating to the Business that are identified on Schedule 1.1(a)(vii);

(viii) All claims of Seller against third parties relating to the Technology Assets as of the Technology Closing Date and the Manufacturing Assets as of the Manufacturing Closing Date, in each case whether choate or inchoate, known or unknown, contingent or noncontingent;

(ix) All rights of Seller relating to deposits and prepaid expenses, claims for refunds and rights to offset in respect thereof relating to the Business and/or the Transferred Assets;

(x) All rights in and to the Contracts used in, related to or necessary for the operation of the Business as presently conducted or as contemplated to be conducted, that are identified on Schedule 1.1(a)(x) (the Assumed Contracts);

(xi) **All of Seller s goodwill relating to the foregoing assets; and**

(xii) **All Business Intellectual Property not otherwise set forth on Schedules 1.1(a)(i), 1.1(a)(iv), 1.1(a)(v) and 1.1(a)(vi).**

Schedule 1.1 Manufacturing Assets identifies all of the Transferred Assets that are being transferred to Purchaser at the Manufacturing Closing (the Manufacturing Assets).

(b) Excluded Assets. Except for the Transferred Assets, Purchaser shall not acquire by virtue of this Agreement, any other Transaction Document, or the transactions contemplated hereby or thereby, and shall have no right, title or interest in any of the assets of Seller with respect to the Business or otherwise, and such assets shall remain the property of the Seller (collectively, the Excluded Assets).

(c) Time for Transfer of the Transferred Assets. The consummation of the transactions contemplated by this Section 1.1 shall take place (i) with respect to the Technology Assets, on the Technology Closing Date (the Technology Asset Transfer) and (ii) with respect to the Manufacturing Assets, on the Manufacturing Closing Date (the Manufacturing Asset Transfer).

Section 1.2 Assumed Liabilities; Retained Liabilities.

(a) On the terms of and subject to the conditions of this Agreement and in reliance upon the representations and warranties contained herein, in addition to purchasing and acquiring the Transferred Assets, Purchaser shall assume and agrees, from and after the date of such assumption, to pay, perform and discharge when due, and to indemnify Seller against and hold it harmless from only the following liabilities and obligations of Seller (but excluding the Retained Liabilities) in respect of the Business (the Assumed Liabilities):

(i) (A) The obligations to perform arising in the ordinary course of the Business after the Technology Closing Date under the Assumed Contracts which constitute a portion of the Technology Assets and (B) the obligations to perform arising in the ordinary course of the Business after the Manufacturing Closing Date under the Assumed Contracts which constitute a portion of the Manufacturing Assets;

(ii) The expenses and liabilities relating to the Business which are incurred or accrued in the ordinary course of the Business consistent with past practice after the Technology Closing Date.

(b) Other than the Assumed Liabilities, Purchaser shall not assume by virtue of this Agreement or the transactions contemplated hereby, and shall have no liability for, any other liability of Seller. All liabilities other than Assumed Liabilities are referred to herein as Retained Liabilities. The Retained Liabilities will include, without limitation, the following:

(i) all trade accounts payable of the Business;

(xii) All Business Intellectual Property not otherwise set forth on Schedules 1.1(a)(i), 1.1(a)(iv), 1.1(a)(v) and 1

(ii) any liabilities or obligations of Seller in respect of indebtedness (whether absolute, accrued, contingent, fixed or otherwise, whether due or to become due) of Seller, of any kind, character or description whatsoever, including, but not limited to, indebtedness owed by Seller to any of its stockholders;

(iii) any liabilities or obligations of Seller related to the employment, termination or compensation of any employee, consultant or service provider of the

(ii) any liabilities or obligations of Seller in respect of indebtedness (whether absolute, accrued, contingent, fix

Seller, including but not limited to compensation claims, Taxes or employer withholdings, workers compensation or benefits (however described) owing to any such person arising out of the operation of the Business by Seller including, for avoidance of doubt, any and all liabilities or obligations to Transferred Employees incurred prior to the time that any such Transferred Employee becomes an employee of Purchaser;

(iv) any liabilities or obligations of Seller which arise from or out of or in connection with any product warranty or product liability claims owing, accrued or the underlying facts with respect to which arising out of the operation of the Business by Seller (including, for avoidance of doubt, the operation of the Business by Seller through and including the Manufacturing Closing Date but excluding liabilities or obligations resulting from either modifications to the Product made by Purchaser or additional warranties extended by Purchaser following the Technology Closing Date);

(v) any liabilities or obligations (whether assessed or unassessed) of Seller for any Taxes, any Transfer Taxes imposed on Seller, any Taxes of the Business for any period (or portion thereof) ending on or prior to the Technology Closing Date and any Taxes of the Business related to the Manufacturing Assets for any period (or portion thereof) ending on or prior to the Manufacturing Closing Date;

(vi) any liabilities or obligations relating to or arising out of a breach or failure of Seller to perform under an Assumed Contract prior to the date on which any such Assumed Contract is transferred by Seller to Purchaser in accordance with the terms of this Agreement;

(vii) any liabilities or obligations relating to or arising under any environmental law or regulation to the extent arising out of the operation of the Business prior to the Technology Closing Date with respect to the Technology Asset and the Manufacturing Closing Date with respect to the Manufacturing Assets; and

(viii) any liabilities or obligations of Seller incurred, arising from or out of or in connection with this Agreement, the Manufacturing Agreement, the License Agreement, the Bill of Sale Technology Assets, the Bill of Sale Manufacturing Assets, the IP Assignment Agreement Patents and the IP Assignment Agreement Trademarks (together, the Transaction Documents) or the events or negotiations leading up to the execution and consummation of the transactions contemplated by the Transaction Documents.

Section 1.3 **Technology Closing; Manufacturing Closing**. The consummation of the Technology Asset Transfer (the Technology Closing) shall be held as soon as reasonably practicable upon satisfaction of the conditions set forth in Article V of this Agreement or such other date and time as Purchaser and Seller shall agree (the Technology Closing Date). The consummation of the Manufacturing Asset Transfer (the Manufacturing Closing) shall be held as soon as reasonably practicable following the earlier to occur of (i) the termination of the Manufacturing Agreement by Purchaser pursuant to Section 7.1 of the Manufacturing Agreement and (ii) the expiration of the Term (as that term is defined in the Manufacturing Agreement) of the Manufacturing Agreement (the Manufacturing Closing Date). The Technology Closing

(iii) any liabilities or obligations of Seller related to the employment, termination or compensation of any emplo

and the Manufacturing Closing shall be held at the offices of DLA Piper US LLP, 4365 Executive Drive, San Diego, California (or via exchange of documents via PDF and overnight mail courier).

Section 1.4 **Initial Purchase Price**. At the Technology Closing, Purchaser shall (i) assume the Assumed Liabilities related to the Technology Assets, and (ii) pay to Seller an aggregate of Thirty Five Million Dollars ($35,000,000) (the Initial Purchase Price). Purchaser shall pay the Initial Purchase Price to Seller by bank or cashiers check or, provided that Seller has delivered wire transfer instructions to Purchaser not less than two (2) business days prior to the Technology Closing Date, by wire transfer in United States dollars of immediately available funds to an account designated in writing by Seller.

Section 1.5 **Additional Purchase Price.**

(a) Milestones; Milestone Payments. From and after the Technology Closing Date, in addition to the consideration set forth in Section 1.4 above, Purchaser shall, subject to, and contingent upon achievement of the post-Technology Closing performance milestones of the Business set forth below (each, a Milestone) not later than the applicable date for satisfaction of each Milestone set forth below (each a Milestone Expiration Date), pay to Seller an amount of cash (in United States dollars of immediately available funds) or common stock, par value $0.001 per share, of Purchaser (Purchaser Common Stock) (the form of payment of which is to be determined in the sole discretion of Purchaser), equal to the First Milestone Payment, Second Milestone Payment, Third Milestone Payment, Fourth Milestone Payment, Fifth Milestone Payment and/or Sixth Milestone Payment, as applicable (the Applicable Milestone Payment) and each Milestone shall be independent of each other Milestone and may be satisfied and payment become due therefore regardless of non-satisfaction of any other Milestone; provided, however, that (i) Purchaser shall not issue shares of Purchaser Common Stock in respect of any Applicable Milestone Payment unless such shares of Purchaser Common Stock may be re-sold by Seller pursuant to Rule 144 of the rules and regulations promulgated under the Securities Act of 1933, as amended (the Securities Act) on the date of such issuance, (ii) if Purchaser elects to issue shares of Purchaser Common Stock in respect of any Applicable Milestone Payment, then prior to such issuance and upon request by the Purchaser, Seller shall deliver to Purchaser such representations and warranties as Purchaser shall reasonably request for purposes of exempting the issuance of such shares from the registration requirements of the Securities Act and (iii) if Purchaser elects to issue shares of Purchaser Common Stock in respect of any Applicable Milestone Payment, the number of shares of Purchaser Common Stock to be issued shall be equal to the Applicable Milestone Payment divided by the Purchaser Common Stock Value. The obligations of Purchaser under this Section 1.5(a) are subject to the provisions of Section 1.5(c) below (regarding Purchaser s Rights of Set-Off). For avoidance of doubt, in no event shall the sum of all Applicable Milestone Payments made by Purchaser to Seller under this Section 1.5 exceed Fifty Million Dollars ($50,000,000) *plus* or *minus* the WIP Value (the Maximum Milestone Amount).

(i) If at any time following the Technology Closing Date but at or prior to April 15, 2009, Seller shall have delivered to Purchaser an aggregate of 125,000 cubic centimeters of Product (the First Delivery Threshold) in accordance with the terms and provisions of, and subject to the specifications set forth in, the Manufacturing Agreement,

Purchaser shall pay to Seller Five Million Dollars ($5,000,000) (the First Milestone Payment).

(ii) If at any time following the Technology Closing Date but prior to the Manufacturing Closing, Seller shall have delivered to Purchaser an aggregate of 250,000 cubic centimeters of Product (including, for avoidance of doubt, any Product delivered in satisfaction of the First Delivery Threshold) (the Second Delivery Threshold) in accordance with the terms and provisions of, and subject to the specifications set forth in, the Manufacturing Agreement, Purchaser shall pay to Seller Five Million Dollars ($5,000,000) (the Second Milestone Payment).

(iii) Subject to the prior satisfaction of the conditions set forth in Article VI of this Agreement, at the Manufacturing Closing, Purchaser shall pay to Seller the sum of (i) Twelve Million, Five Hundred Thousand Dollars ($12,500,000) *plus* or *minus* (ii) the WIP Value (the Third Milestone Payment).

(iv) If prior to the Manufacturing Closing, Seller shall have delivered to Purchaser an aggregate of 275,000 cubic centimeters of Product (including, for avoidance of doubt, the Product delivered pursuant to the Second Delivery Threshold) in accordance with the terms and provisions of, and subject to the specifications set forth in, the Manufacturing Agreement, at the Manufacturing Closing, Purchaser shall pay to Seller Five Million Dollars ($5,000,000) (the Fourth Milestone Payment).

(v) At the Manufacturing Closing, Purchaser shall pay to Seller the Additional Product Delivery Payment, if any (the Fifth Milestone Payment).

(vi) If at any time following the Technology Closing Date the Business shall generate Thirty-Five Million Dollars ($35,000,000) in cumulative Net Sales (the Net Sales Threshold), Purchaser shall pay to Seller Fifteen Million Dollars ($15,000,000) (the Sixth Milestone Payment).

If any payment under this Section 1.5(a) is made in the form of Purchaser Common Stock, then on the date of such payment Purchaser shall provide to Seller (I) a certificate from a duly authorized officer of Purchaser certifying that as of the date of such issuance (x) the Purchaser Common Stock so issued has been duly authorized and is validly issued, fully-paid and non-assessable and, (y) the provisions of Rule 144(c) of the Securities Act, are satisfied and (II) a legal opinion from Purchaser s legal counsel that such Purchaser Common Stock has been duly authorized and validly issued, is fully paid and non-assessable and that the holding period set forth in Rule 144(b) of the Securities Act has been satisfied. If Purchaser is unable to satisfy the requirement set forth in the immediately preceding sentence, Seller shall be under no obligation to accept Purchaser Common Stock as payment for the Applicable Milestone Payment and Purchaser shall make such Applicable Milestone Payment in the form of cash, in United States dollars of immediately available funds.

(b) Time for Determination; Dispute Mechanism.

(i) If at any time following the Technology Closing Date but at or prior to April 15, 2009, Seller shall have deli

(i) As soon as reasonably practicable following each date on which a Milestone is achieved and in any event within five (5) business days of the achievement

(i) As soon as reasonably practicable following each date on which a Milestone is achieved and in any event

of any such Milestone, Purchaser shall pay to Seller the Applicable Milestone Payment for such Milestone; provided, however, that in no event shall Purchaser be liable for the payment of, and Seller shall not be entitled to, any Applicable Milestone Payment for any Milestone that is not achieved on or before the applicable Milestone Expiration Date. At all times following the Manufacturing Closing Date and prior to payment by Purchaser to Seller of the Sixth Milestone Payment pursuant to Section 1.5(a)(vi) hereof, Purchaser shall, as soon as reasonably practicable following each December 31 during such period, deliver to Seller Purchaser s calculation of the cumulative Net Sales for the period commencing on the day immediately following the Manufacturing Closing Date and up to and including each such December 31.

(ii) If Seller believes that it is entitled to payment of all or any portion of an Applicable Milestone Payment hereunder which Seller has not received within five (5) business days following the achievement of the Milestone for which payment is due, Seller may, not later than twelve (12) months following the achievement of such Milestone, deliver to Purchaser a notice setting forth Seller s determination that all or a portion of such Applicable Milestone Payment is due under this Agreement (the Milestone Assessment Notice). If Seller does not deliver to Purchaser a Milestone Assessment Notice within such twelve (12) month period, then Seller shall have been deemed to agree that the Milestone has not been met and no payment with respect to such Milestone is due to Seller hereunder and Seller shall have no further rights to such Applicable Milestone Payment or any portion thereof; provided, however, that Seller s failure to deliver a Milestone Assessment Notice within such twelve (12) month period with respect to the Sixth Milestone Payment shall not relieve Purchaser of its obligations to pay the Sixth Milestone Payment (if and when earned) unless Purchaser is materially prejudiced by such delay.

(iii) If Purchaser shall object to Seller s determination that a Milestone has been achieved as set forth in the Milestone Assessment Notice, then Purchaser shall deliver a dispute notice (a Milestone Dispute Notice) to Seller within five (5) business days following Seller s delivery of the Milestone Assessment Notice. If Purchaser delivers a Milestone Dispute Notice to Seller in connection with the Sixth Milestone Payment under Section 1.5(a)(vi), upon Seller s reasonable request, Purchaser shall provide Seller with such books of account and records and written evidence as Seller shall reasonably request showing Purchaser s calculation of the Net Sales of the Business and, upon Seller s reasonable request and upon two (2) business days prior written notice to Purchaser, Seller or its representative may inspect the gross receipts, credits, sales Tax, Tax reports, costs and any other reports, records or documents reasonably requested by Seller and associated with the Business or the Product for the sole purpose of reviewing, and only to the extent necessary to review, Purchaser s calculation of Net Sales. A representative of Purchaser, on the one hand, and a representative of Seller, on the other, shall attempt in good faith to resolve any such objections within ten (10) business days of the receipt by Seller of the Milestone Dispute Notice.

(iv) If Purchaser and Seller shall be unable to resolve any such dispute within the ten (10) business day period, either Purchaser or Seller by written notice to the other may demand arbitration in accordance with the procedures set forth in Section 9.1 hereof.

of any such Milestone, Purchaser shall pay to Seller the Applicable Milestone Payment for such Milestone, provided

(v) If no Milestone Dispute Notice is delivered within the timeframe set forth above, then Seller s determination that the Milestone has been achieved, and that some or all of the Applicable Milestone Payment is due hereunder, shall be deemed to be accepted and Purchaser shall pay to Seller those amounts set forth in the Milestone Assessment Notice.

(c) Rights of Set-Off. Purchaser shall have the right to withhold and set-off against any amount otherwise due to be paid (but not yet paid) pursuant to this Section 1.5 the amount of any Losses to which any Purchaser Indemnified Party may be entitled under Article VIII hereof or any other agreement entered into pursuant to this Agreement (the Rights of Set-Off); provided, however, that the foregoing shall not apply (i) to the same Loss more than once or (ii) to the extent any such Loss is adjusted as provided for in Section 8.4(b) hereof.

(d) Acknowledgement of Seller and Purchaser. Seller and Purchaser acknowledge that (i) (A) upon the Technology Closing and subject to Purchaser s express obligations under the Manufacturing Agreement, Purchaser has the right to operate the Business and Purchaser s other businesses in any way that Purchaser deems appropriate in Purchaser s sole discretion, and (B) subject to Purchaser s express obligations under the Manufacturing Agreement, Purchaser has no obligation to operate the Business in order to achieve any Milestone or to achieve or maximize any Applicable Milestone Payment, (ii) there is no assurance that the Seller will achieve all or any Milestones or that Purchaser will achieve the Net Sales Threshold, (iii) the parties solely intend the express provisions of this Agreement and the other Transaction Documents to govern their contractual relationship, (iv) the right of the Seller to payment of any Applicable Milestone Payment, if any, shall not bear any interest unless not timely paid, and (v) the right of the Seller to a portion of any Applicable Milestone Payment, if any, shall not be represented by a certificate or other instrument, shall not represent an ownership interest of Seller in Purchaser or the Business and shall not entitle Seller to any rights common to any holder of any debt or equity security of Purchaser. The Seller hereby waives, on its behalf and on behalf of any of its successors and assigns, any fiduciary duty (but, for avoidance of doubt, not any implied covenant of good faith and fair dealing) of Purchaser to Seller, with respect to the matters contemplated by this Section 1.5.

Section 1.6 **Withholding**. Purchaser shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement to Seller such amounts as Purchaser is required to deduct and withhold under the Code, or any provisions of state or local Tax law, with respect to the making of such payment. Purchaser shall notify Seller of the basis for such withholding no less than 10 business days prior to the proposed withholding and shall consider in good faith any views of Seller that such withholding is not required under the Code, or any provisions of state or local Tax law, with respect to the making of such payment.

Section 1.7 **Allocation of Purchase Price**. The Initial Purchase Price shall be allocated for Tax purposes among the Transferred Assets in accordance with Section 1060 of the Code. Purchaser shall prepare and deliver to Seller for Seller s approval, a proposed allocation of the Initial Purchase Price prepared in accordance with the foregoing within 45 days of the Technology Closing; provided, that if Seller withholds its approval to such allocation, Purchaser and Seller shall negotiate in good faith to agree upon the allocation of the Purchase Price within 30 days of Seller s receipt of Purchaser s proposed allocation. Each of Purchaser and Seller shall

(iv) If Purchaser and Seller shall be unable to resolve any such dispute within the ten (10) business day period

file IRS Form 8594 with its Federal income Tax Return consistent with such allocation as determined in accordance with the immediately preceding sentence for the Tax year in which this Agreement is consummated. Seller and Purchaser shall report all Tax consequences of the transactions contemplated by this Agreement in a manner consistent with such allocation, and not take any position inconsistent therewith upon examination of any Tax Return, in any refund claim, in any litigation or investigation or otherwise.

ARTICLE II.

REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Purchaser as of the date hereof as follows:

Section 2.1 **Organization, Good Standing and Authority**. Seller is duly formed, validly existing and in good standing under the laws of the State of Delaware, and is duly qualified as a foreign corporation to transact business and is in good standing in each jurisdiction in which such qualification is required, except where failure to be qualified or to be in good standing would not materially and adversely affect the Business. Seller has full corporate power and authority to own the assets owned by it, to lease the properties and assets held by it under lease, to own and carry on the operation of the Business as it is now being conducted by it, and to operate the Business as heretofore operated by it.

Section 2.2 **Organizational and Governing Documents; Approval.**

(a) Prior to the date hereof, Seller has furnished to Purchaser complete and correct copies of the certificate of incorporation and bylaws of Seller (the Seller Organizational Documents). The Seller Organizational Documents are in full force and effect and Seller is not in violation of any provision of the Seller Organizational Documents.

(b) This Agreement and the other Transaction Documents to which it is a party have been approved by all necessary corporate action of Seller and no other corporate proceedings on the part of Seller and, except for the Stockholder Approval, no corporate proceedings on the part of Seller s stockholders are necessary to authorize the execution and delivery of this Agreement or any other Transaction Document, or the consummation of the transactions contemplated hereby or thereby, under the Delaware General Corporation Law, the Seller Organizational Documents or otherwise.

Section 2.3 **Due Execution and Delivery**. Seller has all necessary power and authority to execute and deliver this Agreement and the other Transaction Documents to which it is a party and each instrument required hereby and thereby to be executed and delivered by it, and, prior to the Technology Closing, will have all necessary power and authority to carry out its obligations hereunder and thereunder. Seller has duly executed and delivered this Agreement and assuming the due authorization, execution and deliver of this Agreement by Purchaser, this Agreement constitutes (and, when executed and delivered, the Transaction Documents to which it is a party will constitute) the legal, valid and binding obligations of Seller enforceable against it in accordance with its terms, except that such enforcement (a) may be limited by bankruptcy, insolvency, moratorium or similar laws affecting creditors rights generally, and (b) is subject to

(a) Prior to the date hereof, Seller has furnished to Purchaser complete and correct copies of the certificate o

the availability of equitable remedies, as determined in the discretion of the court before which such a proceeding may be brought.

Section 2.4 **Title and Sufficiency of Transferred Assets**. Seller is the sole owner and has good and marketable title (or leasehold title, as the case may be) to the Transferred Assets free and clear of all liens, claims, charges, security interests, leases, covenants, options, pledges, rights of others, easements, rights of refusal, reservations, restrictions, encumbrances and other defects in title (collectively, Liens) except for (i) Liens incurred in the ordinary course of the Business, consistent with past practice, of the type identified on Schedule 2.4(i), (ii) Liens for Taxes not yet due and payable and (iii) Liens created by the express provisions of the Assumed Contracts (together, the Permitted Liens) whether imposed by agreement, understanding, law, equity, or otherwise. The Manufacturing Assets are all assets of Seller used in or related to the processing and manufacturing of the Products. The Transferred Assets are suitable for the uses to which they are being put or have been put in the ordinary course of the Business and are in good working order. The Transferred Assets and the Business Intellectual Property of Seller licensed to Purchaser under the License Agreement constitute all of the assets, property, real personal or mixed, tangible or intangible, of Seller used in, held for use in, or necessary for the operation of the Business as presently conducted.

Section 2.5 **Consents; No Conflict.** Except as set forth on Schedule 2.5, no consent, authorization, permit, waiver or approval of or from, or notice to, any person or any governmental authority is required as a condition to the execution and delivery of this Agreement or the other Transaction Documents by Seller or the consummation of the transactions contemplated by this Agreement and the Transaction Documents by Seller. Except as set forth on Schedule 2.5, the execution and delivery of this Agreement and the Transaction Documents and each instrument required hereby to be executed and delivered by Seller and the consummation of the transactions contemplated hereby and thereby by Seller will not give rise to a right of termination of, contravene or constitute a default under, or be an event which with the giving of notice or passage of time or both will become a default under, or give to others any rights of termination or cancellation of, or give rise to a right of acceleration of the performance required by or maturity of, or result in the creation of any Lien, claim, cost, Tax, losses or loss of any rights with respect to the Business or the Transferred Assets pursuant to any of the terms, conditions or provisions of or under any applicable law, the Seller Organizational Documents or under any Assumed Contract.

Section 2.6 **Taxes.**

(a) All Tax Returns required to be filed (after giving effect to applicable extensions) by Seller by any law, rule or regulation have been filed with the appropriate governmental authority and all Taxes required to be paid by Seller prior to the Technology Closing Date have been paid in full. No claim has ever been made in writing or, to Seller s Knowledge otherwise, by a Tax authority in a jurisdiction where the Seller does not pay Tax or file Tax Returns that it is subject to Taxation by that jurisdiction or required to file returns in that jurisdiction.

(b) All Taxes owed by Seller or for which Seller may be held liable (whether or not shown on any Tax Return) which were or will be due on or prior to the Technology Closing have been or will be paid in full. The unpaid Taxes of Seller for periods not included in Tax Returns

(b) All Taxes owed by Seller or for which Seller may be held liable (whether or not shown on any Tax Return)

filed or to be filed prior to the Technology Closing does not include any material liability for Taxes attributable to events that are outside of the ordinary course of Seller s business.

(c) There are no Liens for Taxes (other than for current Taxes not yet due and payable) on any of the Transferred Assets.

Section 2.7 **Financial Information.** Attached hereto as Schedule 2.7 are (i) the unaudited balance sheet, operating income and free cash flows of the Business as of the end of and for the fiscal year ended December 31, 2007 and (ii) the unaudited balance sheet of the Business (the Balance Sheet) as of March 31, 2008 (the Balance Sheet Date) and the unaudited operating income and free cash flows of the Business as of March 31, 2008 (together, the Financial Information). The Financial Information has been, and if required to be reported by Purchaser under Item 9.01 of Form 8-K and Regulation S-X of the federal securities laws for a business acquisition required to be described in answer to Item 2.01 of Form 8-K the unaudited balance sheet, operating income and free cash flows of the Business as of the end of and for the fiscal year ended December 31, 2006 prior to the Technology Closing Date will be, prepared in accordance with GAAP applied on a consistent basis throughout periods covered thereby, fairly represent in all material respects the financial condition, results of operations and cash flows of the Business as of the respective dates thereof and for the periods referred to therein and are consistent with the books and records of the Business, subject to the absence of footnotes and normal, recurring year-end adjustments. Seller does not have any indebtedness or other liability or obligation (whether known, unknown, mature, unmatured, absolute or contingent) of the Business, except for (a) liabilities and obligations shown on the Balance Sheet and (b) liabilities and obligations which have arisen since the date of the Balance Sheet in the ordinary course of business and which are not material to the Business, individually or in the aggregate. All reserves that are set forth in or reflected in the Balance Sheet have been established in accordance with GAAP consistently applied and are reasonably adequate.

Section 2.8 **[Intentionally omitted.].**

Section 2.9 **Contracts.**

(a) Description of Contracts. Schedule 1.1(a)(x) contains a true and complete list of all Contracts to which the Seller is a party and which are used in or are necessary for the operation of the Business or by which any Transferred Assets are bound, true and complete copies of which, together with all amendments, waivers and supplements thereto, have been delivered to Purchaser prior to the date hereof.

(b) Status of Contracts. Each Assumed Contract is in full force and effect in accordance with its terms and is a valid and binding obligation of Seller and, to Seller s Knowledge, each other party thereto, enforceable in accordance with its terms, except that such enforcement (i) may be limited by bankruptcy, insolvency, moratorium or similar laws affecting creditors rights generally, and (ii) is subject to the availability of equitable remedies, as determined in the discretion of the court before which such a proceeding may be brought. Neither Seller, nor to Seller s Knowledge any other party to any of the Assumed Contracts, is in default under any Assumed Contract and no event has occurred which, after notice or lapse of time or both, would constitute a default under any such Assumed Contract, and the

(b) Status of Contracts. Each Assumed Contract is in full force and effect in accordance with its terms and is

consummation of the transactions contemplated by this Agreement and the other Transaction Documents will not give rise to any such default or breach. Each Assumed Contract is in written form.

(c) Disposition of Certain Contracts. Seller is legally entitled to terminate those Contracts identified on Schedule 2.9(c) in accordance with their terms and without penalty or additional payment, effective no later than the date set forth beside the names thereof on Schedule 2.9(c).

Section 2.10 **Litigation and Claims**. There is (a) no Action pending, or to the Seller s Knowledge, threatened against or affecting the Business (including any of the Transferred Assets) or the transactions contemplated hereby, or (b) to Seller s Knowledge, no governmental inquiry or investigation pending or threatened against or affecting the Business (including any of the Transferred Assets). The Seller has not received any written legal opinion or written memorandum or legal advice from legal counsel to the effect that Seller (with respect to the Business or the Transferred Assets) is exposed, from a legal standpoint, to any material liability or material disadvantage with respect to the Business or the prospects, financial condition, operations, property or affairs of the Business. The Seller is not in default with respect to any order, writ, injunction or decree of any governmental entity known to or served upon the Seller and relating to the Business or the Transferred Assets. There is no action or suit by the Seller and relating to the Business or the Transferred Assets that is pending, threatened or contemplated against any other person.

Section 2.11 **Compliance With Laws.** Seller is not in material violation of or in material default under any law, statute, regulation, rule, ordinance, administrative order or court order applicable to Seller with respect to the Business or the Transferred Assets, including, without limitation, the Public Health Services Act (PHSA) and relevant sections of the FDCA, and the United States National Organ Transplant Act, Title 21 of the Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue Based Products. To Seller s Knowledge, the Seller is not under investigation with respect to, has not been threatened to be charged with, nor has been given notice of, any violation of or material default under any law, statute, regulation, rule, ordinance, standard, guideline, administrative order or court order applicable to Seller with respect to the Business or the Transferred Assets. All permits (A) pursuant to which Seller currently operates or holds any interest in the property of the Business, or (B) which is required for the operation of the Business as currently conducted or the holding of any such interest has been issued or granted to Seller and are set forth on Schedule 2.11. All such permits are in full force and effect and constitute all permits required to permit the Seller to operate or conduct the Business or hold any interest in the Transferred Assets.

Section 2.12 **Employees and Independent Contractors.**

(a) Schedule 2.12(a)(i) contains a true and complete list, as of April 28, 2008, of all employees of Seller employed in the Business (the Seller Employees), including, to the extent applicable, each Seller Employee s (i) name, (ii) title, wage, salary, target bonus and accrued vacation or paid time off as of April 30, 2008, (iii) principal location of employment, and (iv) date of hire by Seller. Schedule 2.12(a)(ii) contains a list of all Seller Employees who to Seller s Knowledge are not citizens of the United States. Schedule 2.12(a)(iii) also contains a true and

(a) Schedule 2.12(a)(i) contains a true and complete list, as of April 28, 2008, of all employees of Seller empl

complete list of all Seller Employees who are as of such date on a short- or long-term disability leave or other leave of absence (but not including vacation). Each Seller option plan provides that the vesting of all options to purchase Seller common stock, par value $0.001 per share (Seller Options) granted thereunder to any Seller Employee may be accelerated, in whole or in part, at the discretion of the board of directors of Seller or the plan administrator of the Seller, in either case pursuant to the option plan and related documents governing the Seller Options.

(b) Schedule 2.12(b) contains a true and complete list, as of the date hereof, of all consultants and other independent contractors who are providing material services to the Business (the Independent Contractors), including (i) each Independent Contractor s name, (ii) the type of services being provided by each Independent Contractor, (iii) the principal location where services are provided by each Independent Contractor and (iv) the date when each Independent Contractor was retained by Seller. Copies of all contracts relating to Independent Contractors used in the Business have been furnished to Purchaser.

(c) Seller is in compliance in all material respects with all applicable laws, rules and regulations with respect to employment, employment practices, and terms, conditions and classification of employment (including the proper classification of workers as independent contractors and consultants), wage and hour requirements, immigration status, discrimination in employment, employee health and safety, and the Workers Adjustment and Retraining Notification Act. Seller has withheld or will timely withhold all amounts required by law or by agreement to be withheld from the wages, salaries, and other payments to Seller Employees; and Seller is not liable for any arrears of wages, compensation, Taxes, penalties or other sums for failure to comply with any of the foregoing. Seller has paid in full or will timely pay in full to all Seller Employees all wages, salaries, commissions, bonuses, benefits and other compensation due to or on behalf of such Seller Employees. There are no controversies pending or, to Seller s Knowledge, threatened, between the Seller and any of its Seller Employees, which controversies have or would reasonably be expected to result in an action, suit, proceeding, claim, arbitration or investigation before any governmental entity.

(d) To Seller s Knowledge, no Seller Employee is in violation of any term of any employment or service agreement, patent disclosure agreement, non-competition agreement, or any restrictive covenant to a former employer relating to the right of any such Seller Employee to be employed by the Seller because of the nature of the business conducted or presently proposed to be conducted by the Seller or to the use of trade secrets or proprietary information of others. To Seller s Knowledge, there are no material controversies, grievances or claims pending or threatened, by any of the Seller Employees with respect to their employment. To Seller s Knowledge, no Seller Employee has given notice to Seller that any such Seller Employee intends to terminate his or her employment with the Seller (other than for the purposes of accepting employment with Purchaser following the Technology Closing). The employment of each Seller Employee has been at all times in the past and is at-will , and the Seller has not had any obligation to provide any particular form or period of notice prior to terminating the employment of any Seller Employee. Seller has not (i) entered into any Contract that obligates or purports to obligate Purchaser to make an offer of employment to any Seller Employee and/or (ii) promised or otherwise provided any assurances (contingent or otherwise) to any Seller Employee of any terms or conditions of employment with Purchaser following the Technology Closing.

complete list of all Seller Employees who are as of such date on a short- or long-term disability leave or other leave

Section 2.13 Employee Benefits.

(a) Schedule 2.13(a) sets forth a true and complete list of each employee benefit plan, as defined in Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended (ERISA), and each and every written, unwritten, formal or informal plan, agreement, program, policy or other arrangement involving direct or indirect compensation (other than workers compensation, unemployment compensation and other government programs), employment, severance, consulting, disability benefits, supplemental unemployment benefits, vacation benefits, retirement benefits, deferred compensation, profit-sharing, bonuses, stock options, stock appreciation rights, other forms of incentive compensation, post-retirement insurance benefits, or other benefits, entered into, maintained or contributed to by Seller or any of its subsidiaries or with respect to which Seller or any of its subsidiaries has or may in the future have any liability (contingent or otherwise), and in each case under which any Seller Employee has any present or future right to benefits. Each plan, agreement, program, policy or arrangement required to be set forth on such schedule pursuant to the foregoing is referred to herein as a Seller Benefit Plan.

(b) Each Seller Benefit Plan has been maintained and administered in all respects in compliance with its terms and with the requirements prescribed by any and all statutes, orders, rules and regulations (foreign and domestic), including (without limitation) ERISA and the Code, which are applicable to such Seller Benefit Plan. No action, suit or claim (excluding claims for benefits incurred in the ordinary course) has been brought or is pending or, to Seller s Knowledge, threatened against or with respect to any Seller Benefit Plan or the assets or any fiduciary thereof (in that Person s capacity as a fiduciary of such Seller Benefit Plan). There are no audits, inquiries or proceedings pending or, to the Knowledge of Seller, threatened by the IRS, DOL, or other governmental entity with respect to any Seller Benefit Plan. No event has occurred and, to Seller s Knowledge, there exists no condition or set of conditions in connection with which Purchaser or any Seller Employee could reasonably be expected to become subject to any liability under or with respect to any Seller Benefit Plan.

(c) No Seller Benefit Plan is maintained outside the jurisdiction of the United States, or covers any Seller Employee residing or working outside the United States.

(d) Schedule 2.13(d) discloses each: (i) agreement with any Seller Employee (A) the benefits of which are contingent, or the terms of which are altered, upon the occurrence of a transaction involving Seller of the nature of any of the transactions contemplated by this Agreement, (B) providing any term of employment or compensation guarantee or (C) providing severance benefits or other benefits after the termination of employment of such Seller Employee; (ii) agreement, plan or arrangement under which any Seller Employee may receive payments from Seller that may be subject to the Tax imposed by Section 4999 of the Code or included in the determination of such Seller Employee s parachute payment under Section 280G of the Code; and (iii) agreement or plan binding Seller, including any stock option plan, stock appreciation right plan, restricted stock plan, stock purchase plan, severance benefit plan or Seller Benefit Plan, any of the benefits of which will be increased, or the vesting of the benefits of which will be accelerated, by the occurrence of any of the transactions contemplated by this Agreement or the value of any of the benefits of which will be calculated on the basis of any of the transactions contemplated by this Agreement.

(d) To Seller s Knowledge, no Seller Employee is in violation of any term of any employment or service agre

Section 2.14 **Labor Matters.** (i) Seller is not a party to any collective bargaining agreement or other labor contract applicable to any Seller Employee, (ii) to Seller s Knowledge, no union has bargaining rights with respect to any Seller Employee and there are no threatened or apparent union organizing activities involving any Seller Employee, (iii) there are no strikes, slowdowns or work stoppages pending or, to Seller s Knowledge, threatened between Seller and an Seller Employee, and (iv) to Seller s Knowledge, there are no unfair labor practice complaints involving an Seller Employee pending against Seller. Seller shall be responsible for providing continuation coverage to the extent required by Section 4980B of the Code or similar state law (COBRA) to Seller Employees, and other qualified beneficiaries under COBRA with respect to such employees, who have a COBRA qualifying event (due to termination of employment with the Seller or otherwise) prior to or in connection with the transactions contemplated by this Agreement. Except as required by law, neither Purchaser nor any of its affiliates shall be responsible for the failure of Seller to comply with any of the requirements of COBRA, including applicable notice requirements.

Section 2.15 **Intellectual Property.**

(a) The Transferred Technology set forth on Schedule 1.1(a)(i) and the other Business Intellectual Property set forth on Schedule 1.1(a)(iv) together set forth a true, complete and correct list of all Business Intellectual Property.

(b) The Seller is the sole and exclusive beneficial and record owner of all Transferred Technology.

(c) The Transferred Technology and the Business Intellectual Property of Seller licensed to Purchaser under the License Agreement (the Licensed Technology) is valid, existing, in full force and effect, or, with respect to applications, is still pending, and has not expired or been cancelled or abandoned. All necessary application, registration, maintenance, renewal and other fees, and all necessary documents and certificates, in connection with such Transferred Technology and the Licensed Technology have been paid and filed, respectively, with the relevant patent, copyright, trademark or other authorities in the United States or foreign jurisdictions, as the case may be, for the purposes of perfecting, prosecuting and maintaining such Transferred Technology and the Licensed Technology.

(d) There is no pending or, to the Seller s Knowledge, threatened (and at no time within the two years prior to the date of this Agreement has there been pending any) action, suit, claim or proceeding before any court, government agency or arbitral tribunal in any jurisdiction challenging the use, ownership, validity, enforceability or registerability of any Transferred Technology or the Licensed Technology. The Seller is not a party to any settlements, covenants not to sue, consents, decrees, stipulations, judgments or orders resulting from action, suit, claim or proceeding which permit third parties to use any Transferred Technology.

(e) Schedule 2.15(e) lists all licenses, sublicenses and other agreement as to which Seller is a party and pursuant to which Seller has granted to any third party any right to use any of the Transferred Technology, including the identity of all parties thereto, a description of the nature and subject matter thereof and the applicable royalty and term thereof.

(d) Schedule 2.13(d) discloses each: (i) agreement with any Seller Employee (A) the benefits of wh 24 are co

(f) Schedule 2.15(f) lists all licenses, sublicenses and other agreements as to which Seller is a party and pursuant to which Seller is authorized to use any intellectual property belonging to any third party in connection with the Business, including the identity of all parties thereto, a description of the nature and subject matter thereof, the applicable royalty and term thereof.

(g) The Seller owns, or has valid rights to use all of the Transferred Technology.

(h) The conduct of the Business and manufacture, practice, use and sale of the Product as previously conducted, manufactured, practiced, used and sold, and as currently conducted, manufactured, used and sold did not and does not infringe, misappropriate, or otherwise violate any intellectual property or other proprietary right owned by any third party, or constitute unfair competition or trade practices under the laws of any jurisdiction.

(i) There is no pending or, to the Knowledge of Seller, threatened (and at no time within the two years prior to the date of this Agreement has there been pending or, to the Knowledge of Seller, threatened any) action, suit, claim or proceeding, and Seller has not received any written complaint, claim, demand or notice from any third party, alleging that the conduct of the Business infringes, misappropriates, or otherwise violates or constitutes the unauthorized use of, or will infringe, misappropriate, or otherwise violate or constitute the unauthorized use of, the intellectual property or other proprietary right of any third party (nor does the Seller have Knowledge of any basis therefor). The Seller is not a party to any settlement, covenant not to sue, consent, decree, stipulation, judgment, or order resulting from any Action which (i) restricts the Seller s rights to use any Transferred Technology, (ii) restricts the Business in order to accommodate a third party s intellectual property or (iii) requires any future payment by the Seller. The Seller has not received any written or, to the Seller s Knowledge, oral communication from any third party offering to license to the Seller any intellectual property purported to be used in the Business or claiming that the Seller must license or refrain from using any intellectual property or other proprietary rights of any third party in order to conduct the Business.

(j) To the Knowledge of Seller, no third party is infringing, misappropriating, or otherwise violating or engaged in the unauthorized use of any Transferred Technology, and no actions, suits, claims or proceedings have been brought against any third party by the Seller alleging that a third party is infringing, misappropriating, or otherwise violating or engaged in the unauthorized use of any Transferred Technology.

(k) The Seller has taken commercially reasonable steps to obtain, maintain and protect the Transferred Technology, including requiring each employee, consultant and independent contractor who or that has contributed in any way to the Transferred Technology or has made any contributions to the development of any Product to execute a written agreement that assigns to Seller all rights, title and interest in and to the Transferred Technology and any inventions, improvements, discoveries, information and other know-how relating to the Business and the Product. Other than under an appropriate confidentiality or nondisclosure agreement or contractual provision relating to confidentiality and nondisclosure, there has been no disclosure to any third party of confidential information or trade secrets of the Seller related to any Product, the Business or the Transferred Technology and the Seller has taken all reasonable precautions to

(e) Schedule 2.15(e) lists all licenses, sublicenses and other agreement as to which Seller is a party and purs

protect the secrecy, confidentiality and value of the Transferred Technology (including by the enforcement of a policy requiring each employee, consultant and independent contractor to execute proprietary information and confidentiality agreements substantially in the Seller s standard form which has been provided by Seller to Purchaser). Assignments to the Seller of the Patent Rights, copyrights and copyright applications listed in Schedule 1.1(a)(i) have been duly executed and filed with the United States Patent and Trademark Office or Copyright Office, as applicable. Assignments of trademark registrations and pending trademark applications listed in Schedule 1.1(a)(i) and acquired from any third party have been duly executed and filed with the United States Patent and Trademark Office or foreign trademark authority, as applicable.

(l) Neither the execution of this Agreement nor the consummation by the Seller of the transactions contemplated by this Agreement will result in any violation, loss or impairment of, or payment of any additional amounts with respect to, any Transferred Technology, nor require the consent of any governmental entity or third party with respect to any Transferred Technology. The Seller is not a party to any Contract under which a third party would have or would be entitled to receive a license or any other right to any Transferred Technology any other property or assets of Purchaser or any of Purchaser s affiliates as a result of the execution of this Agreement or the consummation of the transactions contemplated by this Agreement, nor would the consummation of such transactions result in the amendment or alteration of any license or other right which exists on the date of this Agreement.

(m) Except as set forth on Schedule 2.15(m), the Seller has not assigned or granted any exclusive rights in any Transferred Technology to any third party.

(n) No government funding, facilities of a university, college, other educational institution or research center or funding from third parties was used in the development of any Transferred Technology. To the Knowledge of Seller, no current or former employee, consultant or Independent Contractor of the Seller, who was involved in, or who contributed to, the creation or development of any Transferred Technology, has performed services for the government, university, college, or other educational institution or research center during a period of time during which such employee, consultant or independent contractor was also performing services for the Seller.

(o) Seller and Purchaser are parties to that certain Joint Privilege Agreement dated as of March 5, 2008, pursuant to which Seller provided Purchaser with (i) an attorney-client privileged opinion of Seller s retained counsel, dated February 29, 2008, and (ii) an attorney-client privileged opinion of Seller s retained counsel, dated March 4, 2008 (collectively, the JPA Opinions). The representations and warranties as to certain factual matters made by Seller to its counsel as set forth in the product package insert contained in the written certificate delivered by Seller to such counsel (a copy of which is attached as Schedule 2.15(o) hereto), in connection with counsel s rendering the JPA Opinions were true and correct in all respects on the date made.

Section 2.16 **Insurance.** Schedule 2.16 contains a complete and correct list as of the date hereof of all insurance policies maintained by or on behalf of the Seller with respect to the Business and/or the Transferred Assets, including all legally required workers compensation insurance and errors and omissions, casualty, fire, product liability and general liability

(k) The Seller has taken commercially reasonable steps to obtain, maintain and protect the Transferred Tech

insurance. True and complete copies of each listed policy have been furnished to Purchaser. Such policies are in full force and effect, all premiums due thereon have been paid and the Seller has complied in all material respects with the provisions of such policies. The Seller has not received any notice from any issuer of such insurance policies canceling or amending any policies listed on Schedule 2.16. There is no claim by the Seller pending under any of such policies as to which coverage has been denied or disputed by the underwriters or in respect of which the underwriters have reserved their rights. Neither the Seller nor any affiliate thereof has ever maintained, established, sponsored, participated in or contributed to any self-insurance plan with respect to the Business and/or Transferred Assets.

Section 2.17 **Fair Consideration; No Fraudulent Conveyance**. Seller is not now and Seller will not be rendered insolvent by the sale, transfer and assignment of the Transferred Assets pursuant to the terms of this Agreement or the transactions contemplated hereby. Seller has no intention to file for bankruptcy, and, to Seller s Knowledge, no insolvency proceedings of any character including without limitation, bankruptcy, receivership, reorganization, composition or arrangement with creditors, voluntary or involuntary, affecting Seller or any of the Transferred Assets or Assumed Liabilities are pending or threatened. Seller is not entering into this Agreement and the transactions contemplated hereby with the intent to defraud, delay or hinder Seller s creditors and the consummation of the transactions contemplated by this Agreement and the transactions contemplated hereby will not have any such effect. The transactions contemplated hereby do not constitute a fraudulent conveyance, or otherwise give rise to any right of any creditor of Seller whatsoever to any of the Transferred Assets after the Technology Closing.

Section 2.18 **Authorizations; Regulatory Compliance.**

Schedule 2.18 sets forth a complete list of all approvals, clearances, authorizations, licenses or registrations required by any governmental entity having regulatory authority or jurisdiction over the Business and the Products, including the United States Food and Drug Administration (FDA) and any regulatory authority in the jurisdiction or country in which the Products are manufactured, to permit the design, development, pre-clinical and clinical testing, manufacture, labeling, marketing, promotion, import, export, use and sale of the Products, whether required of Seller or, to Seller s Knowledge, required of any of its suppliers or manufacturers. Except as set forth on Schedule 2.18:

(a) The Business and the Products are in compliance in all material respects with all current applicable laws, statutes, rules, regulations, ordinances, standards, guidelines or orders administered, issued or enforced by the FDA or any other governmental entity having regulatory authority or jurisdiction over the Business and the Products, including, without limitation, the PHSA and relevant sections of the FDCA, and the United States National Organ Transplant Act, Title 21 of the Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue Based Products..

(b) Seller and, to the Knowledge of Seller, its suppliers and manufacturers are in compliance in all material respects with all applicable laws, statutes, rules, regulations, ordinances, standards, guidelines or orders administered , issued or enforced by the FDA or any other governmental entity, including the American Association of Tissue Banks, relating to the

methods and materials used in, and the facilities and controls used for, the design, manufacture, processing, packaging, labeling, storage and distribution of the Products and all Products have been processed, manufactured, packaged, labeled, stored, handled and distributed by Seller in compliance with the quality control procedures and specifications furnished by Seller to Purchaser and all applicable laws, statutes, rules, regulations, ordinances, standards, guidelines or orders administered, issued or enforced by the FDA or any other governmental entity, including the American Association of Tissue Banks, including, without limitation, current Good Tissue Practice regulations promulgated by the FDA and the United States National Organ Transplant Act, Title 21 of the Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue Based Products. Further, no governmental action has been taken or, to Seller s Knowledge, is in the process of being taken that will slow, halt or enjoin the manufacturing of the Products or the operation of the Business or subject the manufacturing of the Products or the Business to regulatory enforcement action.

(c) Seller has not received and, to Seller s Knowledge, its manufacturers or suppliers have not received from the FDA or any other governmental entity, and to Seller s Knowledge, there are no facts which would furnish any reasonable basis for, any notice of adverse findings, FDA warning letters, regulatory letters, notices of violations, warning letters, Section 305 criminal proceeding notices under the FDCA or other similar communication from the FDA or other governmental entity, and there have been no seizures conducted or, to Seller s Knowledge, threatened by the FDA or other governmental entity, and no recalls, market withdrawals, field notifications, notifications of misbranding or adulteration, or safety alerts conducted, requested or threatened by the FDA or other governmental entity relating to the Business or to the Products.

(d) For each of the Products, no pre-market notification (510(k)) submission is required and no 510(k) submission has been filed with the FDA or any other governmental entity.

(e) To Seller s Knowledge, there are no currently existing facts which will (i) cause the withdrawal or recall, or require suspension or additional approvals or clearances, of any Products currently sold by Seller, (ii) require a change in the manufacturing, marketing classification, labeling or intended use of any such Products, or (iii) require the termination or suspension of marketing of any such Products.

(f) Except as set forth on Schedule 2.18(f), (i) none of the Products manufactured, marketed or sold by Seller has been recalled or subject to a field safety notification (whether voluntarily or otherwise); (ii) to Seller s Knowledge none of the Products manufactured, marketed or sold by Seller s manufacturers and suppliers has been recalled or subject to a field safety notification (whether voluntary or otherwise); and (iii) Seller has not received written notice (whether completed or pending) of any proceeding seeking recall, suspension or seizure of any products sold or proposed to be sold by Seller.

(g) Seller has submitted to the FDA all Biological Product Deviation Reports relating to performance issues that could lead to serious injury or death that Seller has been required to submit under applicable federal statutes, rules, regulations, standards, guides or orders administered or promulgated by the FDA related to the Products. To Seller s Knowledge, except

(b) Seller and, to the Knowledge of Seller, its suppliers and manufacturers are in compliance in all material re

as set forth on Schedule 2.18(g), no circumstances have arisen that would require Seller to submit a Biological Product Deviation Report to the FDA.

Section 2.19 Products; Product Liability.

(a) Each of the Products (including all Finished Inventory): (i) is, and at all times up to and including the sale thereof has been processed, manufactured, packaged, labeled, stored, handled, distributed, shipped, marketed and promoted, and in all other respects has been, in compliance with all applicable laws, statutes, rules, regulations, ordinances or orders administered, issued or enforced by the FDA or any other governmental entity, including, without limitation, current Good Tissue Practice regulations promulgated by the FDA, the PHSA and relevant sections of the FDCA, and the United States National Organ Transplant Act, Title 21 of the Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue Based Products and (b) is, and at all relevant times has conformed in all material respects to all specifications and any promises, warranties or affirmations of fact made in all regulatory filings or set forth in any regulatory approvals, authorizations or clearances pertaining thereto or made on the container or label for such Product or in connection with its sale. There is no design or manufacturing defect with respect to the Products.

(b) Schedule 2.19(b) sets forth the forms of Seller s service or product warranties that are currently applicable to services or merchandise related to the Business (including, without limitation, the Products). Except as set forth on Schedule 2.19(b), there are no existing or, to Seller s Knowledge, threatened, claims against Seller for services or merchandise related to the Business which are defective or fail to meet any service or product warranties other than in the ordinary course of business consistent with past experience. Seller has not incurred liability arising out of any injury to individuals as a result of the ownership, possession, or use of any Product and, to Seller s Knowledge, there has been no inquiry or investigation made in respect thereof by any governmental entity.

Section 2.20 Environmental.

(a) Except as would not be reasonably likely to result in a material liability of Seller with respect to the Business, (i) Seller is now and always has been in compliance with applicable legal requirements with respect to environmental laws, rules, regulations and ordinances, and (ii) to the Seller s Knowledge, no underground storage tanks and no amount of any substance that has been designated by any governmental entity or by any legal requirements to be radioactive, toxic, hazardous or otherwise a danger to health or the environment, including PCBs, asbestos, petroleum, toxic mold, urea-formaldehyde and all substances listed as hazardous substances pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, or defined as a hazardous waste pursuant to the United States Resource Conservation and Recovery Act of 1976, as amended, and the regulations promulgated pursuant to said laws, but excluding office and janitorial supplies (a Hazardous Material), are present in, on or under any property of Seller used in the Business, including the land and the improvements, ground water and surface water thereof.

(g) Seller has submitted to the FDA all Biological Product Deviation Reports relating to performance issues th

(a) Except as would not be reasonably likely to result in a material liability of Seller with respect to the Busine

(b) Except as would not be reasonably likely to result in a material liability to Seller with respect to the Business, Seller has not transported, stored, used, manufactured, disposed of, released, removed or exposed its employees or others to Hazardous Materials in violation of any legal requirement or manufactured any product containing a Hazardous Material in violation of any legal requirement, nor has Seller received notification from any party that it has or is alleged to have any remediation obligation relating to any Hazardous Material.

Section 2.21 Real Property; Leases. Except as set forth on Schedule 2.21, Seller does not own, lease or sublease any real property used in or necessary for the operation of the Business.

Section 2.22 Brokers. Except as set forth on Schedule 2.22, no broker or other representative has acted on behalf of Seller in connection with the transaction contemplated hereby in such manner as to give rise to any claim by any person against Purchaser or Seller for a finder s fee, brokerage commission or similar payment.

Section 2.23 Capital Expenditures. Set forth on Schedule 2.23 is a list of Seller s approved capital expenditure projects related to the Business and involving in excess of $25,000 including: (i) projects which have been commenced but are not yet completed; (ii) projects which have not been commenced; and (iii) projects which have been completed in respect of which payment has been made, within the last twelve (12) months.

Section 2.24 No Changes. Except as set forth on Schedule 2.24, since December 31, 2007 there has not been, occurred or arisen any of the following:

(a) any amendment to the Seller Organizational Documents;

(b) any incurrence or assumption by the Business of any indebtedness in excess of $5,000 individually or $25,000 in the aggregate;

(c) the imposition of any Lien (other than Permitted Liens) upon any of the Transferred Assets;

(d) any material damage, destruction or loss with respect to the Transferred Assets or any other real or tangible personal property used in the Business, whether or not covered by insurance;

(e) any payment, loan or advance of any amount to, or sale, transfer or lease of any of the Transferred Assets to, or any agreement or arrangement relating to the Business or constituting a Transferred Asset with, any member or equity holder of Seller or any of their respective affiliates;

(f) any change in the Tax or accounting principles, methods, practices or procedures followed by Seller or any change in the depreciation or amortization policies or rates theretofore adopted by Seller, except as required by GAAP or disclosed to Purchaser in writing;

(g) any change or revocation by Seller of any Tax election with respect to the Business or any agreement or settlement with any governmental entity with respect to such Taxes;

(h) any acquisition by Seller by merging or consolidating with, or by purchasing a substantial portion of the assets of, or by any other manner, any business or corporation, partnership, association or other business organization or division thereof comprising all or a portion of the Business or the Transferred Assets;

(i) any sale, lease or other transfer or disposition by Seller of its assets related to the Business, tangible or intangible, other than the sale of Product in the ordinary course of the Business;

(j) any Contract (or series of related Contracts) related to the Business and entered into by Seller either involving more than $25,000 individually (or $50,000 in the aggregate) or outside the ordinary course of business;

(k) any acceleration, termination, modification or cancellation of any Assumed Contract involving more than $25,000 individually (or $50,000 in the aggregate);

(l) any capital expenditure (or series of related capital expenditures) related to the Business by Seller either involving more than $25,000 individually (or $50,000 in the aggregate) or outside the ordinary course of business;

(m) any capital investment in, any loan to or any acquisition of the securities or assets of, any other person by Seller with respect to or in connection with the Business;

(n) any delay or postponement of payment of accounts payable or other liabilities of Seller with respect to or in connection with the Business outside the ordinary course of Business consistent with past practice;

(o) any cancellation, compromise, waiver or release of any right or claim of Seller with respect to or in connection with the Business outside the ordinary course of Business consistent with past practice;

(p) the commencement or written notice to Seller or, to Seller s Knowledge, oral notice or threat of commencement of any lawsuit or proceeding against the Transferred Assets or against Seller with respect to the Transferred Assets, the Product or the Business;

(q) any license or sublicense of any rights of Seller under or with respect to the Transferred Technology;

(r) any written notice or claim to Seller or, to Seller s Knowledge, oral notice or claim of ownership by any Person of Business Intellectual Property or of infringement by the Business of any Person s intellectual property rights;

(s) any material change in pricing charged by Seller for Products; or

(q) any license or sublicense of any rights of Seller under or with respect to the Transferred Technology;

(t) any negotiation or agreement by Seller or any officer or employee thereof to do any of the things described in the preceding clauses (a) through (s) (other than negotiations with Purchaser and its representatives regarding the transactions contemplated by this Agreement).

Since December 31, 2007, no Business Material Adverse Effect has occurred, and no event, circumstance, condition or effect has occurred that could reasonably be expected to result in a Business Material Adverse Effect.

Section 2.25 Obsolete Items. Schedule 2.25 sets forth, as of the date hereof, a complete and accurate list of any category of products, supplies or parts used in the Business that has an aggregate inventory value in excess of $10,000 that has been identified through reasonable business practices to be obsolete, damaged or defective.

Section 2.26 Customers and Suppliers. Schedule 2.26 identifies the Business ten (10) largest customers and suppliers (measured by dollar volume in each case) during the calendar year 2007 and during the first three months of 2008, showing with respect to each, the name and address, dollar volume and nature of the relationship (including the principal categories of Product bought or sold). Seller is not required to provide any bonding or other financial security arrangements in connection with any of the transactions with its customers or supplies. Seller has not received any direct communication (whether written or oral) of any intention of any customer or supplier identified on Schedule 2.26 to discontinue its relationship as a customer or supplier of, or materially reduce its purchases from or sales to Seller (or, post-Technology Closing, from Purchaser).

Section 2.27 Disclosure. No statement (including without limitations, the representations and warranties and covenants contained in this Agreement) by Seller contained in this Agreement and none of the information contained in the schedules hereto, in any other Transaction Document and any document, written statement or certificate furnished to Purchaser and its representatives to Seller contains or will contain any untrue statement of a material fact or omits or will omit to state a material fact necessary to make the statements herein or therein, in light of the circumstances in which they were made, not misleading. To the Seller s Knowledge, there exists no fact that adversely affects the value of the Transferred Assets or the Business, prospects, financial condition or operations of the Business which has not been set forth in this Agreement or the schedules hereto. Seller has afforded to the officers, employees and authorized representatives of Purchaser (including, without limitation, independent public accountants and attorneys) access to all financial and other books and records (including computer files, retrieval programs and similar documentation) of Seller with respect to the Business.

ARTICLE III.

REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser hereby represents and warrants to Seller as of the date hereof as follows:

Section 3.1 Organization and Authority. Purchaser is duly formed, validity existing and in good standing under the laws of the State of Delaware and is duly qualified as a foreign corporation to transact business and is in good standing in each jurisdiction in which such qualification is required, except when failure to be so qualified would not materially and

adversely affect Purchaser s business. Purchaser has full corporate power and authority to execute and deliver this Agreement and the Transaction Documents to which it is party, to perform its obligations hereunder and under the Transaction Documents, to consummate the transactions contemplated hereby and thereby and to own and carry on the operation of its business as currently operated by it.

Section 3.2 **Organizational and Governing Documents; Approval.**

(a) Prior to the date hereof, Purchaser has furnished to Seller complete and correct copies of the certificate of incorporation and bylaws of Purchaser (the Purchaser Organizational Documents). The Purchaser Organizational Documents are in full force and effect and Purchaser is not in violation of any provision of the Purchaser Organizational Documents.

(b) This Agreement and the Transaction Documents to which Purchaser is a party have been approved by all necessary corporate action of Purchaser.

Section 3.3 **Due Execution and Delivery.** Purchaser has all necessary corporate power and authority to execute and deliver this Agreement and the other Transaction Documents to which it is a party and each instrument required hereby and thereby to be executed and delivered by it, and to carry out its obligations hereunder and thereunder. Purchaser has duly executed and delivered this Agreement and, assuming the due authorization, execution and deliver of this Agreement by Seller, this Agreement constitutes (and, when executed and delivered, the Transaction Documents to which it is a party will constitute) the legal, valid and binding obligations of Purchaser enforceable against it in accordance with its terms, except that such enforcement (a) may be limited by bankruptcy, insolvency, moratorium or similar laws affecting creditors rights generally, and (b) is subject to the availability of equitable remedies, as determined in the discretion of the court before which such a proceeding may be brought.

Section 3.4 **Consents; No Conflicts.** No consent, authorization, permit, waiver or approval of or from or notice to any person or any governmental authority is required as a condition to the execution and delivery of this Agreement by Purchaser or any of the Transaction Documents to which it is a party and the consummation of the transactions contemplated by this Agreement and such Transaction Documents by Purchaser. The execution and delivery of this Agreement and the other Transaction Documents and each instrument required hereby to be executed and delivered by Purchaser and the consummation of the transactions contemplated hereby and thereby by Purchaser will not contravene any applicable law or the Purchaser Organizational Documents.

Section 3.5 **Brokers.** No broker or other representative has acted on behalf of Purchaser in connection with the transaction contemplated hereby in such manner as to give rise to any valid claim by any person against Seller for a finder s fee, brokerage commission or similar payment.

ARTICLE IV.

CERTAIN COVENANTS AND AGREEMENTS

Section 4.1 **Further Assurances.** Each of Seller and Purchaser covenants and agrees with the other that at any time and from time to time hereafter, and without further consideration,

each will promptly execute and deliver to the other such further assurances, instruments and documents and take such further action as the other may reasonably request in order to carry out the full intent and purpose of this Agreement and to consummate the transactions contemplated hereby. Without limiting the foregoing, Seller covenants and agrees with Purchaser that at any time and from time to time following the Technology Closing Date, if Seller shall be in breach of its representations and warranties set forth in Section 2.4 (Title and Sufficiency of Transferred Assets), Seller will, without further consideration, promptly execute and deliver to Purchaser such further assurances, instruments and documents and take such further action as Purchaser may reasonably request in order to remedy the breach of such representations and warranties.

Section 4.2 **Conduct of Activities Associated with the Transferred Assets.** During the period from the date of this Agreement to (i) the Technology Closing with respect to the Technology Assets and (ii) the Manufacturing Closing with respect to the Manufacturing Assets, Seller will conduct its activities associated with the Transferred Assets in their ordinary and usual course, consistent with past practice, and will use commercially reasonable efforts to (i) preserve intact all rights, privileges, franchises and other authority related to the activities associated with the Transferred Assets and (ii) maintain in their current or currently planned condition (as such currently planned condition has been expressly communicated to Purchaser including but not limited to those matters set forth in the schedules hereto) its current relationships with licensors, licensees, suppliers, contractors, distributors, customers, and others having relationships related to the activities associated with the Business and the Transferred Assets. Without limiting the generality of the foregoing, and except as (i) expressly contemplated by this Agreement, (ii) set forth on Schedule 4.2 or (iii) approved in writing by Purchaser in advance, prior to the Technology Closing with respect to all Transferred Assets and the Manufacturing Closing with respect to the Manufacturing Assets, Seller will not:

(a) create, incur or assume any obligation which would materially and adversely affect the Transferred Assets or Purchaser s ability to conduct Business in substantially the same manner and condition as conducted by Seller on the date of this Agreement;

(b) enter into any contract that, if entered into prior to the date hereof would be required to be set forth on Schedule 1.1(a)(x) or violate, terminate, amend or otherwise modify or waive any of the terms of any Assumed Contract;

(c) sell, lease, license, transfer or dispose of any of the Transferred Assets (except for sales of Product in the ordinary course of business consistent with its past practices);

(d) change any of its accounting methods with respect to the Business or the Transferred Assets;

(e) terminate, waive or release any material right or material claim with respect to the Business or any of the Transferred Assets;

(f) license any of the Transferred Technology (except for licenses under its standard customer agreement made in the ordinary course of business consistent with its past practices);

(a) create, incur or assume any obligation which would materially and adversely affect the Transferred Assets

(g) (i) initiate any litigation, action, suit, proceeding, claim or arbitration or (ii) settle or agree to settle any litigation, action, suit, proceeding, claim or arbitration, in each case with respect to the Business or the Transferred Assets;

(h) change the manner in which it extends warranties, discounts or credits to customers with respect to the Products;

(i) modify, allow to lapse or otherwise fail to maintain insurance coverage with respect to the Transferred Assets at levels consistent with the amounts of such coverage in effect as of the date hereof;

(j) sell, dispose of or encumber any of the Transferred Assets or license any Transferred Assets to any person;

(k) enter into any agreements or commitments relating to the activities associated with the Transferred Assets;

(l) fail to comply in all material respects with all laws and regulations applicable to the activities associated with the Transferred Assets;

(m) change or announce any change to the Business or the Transferred Assets; or

(n) (i) agree to do any of the things described in the preceding clauses (a)-(m) or (ii) take or agree to take any action which would reasonably be expected to prevent Seller from performing or cause Seller not to perform one or more covenants required hereunder or under any other Transaction Document to be performed by Seller.

Section 4.3 Financial Statements.

(a) Prior to the Technology Closing, Seller shall deliver to Purchaser historical financial statements for the Business for the fiscal year 2007 and, for each completed month period of 2008 and for the period between the last completed month and the Technology Closing Date, in each case in a form that complies with what is required by Item 9.01 of Form 8-K and Regulation S-X of the federal securities laws for a business acquisition required to be described in answer to Item 2.01 of Form 8-K, including information required in order for Purchaser to prepare the pro forma financial information required by Item 9.01 of Form 8-K. The historical financial statements for the Business for the fiscal year 2007 shall be accompanied by an unqualified report from Seller s independent registered accounting firm (with notes thereto) stating to the effect that such financial statements present fairly, in all material respects, the financial position of the Business, as well as the results of operations and cash flows of the Business, for each of the periods covered by such financial statements, in conformity with GAAP.

(b) Not later than thirty (30) days after the completion of each fiscal quarter of Seller that occurs during the period from the date of this Agreement through and up to the Technology Closing Date, Seller shall deliver to Purchaser quarterly financial statements for the Business (together with any required notes) in a form that Seller prepares for internal financial reporting; provided, however, that Seller shall provide Purchaser with such additional information as

Purchaser may reasonably request in order to comply with the requirements for financial statements included in Quarterly Reports on Form 10-Q filed under the Securities Exchange Act of 1934, as amended.

(c) On or prior to the Technology Closing Date, Seller shall deliver to Purchaser the audited balance sheets and statements of income, changes in stockholders equity and cash flows of the Business as of the end of and for each of the fiscal years ended December 31, 2006 and December 31, 2007 or such other periods as shall be required to be reported by Purchaser by Item 9.01 of Form 8-K and Regulation S-X of the federal securities laws for a business acquisition required to be described in answer to Item 2.01 of Form 8-K (the Audited Financial Statements). The Audited Financial Statements shall be accompanied by an unqualified report from Seller s independent registered accounting firm stating to the effect that the Audited Financial Statements present fairly, in all material respects, the financial position of the Business, as well as the results of operations and cash flows of the Business, for each of the periods covered by the Audited Financial Statements, in conformity with GAAP.

(d) After the Technology Closing, at the reasonable request of Purchaser, Seller shall, and shall cause its affiliates to, cooperate fully in the preparation of all financial statements reasonably determined by Purchaser to be necessary to meet its financial reporting and Tax obligations in connection with the consummation of the transactions contemplated hereby. Seller shall provide Purchaser with any records and other information in Seller s possession or control as shall be reasonably requested by Purchaser in connection therewith and shall use commercially reasonable efforts to cause to be provided to Purchaser any records and other information that is not in the possession or control of Seller as shall be reasonably requested by Purchaser in connection therewith and shall use commercially reasonable efforts to provide Purchaser with access to Seller s accountants.

Section 4.4 Post-Technology Closing Receipts. Seller shall hold in trust for, and promptly remit to Purchaser without deduction, any amounts collected or received by Seller that relate to the Business or Purchaser following the Technology Closing. Purchaser shall hold in trust for, and promptly remit to Seller without deduction, any amounts collected or received by Purchaser that either constitute accounts receivable related to Product sold by Seller prior to the Technology Closing Date or that do not relate to the Transferred Assets.

Section 4.5 Confidentiality. Seller will maintain confidential all information related to the Business, the Product and the Transferred Assets including, without limitation, business plans and proposals, marketing strategies, standard operating procedures, personnel data, pricing, intellectual property and all other information that would be considered confidential and proprietary (Confidential Information).

(b) For a period of five (5) years from the Technology Closing Date, Seller will treat all Confidential Information with the same degree of care that it employs with respect to its own confidential information which it does not desire to have published or disseminated. In no event will that degree of care be less than that employed by a reasonable person. Notwithstanding the foregoing, Seller shall have no such obligation with respect to that portion of the Confidential Information that Seller can demonstrate is (i) in the public domain or enters the public domain without the wrongful act or breach of this Agreement by Seller, (ii) approved in advance in

writing by Purchaser for release by Seller or (iii) disclosed by order of a court of competent jurisdiction, provided that such disclosure is subject to all applicable governmental or judicial protection for like material and reasonable advance notice is give by Seller to Purchaser.

The fact that Confidential Information may be in or becomes part of the public domain, in and of itself, does not exclude any specific information from obligations of this Agreement.

Section 4.6 No Other Bids.

(a) Until the earlier to occur of (a) the Manufacturing Closing or (b) the earlier termination of this Agreement pursuant to its terms, neither Seller nor any of Seller s officers, managers, employees, agents or other representatives shall, directly or indirectly, (i) initiate, solicit, entertain or encourage (including by way of furnishing information regarding the Transferred Assets) any Asset Acquisition Proposal, or make any statements to third parties which may reasonably be expected to lead to any Asset Acquisition Proposal or (ii) negotiate, engage in any substantive discussions, or enter into any agreement, with any Person concerning any Asset Acquisition Proposal. Notwithstanding the foregoing, if at any time prior to obtaining the Stockholder Approval (i) Seller receives an unsolicited bona fide written Asset Acquisition Proposal that did not result from any breach of this Section 4.6, (ii) the Board of Directors of Seller shall have first determined in good faith that such Asset Acquisition Proposal constitutes a Superior Proposal, (iii) the Board of Directors of Seller shall have first determined in good faith, after consultation with outside counsel, that failure to take such action would result in a breach of its fiduciary duties under the Delaware General Corporation Law (DGCL), and (iv) Seller shall have notified Purchaser of such determination (a Notice of Superior Proposal) and offered to discuss in good faith with Purchaser (and, if Purchaser accepts, thereafter negotiated in good faith), for a period of no less than five (5) business days, any adjustments in the terms and conditions of this Agreement proposed by Purchaser. If, following such notice and discussions, the Board of Directors of Seller (after consultation with its outside counsel and regionally-recognized independent financial advisor) shall have resolved, after taking into account the results of such discussions and proposals by Purchaser, if any, that the Asset Acquisition Proposal remains a Superior Proposal, then Seller may (A) furnish non-public information with respect to Seller to the person or group making such Asset Acquisition Proposal and their representatives pursuant to a customary confidentiality agreement, and (B) participate in discussions or negotiations with such person or group and their respective representatives regarding such Asset Acquisition Proposal, provided, however, that Seller shall provide or make available to Purchaser any material non-public information concerning Seller, the Business or the Transferred Assets that is provided to the person making such Asset Acquisition Proposal or its representatives which was not previously provided or made available to Purchaser. Each Notice of Superior Proposal delivered pursuant to this Section 4.6(a) shall include the forms of agreements pursuant to which the Superior Proposal would be implemented or, if no such agreements have been proposed, a written summary of the material terms and conditions of such Superior Proposal (it being understood that Seller must deliver a new Notice of Superior Proposal and thereafter negotiate as provided herein in the event of any modification to an Asset Acquisition Proposal if such modification results in the determination that such Asset Acquisition Proposal is a Superior Proposal).

(b) Nothing contained in this Section 4.6 or in Section 4.21 shall prohibit Seller from taking and disclosing to its stockholders a position with respect to a tender offer contemplated by Rule 14d-9 or Rule 14e-2 promulgated under the Exchange Act or from making any disclosure to Seller s stockholders if, in the good faith judgment of the Board of Directors of Seller, after consultation with outside counsel, failure to so disclose would result in a breach of its fiduciary duties under the DGCL; provided that disclosure to stockholders pursuant to Rule 14e-2 relating to an Asset Acquisition Proposal shall be deemed to be a Change in the Seller Board Recommendation under Section 4.21(c) unless the Board of Directors of Seller expressly, and without qualification, concurrently with such disclosure reaffirms the Seller Board Recommendation.

(c) Seller will promptly inform Purchaser in writing of any Asset Acquisition Proposal (whether or not such Asset Acquisition Proposal shall be determined by the Board of Directors of Seller to constitute a Superior Proposal) received by them and shall provide to Purchaser the name of such third party and the terms of any such Asset Acquisition Proposal. The covenants in this Section 4.6 will apply to any and all discussions in which Seller is currently involved with third parties with respect to an Asset Acquisition Proposal, and Seller shall immediately terminate all such discussions.

Section 4.7 Post-Technology Closing Cooperation Relating to Transferred Assets.

(a) Seller agrees that, during the term of the Manufacturing Agreement, if reasonably requested by Purchaser, it will cooperate with Purchaser in enforcing the terms of any Assumed Contract as well as the protection of any and all intellectual property rights related to the Transferred Technology (Intellectual Property Rights). In the event that Purchaser is unable to enforce its Intellectual Property Rights against a third party as a result of a rule or law barring enforcement of such rights by a transferee of such rights, Seller agrees to, during the period commencing on the Technology Closing Date and ending on the date that is eighteen (18) months following the Manufacturing Closing Date, reasonably cooperate with Purchaser by assigning to Purchaser such rights as may be reasonably required by Purchaser to enforce its Intellectual Property Rights in its own name.

(b) Seller agrees further that, following the Technology Closing Date, if any consent or waiver set forth in Schedule 5.2(f) has not been delivered to Purchaser by Seller at or prior to the Technology Closing Date, Seller shall use commercially reasonable efforts to obtain such approval or permit at the sole expense of Seller following the Technology Closing Date.

(c) Seller agrees further that, following the Technology Closing Date, Seller shall, upon the request of Purchaser and at the sole cost and expense of Purchaser, reasonably cooperate with Purchaser to enforce Seller s and/or Purchaser s rights with respect to confidentiality and non-disclosure covenants executed by any person in favor of Seller with respect to the Business and/or the Transferred Assets prior to the Technology Closing Date.

(d) Seller agrees further that, if reasonably requested by Purchaser, Seller shall reasonably cooperate with Purchaser to provide reasonable access to records and personnel of Seller to the extent Purchaser finds such access necessary in order to transition the Transferred Assets into service of Purchaser.

(e) At or prior to the Technology Closing Date, Seller shall cause Purchaser to be designated as an additional loss payee with respect to any loss related to the Manufacturing Assets on all insurance policies identified on Schedule 2.16. From the Technology Closing through the date immediately following the Manufacturing Closing, Seller shall maintain each such insurance policy in full force and effect (or replace with coverage of similar level) and pay all premiums thereon when due and payable and comply in all material respects with the provisions of such policies.

(f) Seller hereby constitutes and appoints Purchaser (and its successors and assigns), from and after the Technology Closing Date, the true and lawful attorney or attorneys of Seller, with full power of substitution, for Seller and in its name and stead, or otherwise, but on behalf and for the benefit of Purchaser (and its successors and assigns), to (i) from and after the Technology Closing Date, demand and receive from time to time the Technology Assets sold, transferred, assigned, set over, conveyed and delivered hereunder and under the Bill of Sale Technology Assets and (ii) from and after the Manufacturing Closing Date, demand and receive from time to time the Manufacturing Assets sold, transferred, assigned, set over, conveyed and delivered hereunder and under the Bill of Sale Manufacturing Assets, and to give receipts and releases for and in respect of the same and any part thereof, and from time to time to institute and prosecute in the name of Seller or otherwise, but for the benefit of Purchaser (and its successors and assigns), any and all proceedings at law, in equity or otherwise, which Purchaser (and its successors or assigns) may deem proper in order to collect, assert or enforce any claim, right or title of any kind in and to the Technology Assets and Manufacturing Assets sold, transferred, assigned, set over, conveyed and delivered hereunder and under the Bill of Sale Technology Assets and Bill of Sale Manufacturing Assets, and to defend or compromise any or all actions, suits or proceedings in respect of the Technology Assets and/or the Manufacturing Assets and do all such acts and things in relation thereto as Purchaser (and its successors and assigns) shall reasonably deem advisable, Seller hereby declaring that the appointment made and the powers hereby granted are coupled with an interest and are and shall be irrevocable by Seller in any manner and for any reason.

Section 4.8 **No Post-Technology Closing Retention of Copies**. Immediately after (i) the Technology Closing with respect to the Technology Assets and (ii) the Manufacturing Closing with respect to the Manufacturing Assets, Seller shall deliver to Purchaser or destroy copies of any Transferred Assets in Seller s possession that are in addition to those delivered to Purchaser, whether such copies are in paper form, on computer media or stored in another form; provided, however, that Seller may retain and use copies of books and records (financial or otherwise) relating to the activities associated with the Transferred Assets to the extent necessary to comply with applicable law.

Section 4.9 **Noncompetition and Nonsolicitation**.

(a) From the Technology Closing Date to the date that is eighteen (18) months following the Manufacturing Closing (such period, the Restricted Period), Seller agrees that Seller will not, whether on Seller s own behalf or on behalf of or in conjunction with any person, directly or indirectly; (i) engage in any business or activities that compete with the Business (a Competitive Business); (ii) enter the employ of, or render services to, any person (or any affiliate of any person) who or which is engaged in a Competitive Business with respect to such

Competitive Business (whether directly or indirectly); or (iii) acquire a financial interest in, or otherwise become actively involved with, any Competitive Business, directly or indirectly, as a partner, shareholder, officer, director, principal, agent, trustee or consultant. Notwithstanding the foregoing, nothing in this Section 4.9 shall prevent, prohibit, restrict or otherwise limit Seller s right or ability to, subject to Purchaser s rights pursuant to Section 4.13 hereof (i) engage in or operate the business of any second generation mesenchymal stem cells product for bone repair utilizing culturally-expanded mesenchymal stem cells to create a synthetic version of the Product, including, without limitation, Osteocel® XC or (ii) consummate a transaction with a third party, through stock or asset acquisition, merger, consolidation or otherwise, where any such third party acquires all or a portion of the outstanding common stock or assets of Seller, provided that any such third party who acquires all of the outstanding commons stock or substantially all of the assets of Seller shall expressly agree, in writing, to be bound by the terms of this Section 4.9, provided further, however. that any such third party acquiror will not be prevented from engaging in a Competitive Business if, and to the extent to which, such acquiror engaged in the Competitive Business prior to such transaction.

(b) During the Restricted Period, Seller will not, whether on Seller s own behalf or on behalf of or in conjunction with any person, directly or indirectly: (i) solicit, encourage or attempt to solicit or encourage any person who is at the time of such solicitation, encouragement, or attempted solicitation or encouragement an employee of Purchaser or any of its affiliates and who was immediately prior to the Technology Closing or Manufacturing Closing (as applicable), a Seller Employee to leave the employment of Purchaser or its affiliates; (ii) hire any Seller Employee who left the employment of Seller or its affiliates coincident with or in connection with the Technology Closing or the Manufacturing Closing; or (iii) hire any Seller Employee who terminates employment with Purchaser or its affiliates in the one year period following the Manufacturing Closing.

(c) During the Restricted Period, Seller agrees that Seller will not, whether on Seller s own behalf or on behalf of or in conjunction with any person, directly or indirectly solicit, encourage or attempt to solicit or encourage to cease to work with Purchaser or its affiliates any employee of, or consultant then under contract with, Purchaser or its affiliates who is or has been engaged in the Business.

(d) During the Restricted Period, Seller agrees that Seller will not, directly or indirectly (i) solicit, induce or attempt to induce any customer to cease doing business in whole or in part with Purchaser or its affiliates with respect to the Business; (ii) attempt to limit or interfere with any business agreement existing between the Purchaser and/or its affiliates and any third party; or (iii) disparage the business reputation or employees of Purchaser, or any of its affiliates, or take any actions, knowingly, willfully or, recklessly, that are harmful to the Purchaser s or its affiliates goodwill with their customers, clients, publishers, advertisers, marketers, vendors, employees, service providers, media or the public.

Section 4.10 **Notice of Breaches**. From the date of this Agreement until (i) the Technology Closing date with respect to all Transferred Assets and (ii) the Manufacturing Closing with respect to the Manufacturing Assets, the Seller shall promptly deliver to the Purchaser a written notice containing supplemental information concerning events or circumstances first occurring subsequent to the date hereof which would render any

representation, warranty or statement in this Agreement inaccurate or incomplete, or any covenant breached, as of any date after the date of this Agreement, specifying the applicable section of this Agreement to which such supplemental information applies (including any changes pursuant to subsection (b) of this Section, the Notice of Breach). Following the delivery of any such Notice of Breach, Seller shall promptly deliver to Purchaser all additional information reasonably requested by Purchaser with respect to the content of such Notice of Breach. No delivery of any Notice of Breach pursuant to this Section 4.10 or knowledge of any such breach (however obtained) shall be deemed to amend or supplement any schedule to this Agreement or affect the rights and remedies of Purchaser under Article VIII of this Agreement.

Section 4.11 Certain Employee Matters.

(a) As soon as reasonably practicable following the date hereof, Seller shall provide Purchaser reasonable access during normal working hours to active employees of Seller performing services with respect to the Business (Seller Employees) to enable Purchaser to discuss compensation terms and present offers or employment or service to such employees.

(b) Purchaser may, in its sole discretion, offer employment to Seller Employees commencing as of the Manufacturing Closing (each Seller Employee who executes and delivers to the Purchaser such an offer of employment, a Transferred Employee). With respect to any Seller Employee who receives an offer of employment from Purchaser prior to the Manufacturing Closing Date, Seller shall assist Purchaser with its efforts to enter into an offer letter with such employee as soon as reasonably practicable after the date hereof and in any event prior to the Manufacturing Closing Date. Notwithstanding any of the foregoing, Purchaser shall not have any obligation to make an offer of employment to any Seller Employee. Purchaser agrees that Purchaser will not, directly or indirectly, solicit, encourage or attempt to solicit or encourage to cease to work with Seller any Seller Employee for employment with Purchaser commencing prior to the Manufacturing Closing Date without the consent of Seller, which consent shall not be unreasonably withheld.

(c) From and after the Technology Closing Date or the Manufacturing Closing Date, as applicable, Purchaser shall recognize each Transferred Employee s original hire date with Seller and prior service with Seller (as recognized by Seller immediately prior to the Technology Closing Date or the Manufacturing Closing Date, as applicable) as service with Purchaser for purposes of eligibility to participate in, and determining vesting and any accrued benefits based on length of service under, Purchaser s employee benefit plans, policies, arrangements and payroll policies, including vacation benefits.

(d) Seller shall make employment files of the Seller Employees available for inspection by Purchaser, to the extent permitted by and in accordance with applicable law.

(e) Seller shall, at Purchasers request, accelerate the vesting of any Seller Options held by one or more Transferred Employees at or following the Technology Closing on the terms and subject to the conditions as Purchaser shall reasonably request and in a manner consistent with the applicable plan option agreements and related documents.

Section 4.12 Right of First Negotiation; Purchase Option.

(a) Purchase Option. For a period commencing on the Technology Closing Date and ending at 11:59 p.m. pacific time on December 31, 2009, Purchaser shall have the right to acquire, and Seller shall be obligated to provide, the exclusive rights to any second generation mesenchymal stem cell product for bone repair utilizing culture expanded mesenchymal stemcells to create a synthetic version of the Product (Osteocel XC®) on the terms and conditions set forth on Schedule 4.12.

(b) Right of First Negotiation. From the Technology Closing Date until December 31, 2009, and subject to Purchaser s rights under Section 4.12(a) hereof, if Seller desires to enter into a transaction or accept a third-party proposal for the sale (whether directly or by merger, acquisition or any other asset sale or change of control transaction), license, joint-venture arrangement, transfer or partial transfer (or similar arrangement) of Osteocel XC® (an Osteocel XC Transaction), it shall first provide Purchaser with a notice of such desired Osteocel XC Transaction (a Negotiation Notice). The Negotiation Notice shall include in reasonable detail all material economic, legal and business terms of the Osteocel XC Transaction proposed by Seller. If, within five (5) business days of receipt of a Negotiation Notice, Purchaser gives Seller written notice of its interest to negotiate such Osteocel XC Transaction on the terms contained in the Negotiation Notice (an Affirmative Response Notice), then Seller and Purchaser agree, promptly and in good faith, to exclusively negotiate a legally-binding agreement to carry out such Osteocel XC Transaction. If Purchaser fails to respond to the Negotiation Notice within said five (5) business day period, or if Seller and Purchaser fail, after good faith efforts, to enter into a written agreement for such Osteocel XC Transaction within thirty (30) days after delivery of Seller s Negotiation Notice, then neither Purchaser nor Seller shall have a right or be under any obligation to enter into such Osteocel XC Transaction, and Seller (subject to the right of Purchaser to exercise its right pursuant to Section 4.12(a)) may consummate with a third-party a transaction on terms not materially less favorable to Seller, taken as a whole, than the terms contained in the Negotiation Notice. If Purchaser delivers an Affirmative Response Notice to Seller pursuant to this Section 4.12(b), Purchaser shall provide to Seller a draft definitive agreement for the Osteocel XC Transaction.

Section 4.13 Brand and Trademarks. Except as expressly provided in this Agreement or in the Manufacturing Agreement, Purchaser shall have no rights to any of Seller s intellectual property other than the Transferred Technology, and Seller shall have no rights to any of Purchaser s intellectual property.

Section 4.14 Consents. Prior to the Technology Closing Date, Seller shall use its commercially reasonable efforts to obtain in writing and at its own expense all consents and waivers referred to on Schedule 2.5 hereto. To the extent that an attempted assignment or transfer of any Assumed Contract would constitute a breach thereof, this Agreement shall not constitute an assignment or attempted assignment thereof. In such a case, Seller shall establish with Purchaser any back-to-back arrangement reasonably requested by Purchaser in order to provide for Purchaser the benefits intended to be assigned under any such Assumed Contract (subject to the right of any third party thereunder to terminate such Assumed Contract), including, without limitation, the enforcement by Seller for the benefit of Purchaser, at Purchaser s sole cost and expense, of any and all rights of Seller against a third party to such Assumed Contract arising out of the breach by such third party or otherwise.

(e) Seller shall, at Purchasers request, accelerate the vesting of any Seller Options held by one or more Tran

Section 4.15 Hart-Scott-Rodino Notification.

(a) Seller and Purchaser shall each promptly prepare, execute and file a notification with the United States Justice Department and the Federal Trade Commission as required by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (HSR). Seller and Purchaser shall cooperate with each other in connection with the preparation of such notification, including sharing information concerning sales and ownership and such other information as may be needed to complete such notification, and providing a copy of such notification to the other prior to filing. Each of Seller and Purchaser shall keep all information about the other obtained in connection with the preparation of such notification confidential. Purchaser and Seller shall each pay one-half of the filing fee required under by the regulations promulgated pursuant to HSR. Purchaser and Seller shall promptly inform the other of any material communication between such party and any governmental entity regarding any of the transactions contemplated hereby. If either party received any formal or informal request for supplemental information or documentary material from any governmental entity with respect to the transactions contemplated hereby, then the recipient of such request shall make, or case to be made, as soon as reasonably practicable, a response in compliance with such request and, in making any such response, the responding party shall consider in good faith the views of the other party hereto. Seller and Purchaser covenant and agree that the Technology Closing shall be subject and conditioned upon the receipt of requisite approvals or the expiration of the applicable waiting period under HSR.

(b) Notwithstanding anything in this Agreement to the contrary, if any administrative or judicial action or proceeding is instituted (or threatened to be instituted) challenging any transaction contemplated by this Agreement as violative of any federal, state or foreign statutes, rules, regulations, orders or decrees that are designed to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraining o trade (collectively, Antitrust Laws), it is expressly understood and agreed that: (i) Purchaser and Seller shall provide information required by law or governmental regulation and shall use commercially reasonably efforts to substantially comply as promptly as practicable with any second request for information pursuant to the Antitrust Laws; (ii) Purchaser and Seller shall use their commercially reasonably efforts to resolve such objections, if any, as may be asserted by any governmental entity with respect to the transactions contemplated by this Agreement under Antitrust Laws; provided, however, that (A) neither Purchaser nor Seller shall have any obligation to litigate or contest any administrative or judicial action or proceeding or any decree, judgment, injunction or other order, whether temporary, preliminary or permanent; and (B) Purchaser shall be under no obligation to make proposals, execute or carry out agreements or submit to orders providing for (1) the sale, license or other disposition or holding separate (through the establishment of a trust or otherwise) of any assets or categories of assets of Purchaser or any of its affiliates or the Transferred Assets, or (2) the imposition of any limitation or regulation on the ability of Purchaser or any of its affiliates to freely conduct their business or own such assets.

Section 4.16 Public Announcement. Except as required by law, neither party (nor any director, officer, employee or affiliate of either party) shall make any public announcement, whether written or oral, concerning this Agreement or the subject matter hereof without the prior written consent of the other.

Section 4.17 **Bulk Sales Laws.** Seller shall comply, in connection with transactions contemplated by this Agreement, with any applicable bulk sales laws and any other applicable bulk sales laws with respect to or requiring notice to Seller s creditors, in effect as of the Technology Closing Date with respect to the Technology Assets and the Manufacturing Closing Date with respect to the Manufacturing Assets.

Section 4.18 **Transfer Taxes.** All sales or use, transfer, real property gains, excise, stamp, business and occupation, or other similar Taxes, resulting or arising out of or in connection with the consummation of the transactions contemplated hereby (Transfer Taxes) and imposed on Seller shall be paid by Seller and Seller shall promptly discharge such Transfer Taxes when due. All Transfer Taxes imposed on Purchaser other than Transfer Taxes resulting from Seller s breach of this Section 4.19 shall be paid by Purchaser.

Section 4.19 **Termination of Certain Contracts.** At or prior to the Technology Closing Date, Seller shall deliver to each party to those Contracts identified on Schedule 2.9(c) a notice of termination, which termination shall be effective as of the date set forth opposite each such Contract on Schedule 2.9(c). Notwithstanding the foregoing, Seller shall give any such notice of termination following the Technology Closing Date within two (2) business days of receipt of a written request of Purchaser to earlier deliver such notice of termination. Seller acknowledges that Seller s failure to comply with the provisions of this Section 4.20 shall be a material breach of this Agreement for purposes of Section 5.2(b) hereof.

Section 4.20 **Preparation of Proxy Statement; Stockholder Meeting.**

(a) As promptly as reasonably practicable following the date of this Agreement, Seller shall prepare and file with the Securities and Exchange Commission (the SEC) a proxy statement relating to the approval of the transactions contemplated by this Agreement by Seller s stockholders (as amended or supplemented from time to time, the Proxy Statement) and Seller shall use its reasonable best efforts to respond as promptly as practicable to any comments of the SEC with respect thereto and to cause the Proxy Statement to be mailed to Seller s stockholders as promptly as reasonably practicable following the date of this Agreement. Seller shall promptly notify Purchaser upon the receipt of any comments from the SEC or its staff or any request from the SEC or its staff for amendments or supplements to the Proxy Statement and shall provide Purchaser with copies of all correspondence between Seller and its representatives, on the one hand, and the SEC and its staff, on the other hand. Notwithstanding anything to the contrary stated above, prior to filing or mailing the Proxy Statement (or any amendment or supplement thereto) or responding to any comments of the SEC with respect thereto, Seller shall (i) provide Purchaser the reasonable opportunity to review and comment on such document or response prior to any filing of such document or response to any comments of the SEC and consider in good faith Purchaser s comments, (ii) include in such document or response all comments reasonably proposed by Purchaser with respect to any statement or information specifically relating to the Purchaser.

(b) Seller shall, as promptly as reasonably practicable following the date of this Agreement (taking into consideration regulatory review processes and timing therefore), establish a record date for, duly call, give notice of, convene and hold a meeting of its stockholders (the Stockholders Meeting) for the purpose of obtaining the affirmative vote of

the holders of a majority of the outstanding shares of Seller s common stock, par value $0.001 per share, in favor of approval of the transactions contemplated by this Agreement (the Stockholder Approval). Seller shall cause the Stockholders Meeting to be held as promptly as reasonably practicable after the date of this Agreement. Except as set forth in Section 4.6(b), Seller shall, through its board of directors, recommend to its stockholders that they approve this Agreement and the transactions contemplated hereby, and shall include such recommendation in the Proxy Statement (Seller Board Recommendation).

(c) Except as set forth in this Section 4.20(c), the Board of Directors of Seller shall not (i) withdraw or modify in a manner adverse to Purchaser, or publicly propose to withdraw or modify in a manner adverse to Purchaser, the Seller Board Recommendation; (ii) approve or recommend any letter of intent, agreement in principle, acquisition agreement, option agreement or similar agreement constituting or relating to, or that is intended to be or would reasonably be likely to result in, any Asset Acquisition Proposal; or (iii) approve or recommend, or publicly propose to approve, endorse or recommend, any Asset Acquisition Proposal. Notwithstanding the foregoing, if, prior to receipt of the Stockholder Approval, the Board of Directors of Seller determines in good faith that an unsolicited bona fide written Alternative Proposal received by Seller constitutes a Superior Proposal (after compliance with the notification and negotiation provisions set forth herein), the Board of Directors of Seller may withdraw, modify or qualify its Seller Board Recommendation (a Change in Seller Board Recommendation) and may recommend such Superior Proposal.

ARTICLE V.

CONDITIONS TO CLOSING

Section 5.1 **Conditions to Obligations of Each Party.** The respective obligations of each of Purchaser and Seller to consummate the transactions contemplated in this Agreement are subject to the satisfaction of the following conditions:

(a) All applicable waiting periods (and any extensions thereof) under HSR shall have expired or otherwise been terminated;

(b) No law or regulation shall have been adopted or promulgated, and no temporary restraining order, preliminary or permanent injunction or other judgment or order issued by any governmental entity shall be in effect, in each case which has the effect of making the transactions contemplated by this Agreement illegal, or otherwise enjoining or prohibiting the consummation of the transactions contemplated by this Agreement; and

(c) The Stockholder Approval shall have been obtained.

Section 5.2 **Conditions to the Obligations of the Purchaser.** The obligation of Purchaser to consummate the transactions contemplated in this Agreement are subject to the satisfaction (or waiver by Purchaser) of the following additional conditions:

(a) (i) The representations and warranties of Seller set forth in Sections 2.1, 2.2, 2.3 and 2.4 shall be true and correct in all respects at and as of the Technology Closing Date as if first made on the Technology Closing Date, and (ii) the other representations and warranties of Seller set forth in Article II shall be true and correct in all material respects (except for any such

(a) All applicable waiting periods (and any extensions thereof) under HSR shall have expired or otherwise be

representations and warranties that are qualified by materiality, which shall be true and correct in all respects) on and as of the date hereof and on and as of the Technology Closing Date, as though first made on and as of the Technology Closing Date (other than representations and warranties made as of a specified date, which need be true and correct only as of the specified date);

(b) Seller shall have (i) performed and complied with its agreements and covenants under Section 4.3 (Financial Statements), including, for avoidance of doubt, delivery of the Audited Financial Statements pursuant to Section 4.3(c) hereof and (ii) performed and complied in all material respects with all of its other agreements and covenants required to be performed or complied with under this Agreement as of the Technology Closing;

(c) There shall not have occurred, from the date of this Agreement through the Technology Closing Date, any Business Material Adverse Effect or any event or development which, individually or in the aggregate, would have a Business Material Adverse Effect;

(d) No action suit, proceeding claim, arbitration or investigation before any governmental entity or before any arbitrator shall be pending that would reasonably be expected to result in an unfavorable judgment, order, decree, stipulation or injunction that would: (i) prevent consummation of the transactions contemplated by this Agreement or (ii) cause the transactions contemplated by this Agreement to be rescinded following consummation;

(e) Seller shall have delivered to Purchaser a certificate executed by an authorized officer of the Seller to the effect that each of the conditions specified in clauses (a), (b), (c) and (d) of this Section 5.2 has been satisfied as of immediately prior to the Technology Closing in all respects;

(f) Seller shall have given such notices and obtained in writing and at its own expense all consents and waivers referred to on Schedule 5.2(f) hereto, and Seller shall have delivered to Purchaser copies of each such fully executed notice, consent and/or waiver;

(g) Seller shall have delivered to Purchaser a bill of sale and assignment and assumption agreement in the form attached hereto as Exhibit A (the Bill of Sale Technology Assets) dated as of the Technology Closing Date and duly executed by an authorized officer of Seller;

(h) Seller shall have delivered to Purchaser (i) an assignment of intellectual property in the form attached hereto as Exhibit B (the IP Assignment Agreement Patents) and (ii) an assignment of intellectual property in the form attached hereto as Exhibit C (the IP Assignment Agreement Trademarks), in each case dated as of the Technology Closing Date and duly executed by an authorized officer of Seller;

(i) Seller shall have delivered to Purchaser a manufacturing and supply agreement in the form attached hereto as Exhibit D (the Manufacturing Agreement) dated as of the Technology Closing Date and duly executed by an authorized officer of Seller;

(i) Seller shall have delivered to Purchaser a manufacturing and supply agreement in the form attached here

(j) Seller shall have delivered to Purchaser a license agreement in the form attached hereto as Exhibit E (the License Agreement) dated as of the Technology Closing Date and duly executed by an authorized officer of Seller;

(k) McKenna Long & Aldridge LLP, counsel to Seller, shall have delivered to Purchaser an opinion in the form attached hereto as Exhibit F, dated as of the Technology Closing Date;

(l) All Liens *other than* Permitted Liens to which any of the Technology Assets are subject or by which any of the Technology Assets are bound shall have been removed and Seller shall have delivered to Purchaser evidence of the removal of such Liens that is reasonably acceptable to Purchaser;

(m) Seller shall have delivered to Purchaser a secretary s certificate in the form attached hereto as Exhibit G, dated as of the Technology Closing Date and duly executed by the Secretary or Assistant Secretary of Seller; and

(n) Seller shall have obtained from the Secretary of State of the State of Delaware, and delivered to Purchaser, a certificate of good standing of Seller.

Section 5.3 Conditions to the Obligations of Seller. The obligation of Seller to consummate the transactions contemplated in this Agreement are subject to the satisfaction (or waiver by Seller) of the following additional conditions:

(a) (i) The representations and warranties of Purchaser set forth in Sections 3.1, 3.2 and 3.3 shall be true and correct in all respects at and as of the Technology Closing Date as if first made on the Technology Closing Date, and (ii) the other representations and warranties of Purchaser set forth in Article III shall be true and correct in all material respects (except for any such representations and warranties that are qualified by materiality, which shall be true and correct in all respects) on and as of the date hereof and on and as of the Technology Closing Date, as if first made at and as of the Technology Closing Date (other than representations and warranties made as of a specified date, which need be true and correct only as of the specified date);

(b) Purchaser shall have performed and complied in all material respects with all of its agreement and covenants required to be performed or complied with under this Agreement as of the Technology Closing;

(c) No action, suit, proceeding claim, arbitration or investigation before any governmental entity or before any arbitrator shall be pending that would reasonably be expected to result in an unfavorable judgment, order, decree, stipulation or injunction that would: (i) prevent consummation of the transactions contemplated by this Agreement or (ii) cause the transactions contemplated by this Agreement to be rescinded following consummation;

(d) Purchaser shall have delivered to Seller a certificate executed by an authorized officer of the Seller to the effect that each of the conditions specified in clauses (a), (b) and (c) of this Section 5.3 has been satisfied as of immediately prior to the Technology Closing in all respects;

(d) Purchaser shall have delivered to Seller a certificate executed by an authorized officer of the Seller to the

(e) Purchaser shall have delivered to Seller the Bill of Sale Technology Assets dated as of the Technology Closing Date and duly executed by an authorized officer of Purchaser;

(f) Purchaser shall have delivered to Seller the Manufacturing Agreement dated as of the Technology Closing Date and duly executed by an authorized officer of Purchaser;

(g) Purchaser shall have delivered to Seller the License Agreement dated as of the Technology Closing Date and duly executed by an authorized officer of Purchaser;

(h) DLA Piper US LLP, counsel to Purchaser, shall have delivered to Purchaser an opinion in the form attached hereto as Exhibit H, dated as of the Technology Closing Date;

(i) Purchaser shall have delivered to Seller a secretary s certificate in the form attached hereto as Exhibit I, dated as of the Technology Closing Date and duly executed by the Secretary or Assistant Secretary of Purchaser; and

(j) Purchaser shall have obtained from the Secretary of State of the State of Delaware, and delivered to Seller, a certificate of good standing of Purchaser.

ARTICLE VI.

CONDITIONS TO THIRD MILESTONE PAYMENT

Section 6.1 **Conditions to Third Milestone Payment**. Purchaser s obligation to make the Third Milestone Payment on the Manufacturing Closing Date shall be subject to the satisfaction (or waiver by Purchaser) of the following conditions:

(a) (i) The representations and warranties of Seller set forth in Sections 2.1, 2.2, 2.3 and 2.4 shall be true and correct in all respects with respect to Seller and the Manufacturing Assets, as applicable, at and as of the Manufacturing Closing Date as if first made on the Manufacturing Closing Date, and (ii) the other representations and warranties of Seller set forth in Article II shall be true and correct in all material respects with respect to Seller and the Manufacturing Assets, as applicable, at and as of the Manufacturing Closing Date, as if first made at and as of such time;

(b) Seller shall have performed and complied in all material respects with all of its agreements and covenants required to be performed or complied with under this Agreement with respect to the Manufacturing Assets as of the Manufacturing Closing Date;

(c) There shall not have occurred, from the date of this Agreement through the Manufacturing Closing Date, any event, circumstance, development with respect to, change in or effect on the Manufacturing Assets that is, or could reasonably be expected to be, materially adverse to such Manufacturing Assets, taken as a whole;

(d) No action, suit, proceeding, claim, arbitration or investigation before any governmental entity or before any arbitrator shall be pending that would reasonably be expected to result in an unfavorable judgment, order, decree, stipulation or injunction that would: (i) prevent the transfer of the Manufacturing Assets as contemplated hereby or (ii) cause the transfer

(a) (i) The representations and warranties of Seller set forth in Sections 2.1, 2.2, 2.3 and 2.4 shall be true and

of the Manufacturing Assets as contemplated hereunder to be rescinded following consummation;

(e) None of the Work in Process shall be held under a consignment or similar arrangement or be in transit. The Work in Process shall have been manufactured in accordance with then current Good Tissue Practices, as set forth by the FDA, and all applicable laws, rules, regulations, ordinances, standards and guidelines, including, without limitation, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq*., and the United States National Organ Transplant Act, Title 21 of the Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue Based Products.

(f) Seller shall have delivered to Purchaser a certificate executed by an authorized officer of the Seller to the effect that each of the conditions specified in clauses (a), (b), (c), (d) and (e) of this Section 6.1 has been satisfied as of the Manufacturing Closing Date in all respects;

(g) Seller shall have delivered to Purchaser a bill of sale and assignment and assumption agreement in the form attached hereto as Exhibit J (the Bill of Sale Manufacturing Assets) dated as of the Manufacturing Closing Date and duly executed by an authorized officer of Seller;

(h) All Liens *other than* Permitted Liens to which any of the Manufacturing Assets are subject or by which any of the Manufacturing Assets are bound shall have been removed and Seller shall have delivered to Purchaser evidence of the removal of such Liens that is reasonably acceptable to Purchaser; and

(i) Seller shall have obtained from the Secretary of State of the State of Delaware, and delivered to Purchaser, a certificate of good standing of Seller.

ARTICLE VII.

TERMINATION

Section 7.1 **Termination of Agreement**. This Agreement may be terminated at any time prior to the Technology Closing:

(a) By mutual written consent of Purchaser and Seller;

(b) By Purchaser or Seller if, without the fault of the terminating party, the Technology Closing shall not have occurred on of before September 8, 2008 (the End Date); provided that, if by the End Date the condition set forth in Section 5.1(a) shall not have been satisfied but all other conditions shall be or are capable of being satisfied, the End Date may be extended by either Purchaser or Seller, in its discretion, by three (3) months from its scheduled expiry (in which case any references to the End Date herein shall mean the End Date as extended);

(c) By Purchaser, if Seller shall be in material breach of any of its representations, warranties, covenants or agreements set forth in this Agreement, which breach is not cured by Seller within ten (10) calendar days following receipt of written notice of such breach or failure to perform from Purchaser, provided that Purchaser is not in material breach of any of its

representations, warranties, covenants or agreements set forth in this Agreement at the time such notice is delivered;

(d) By Seller, if Purchaser shall be in material breach of any of its representations, warranties, covenants or agreements set forth in this Agreement, which breach is not cured by Purchaser within ten (10) calendar days following receipt of written notice of such breach or failure to perform from Seller, provided that Seller is not in material breach of any of its representations, warranties, covenants or agreements set forth in this Agreement at the time such notice is delivered;

(e) By Purchaser or Seller if any governmental entity shall have entered a final, non-appealable order or injunction restraining, enjoining or otherwise prohibiting the transactions contemplated by this Agreement, provided that such right of termination shall not be available to any party if such party shall have failed to take reasonable efforts to prevent or contest the imposition of such order or injunction;

(f) By Purchaser or Seller if the Stockholder Approval shall not have been obtained at the Stockholders Meeting duly convened or at any adjournment or postponement thereof; provided, however, that the right to terminate this Agreement under this Section 7.1(f) shall not be available to Seller where the failure to obtain the Stockholder Approval shall have been caused by the action or failure to act of Seller and such action or failure to act constitutes a breach by Seller of this Agreement; or

(g) By Purchaser if there shall have been a Change in Seller Board Recommendation.

Section 7.2 Procedures and Effect of Termination. In the event of termination of this Agreement by Purchaser or Seller pursuant to Section 7.1, all obligations of the parties hereunder shall terminate without any liability of any party to the other party, except for any liability of a party for breaches of this Agreement prior to such termination. This Section 7.2, Section 4.5 (Confidentiality), Section 7.3 and Article IX shall survive any termination of this Agreement.

Section 7.3 Reimbursement of Expenses. Seller agrees that, if Purchaser or Seller terminates this Agreement (i) pursuant to Section 7.1(b) hereto and, at the time of such termination, the Stockholder Approval shall not have been obtained or (ii) pursuant to Section 7.1(f), then Seller shall pay to Purchaser promptly (but in any even no later than two business days after such termination) an amount of Three Hundred Fifty Thousand Dollars ($350,000.00) as reimbursement for Purchaser s costs and expenses associated with the negotiation, implementation and performance of this Agreement prior to such termination. Seller further agrees that, (i) if Purchaser or Seller terminates this Agreement pursuant to Section 7.1(f) hereto and at the time of such termination the Stockholder Meeting shall have been held, the Stockholder Approval shall not have been obtained and, prior to the Stockholder Meeting, there shall have been a Change in Seller Board Recommendation or (ii) Purchaser terminates this Agreement pursuant to Section 7.1(g), then Seller shall pay to Purchaser promptly (but in any event no later than two business days after such termination) an amount of Two Million Dollars ($2,000,000). All amounts payable by Seller to Purchaser pursuant to this Section 7.3 shall be

paid in a wire transfer of United States dollars in immediately available funds to an account designated by Purchaser to Seller in writing.

ARTICLE VIII.

INDEMNIFICATION

Section 8.1 **Indemnification by Seller**. Seller hereby agrees to indemnify, defend and save harmless Purchaser and its directors, officers, employees, affiliates, agents, advisors, representatives, stockholders and assigns (collectively, the Purchaser Indemnified Parties) from, against and in respect of any and all Losses incurred or suffered by any Purchaser Indemnified Party arising out of, or related to, the following (each, a Purchaser Claim):

(a) any misrepresentation or breach of warranty made by the Seller in any Transaction Document or in any document, certificate or other instrument required to be delivered by the Seller under any Transaction Document;

(b) any breach or non fulfillment by the Seller when required to be performed of any covenant or agreement made or to be performed by the Seller in any Transaction Document or in any agreement or instrument entered in connection with any Transaction Document;

(c) any fraud or intentional misrepresentation with respect to, or intentional breach of, any Transaction Document by the Seller; and

(d) the Retained Liabilities.

Except as set forth in Section 8.6 with respect to third party Actions, in the event of any Purchaser Claim, Purchaser shall notify Seller and such notice shall be in writing and shall describe with reasonable specificity the nature and amount of such Purchaser Claim (a Purchaser Notice of Claim). A delay on the part of a Purchaser Indemnified Party in giving Seller a Purchaser Notice of Claim shall relieve Seller from its obligations under this Section 8.1 only to the extent that Seller is materially prejudiced thereby. A Purchaser Notice of Claim may be delivered at any time during the applicable survival period for such claim as set forth in Section 8.3 of this Agreement.

Section 8.2 **Indemnification by Purchaser**. Purchaser hereby agrees to indemnify, defend and save harmless Seller and its directors, officers, employees, affiliates, agents, advisors, representatives, stockholders and assigns (collectively, the Seller Indemnified Parties) from, against and in respect of any and all Losses incurred or suffered by any Seller Indemnified Party arising out of, or related to, the following (each, a Seller Claim):

(a) any misrepresentation or breach of warranty made by the Purchaser in any Transaction Document or in any document, certificate or other instrument required to be delivered by the Purchaser under any Transaction Document;

(b) any breach or non fulfillment of any covenant or agreement made or to be performed by the Purchaser in any Transaction Document or in any agreement or instrument entered in connection with any Transaction Document;

(a) any misrepresentation or breach of warranty made by the Seller in any Transaction Document or in any do

(c) any fraud or intentional misrepresentation with respect to, or intentional breach of, any Transaction Document by Purchaser; and

(d) the Assumed Liabilities.

Except as set forth in Section 8.6 with respect to third party Actions, in the event of any Seller Claim, Seller shall notify Purchaser and such notice shall be in writing and shall describe with reasonable specificity the nature and amount of such Seller Claim (a "Seller Notice of Claim"). A delay on the part of a Seller Indemnified Party in giving Purchaser a Seller Notice of Claim shall relieve Purchaser from its obligations under this Section 8.2 only to the extent that Purchaser is materially prejudiced thereby. A Seller Notice of Claim may be delivered at any time during the applicable survival period for such claim as set forth in Section 8.3 of this Agreement.

Section 8.3 **Survival**. If the Technology Closing occurs, all representations and warranties of Purchaser and Seller contained herein or in any other Transaction Document or document, certificate or other instrument required to be delivered hereunder or thereunder in connection with the transactions contemplated hereby shall survive the Technology Closing and shall continue until eighteen months (18) months after the Manufacturing Closing, provided that the representations and warranties set forth in Section 2.6 (Taxes), Section 2.9(c) (Disposition of Certain Contracts), Section 2.15 (Intellectual Property), Section 2.18 (Authorizations; Regulatory Compliance), Section 2.20 (Environmental), Section 2.22 (Brokers), shall survive until sixty (60) days after the expiration of the applicable statutes of limitations (including any extensions or waivers thereof) (the "Specified Representations"); provided, further, that the representations and warranties on which any Claims for indemnification are based shall continue in effect until final resolution of such claims and such expiration thereof shall not effect the right of any Indemnified Party to seek indemnification for Losses pursuant to Article 8 hereof.

Section 8.4 **Limitations**. Notwithstanding anything contained in this Agreement to the contrary:

(a) Neither party shall be liable or be obligated to make any payment in respect of Losses suffered by an Indemnified Party under Section 8.1(a) (other than the representations and warranties set forth in Section 2.4 hereof), 8.1(b), 8.2(a) or 8.2(b) hereof (as the case may be) until the aggregate of all Losses suffered by such Indemnified Party under this Article VIII exceeds Two Hundred Fifty Thousand Dollars ($250,000) (the "Basket Amount"); after which such other party shall be entitled to recover all such Losses (subject to the General Cap Amount); provided that in no event shall the aggregate indemnity amount payable by any indemnifying party pursuant to Section 8.1(a), 8.1(b) or 8.2(a) hereof (other than with respect to any Specified Representations) exceed Fifteen Million Dollars ($15,000,000) (the "General Cap Amount").

(b) Neither party shall be liable or be obligated to make any payment in respect of Losses suffered by an Indemnified Party under (i) Section 8.1(a) with respect to any Specified Representation (other than the representations set forth in Section 2.9(c) hereof), or (ii) Section 8.2(b) (the "Special Cap Liabilities") until the aggregate of all Losses suffered by such Indemnified Party under this Article VIII exceeds the Basket Amount, after which such other party shall be entitled to recover all such Losses (subject to the Special Cap Amount), provided

that in no event shall the aggregate indemnity amount payable by any indemnifying party with respect to the Special Cap Liabilities and liability under Section 8.1(a) with respect to the representations set forth in Section 2.9(c) hereof, when taken together with all Losses paid or payable to an Indemnified Party pursuant to Section 8.4(a) above, exceed Twenty Million Dollars ($20,000,000) *plus* any Applicable Milestone Payments that become payable (prior to Purchaser s Rights of Set-Off) pursuant to Section 1.5 hereof; provided, however, that in no event shall the aggregate indemnity amount for Losses payable by any Indemnifying Party under this Section 8.4(b), when taken together with all Losses paid or payable by an Indemnifying Party pursuant to Section 8.4(a), exceed Thirty Five Million Dollars ($35,000,000) (the Special Cap Amount).

(c) Each party s liability and obligation to make any payment in respect of Losses suffered by an Indemnified Party under (i) Sections 8.1(c) and 8.1(d) or (ii) Sections 8.2(c) and 8.2(d) shall be unlimited.

(d) The amount of any Losses indemnifiable by either party pursuant to this Article VIII shall be adjusted to reflect the value of any insurance proceeds actually received (net of any deductibles, retention or self-insurance) by the Indemnified Party or its successors or assigns in respect of such Losses provided, however, that no Indemnified Party shall have any obligation to pursue such insurance proceeds or recovery from third persons. If any such proceeds or recoveries are received by an Indemnified Party (or any of its affiliates) with respect to any Claims after a party hereto has made a payment to the Indemnified Party with respect to such Claim, the Indemnified Party (or such affiliate) shall pay to such party the amount of such proceeds or recoveries (up to the amount of such party s payment with respect to such Claim).

(e) No Indemnified Party shall be entitled to recover under this Article VIII an amount in respect of Losses, or otherwise obtain reimbursement or restitution from any party to this Agreement, more than once in respect of the same Loss.

Section 8.5 **Resolution of Notice of Claim**. Each Purchaser Notice of Claim and Seller Notice of Claim (each, a Notice of Claim) delivered hereunder shall be resolved as follows:

(a) If, within thirty (30) days after a Notice of Claim is received by the indemnifying party, the indemnifying party does not contest such Notice of Claim in writing to the Indemnified Party, the indemnifying party shall be conclusively deemed to have consented to the recovery by the Indemnified Party of the full amount of Losses (subject to the limits contained in this Article VIII) specified in the Notice of Claim in accordance with this Article VIII, and the indemnifying party shall be obligated to pay to the Indemnified Party the total amount of Losses set forth in the Notice of Claim within fifteen (15) days following such thirty (30) day period.

(b) Following the delivery of a Notice of Claim to an indemnifying party, the indemnifying party shall be given such access as they may reasonably require during the Indemnified Party s normal business hours (or such other times as the parties may agree) to those books and records of the Indemnified Party relating to the Claim in the possession of, and/or under the control of, the Indemnified Party, and access to such personnel or representatives of

the Indemnified Party as they may reasonably require for the purposes of determining whether to contest all or any portion of a Notice of Claim.

(c) If the indemnifying party gives the Indemnified Party written notice contesting all or any portion of a Notice of Claim (a Contested Claim) within the thirty (30) day period specified in Section 8.5(a) above, then such Contested Claim shall be resolved by either (i) a written settlement agreement or memorandum executed by the Indemnified Party and the indemnifying party or (ii) in the absence of such a written settlement agreement within fifteen (15) days following receipt by the Indemnified Party of the written notice from the indemnifying party, by binding arbitration between the Indemnified Party and indemnifying party in accordance with the terms and provisions of Section 9.1 below. The decision of the arbitrators as to the validity and amount of any claim in any disputed Notice of Claim shall be binding and conclusive upon the parties to this Agreement, and the Indemnified Party shall be entitled to act in accordance with and in reliance on such decision, and the indemnifying party shall be obligated to pay to the Indemnified Party the total amount of Losses as determined by the arbitrator within fifteen (15) days following such decision.

(d) Judgment upon any award rendered by the arbitrators may be entered in any court having jurisdiction. Seller and Purchaser shall instruct the arbitrators to determine and set forth in judgment of the arbitrators the non-prevailing party to an arbitration and such non-prevailing party shall pay its own expenses, the fees of each arbitrator, the administrative fee of the American Arbitration Association, and the expenses, including, without limitation, the reasonable attorneys fees and costs, incurred by the prevailing party to the arbitration. The arbitration panel shall be authorized to determine which party to the arbitration is the prevailing party and which party is the non-prevailing party.

(e) Any amounts owed to any Purchaser Indemnified Party following the resolution of a Purchaser Claim, as determined by this Section 8.5, shall be satisfied, at the sole discretion of Purchaser, by payment of Seller to Purchaser, from any earned but unpaid portion of the Maximum Milestone Amount.

Section 8.6 **Third Party Actions**. In the event any Action is instituted against an Indemnified Party, which involves a Claim for which indemnification may be sought, the Indemnified Party will, promptly after receipt of notice of any such Action, notify the indemnifying party of the commencement thereof. The failure to so notify the indemnifying party of the commencement of any such Action will relieve the indemnifying party from liability in connection therewith only to the extent that such failure materially and adversely affects the ability of the indemnifying party to defend the interests of the indemnifying party in such Action. Except as set forth on Schedule 8.6 hereto, the Indemnified Party shall have the right to control the defense or settlement of such Action; provided that the indemnifying party and its counsel (at such party s sole expense) may participate in (but not control the conduct of) the defense of such Action, but only to the extent that such participation does no affect any privilege relating to the Indemnified Party. Any settlement by the Indemnified Party of any such Action with third party claimants, or any judgment by any governmental entity with respect to such Action with third party claimants, shall be determinative of the amount of Losses relating to such matter for purposes of this Article VIII.

Section 8.7 **Exclusive Remedy.** If the Technology Closing occurs, except for the rights of Purchaser set forth in Section 9.1(b) hereto, following the Technology Closing the right of the parties hereto to demand and receive indemnification pursuant to this Article VIII shall be the sole and exclusive remedy exercisable by a party with respect to this Agreement or the transactions contemplated hereby except for the right to seek specific performance of any of the agreements contained herein, and except in the case of fraud or intentional misrepresentation.

Section 8.8 **Reliance**. No Indemnified Party shall be required to show reliance on any representation, warranty, certificate or other agreement in order for such Indemnified Party to be entitled to indemnification hereunder.

Section 8.9 **Tax Treatment of Indemnity Payments.** Any payment pursuant to this Article VIII shall be considered an adjustment to the initial Purchase Price for Tax purposes, to the maximum extent permitted by law.

ARTICLE IX.

MISCELLANEOUS

Section 9.1 Disputes.

(a) Any dispute, controversy, difference or claim arising out of, relating to or in connection with this Agreement, any other Transaction Document, any transaction hereunder or thereunder or breach hereof or thereof shall be finally settled by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association (the Rules) then in effect by one (1) arbiter appointed with the consent of both Seller and Purchaser (and in the event such consent cannot be obtained within thirty (30) days following the request by Seller or Purchaser for the consent of the other, in accordance with the Rules). The arbiter s award shall be final and binding, and, in all instances, be subject to the limitations set forth in Article VIII hereof. Judgment upon the award rendered by the arbiter may be entered in any court having jurisdiction thereof. The arbitration shall take place in the Cook County in the State of Illinois, or such other place as the parties may agree. The arbiter s award shall be in writing and shall include (i) a provision that the prevailing party in the arbitration shall recover its costs of the arbitration and reasonable attorneys fees from the other party, and (ii) the amount of such costs and fees.

(b) Notwithstanding subsection (a), (i) either party may, if it believes that it requires or is entitled to injunctive relief, file a civil action in any court having jurisdiction seeking injunctive relief, (ii) Purchaser shall be entitled to specific performance to remedy any breach by Seller of its representations and warranties contained in Section 2.4 (Title and Sufficiency of Transferred Assets) and the covenants contained in Section 4.1 (Further Assurances) and shall be entitled to file a civil action in any court having jurisdiction seeking such relief and (iii) Purchaser shall be entitled to specific performance and shall be entitled to file a civil action in any court having jurisdiction seeking such relief if Seller is in breach of its obligations under Section 4.6 (No Other Bids) hereof or if following the termination of the Manufacturing Agreement, Purchaser has requested that the Manufacturing Closing take place and the

(b) Notwithstanding subsection (a), (i) either party may, if it believes that it requires or is entitled to injunctive

Manufacturing Assets be transferred to Purchaser in accordance with the terms of this Agreement and Seller has not, within ten (10) business days following such request, delivered and transferred the Manufacturing Assets to Purchaser. Any claim to or demand for monetary damages shall, however, be governed exclusively by the provisions for arbitration set forth in subsection (a).

Section 9.2 **Merger Clause.** This Agreement, the other Transaction Documents and the agreements, documents and instruments to be executed and delivered in connection herewith and therewith contain the final, complete and exclusive statement of the agreement between the parties with respect to the transactions contemplated herein and all other prior or contemporaneous oral communications (including, for avoidance of doubt, communications in connection with the preparation of this Agreement and the other Transaction Documents) and agreements, and all prior written communications (including, for avoidance of doubt, written drafts of this Agreement and the other Transaction Documents) and agreements, with respect to the subject matter hereof are merged herein and superseded. For the avoidance of doubt, it is the parties intent that no term contained in or omitted from any prior written draft of this Agreement or the other Transaction Documents be used as extrinsic evidence under any state law or judicial interpretation to determine the intent of the parties hereto.

Section 9.3 **Amendments.** No amendment to, or any waiver with respect to any provision of, this Agreement shall be effective unless in writing and executed, in the case of an amendment by each party to this Agreement or, in the case of a waiver by each party against whom the waiver is to be effective. No course of dealing and no failure or delay on the part of any party hereto in exercising any right, power or remedy conferred by this Agreement shall operate as a waiver thereof or otherwise prejudice such party s rights, powers and remedies. The failure of either party to this Agreement to require the performance of a term or obligation under this Agreement or the waiver by the other party to this Agreement of any breach hereunder shall not prevent subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach hereunder. No single or partial exercise of any right, power or remedy conferred by this Agreement shall preclude any other or further exercise thereof or the exercise of any other right, power or remedy.

Section 9.4 **Notices.** All notices, requests and demands and other communications hereunder must be in writing and shall be deemed to have been duly given (i) if given by telecopy, when such telecopy is transmitted to the telecopy number specified in this Agreement, if written confirmation of receipt thereof is obtained, (ii) on the date of delivery shown on the return receipt (or, if none shown, three (3) days after deposit in the mail) if placed in the United States mails and forwarded by registered or certified mail, return receipt requested, postage prepaid, or (iii) one (1) business day after deposit in the mail, if delivered, prepaid, to an overnight courier. All such communications shall be addressed as follows:

(a) if to Seller:

Osiris Therapeutics, Inc.

7015 Albert Einstein Avenue

Columbia, Maryland 21046

Attention: Chief Executive Officer

Facsimile: (443) 283-4259

with a required copy to:

McKenna Long & Aldridge LLP

303 Peachtree St., NE, Suite 5300

Atlanta, Georgia 30308

Attention: Michael Cochran, Esq.

Facsimile: (404) 527-4198

(b) if to Purchaser:

NuVasive, Inc.

7473 Lusk Boulevard

San Diego, California 92121

Attention: General Counsel

Facsimile: (858) 909-2479

with a required copy (which shall not constitute notice) to:

DLA Piper US LLP

4365 Executive Drive, Suite 1100

San Diego, California 92122

Attention: Michael Kagnoff

Facsimile: (858) 456-3075

Any party may change the address(es) to which notices to it are to be sent by giving notice of such change to the other parties in accordance with this Section.

Section 9.5 **Captions.** The captions are for convenience of reference only and shall not be construed as a part of this Agreement.

Section 9.6 **Governing Law.** This Agreement, including the validity hereof and the rights and obligations of the parties hereunder, shall be construed, interpreted, enforced and governed by and under the laws of the State of Delaware applicable to contracts made and to be performed entirely in such state, without regard to its rules regarding conflicts of law provisions.

Section 9.7 **Schedules and Exhibits.** All the schedules and exhibits referenced in and attached to this Agreement are incorporated herein by reference and shall be deemed to be a part of this Agreement for all purposes. If any provision of this Agreement is so broad as to be unenforceable, such provision shall be interpreted to be only so broad as if enforceable.

Section 9.8 **Severability.** The invalidity, unenforceability or illegality of any one or more phrases, sentences, clauses or provisions of this Agreement shall not affect the validity, enforceability or legality of the remaining portions of this Agreement or any part thereof (so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any party), it being intended that each party s rights and privileges shall be enforceable to the fullest extent permitted by applicable law, and any such invalidity,

unenforceability or illegality in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction (so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any party).

Section 9.9 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall constitute an original but all of which shall constitute one and the same instrument. The parties need not sign the same counterpart.

Section 9.10 **Fees and Expenses.** Except as expressly set forth herein, Seller on the one hand, and Purchaser, on the other hand, shall each bear their own expenses in connection with the negotiation and preparation of this Agreement, all agreements, documents, and instruments contemplated hereby, and the consummation of the transactions contemplated hereby, including, without limitation, the fees and expenses of their respective counsel, accountants, and consultants.

Section 9.11 **Benefits and Binding Effect.** No party may assign or transfer any of their respective rights, benefits or obligations under this Agreement without the consent in writing of the other party hereto; provided, however, that any party may assign its rights, benefits and obligations hereunder in whole or in part to any successor or successors to (i) in the case of Purchaser, all or part of the Transferred Assets or its business in the event of a reorganization, merger or consolidation, sale or other transfer of a substantial portion of its assets or (ii) in the case of Seller, all of its business in the event of a reorganization, merger or consolidation (each of the events in (i) and (ii), a Corporate Event); provided that any acquiror or successor of Purchaser or Seller, as applicable, in connection with a Corporate Event shall, in the consenting parties reasonable discretion, be at least as creditworthy as the assigning party; provided further, however, that Seller may not assign or transfer any of its rights, benefits or obligations under this Agreement in connection with a Corporate Event prior to the Manufacturing Closing Date to any person identified on Schedule 9.11. Notwithstanding the foregoing, no assignment shall relieve the assigning party of responsibility for the performance of its obligations hereunder.

Section 9.12 **No Third Party Beneficiary.** The parties hereto do not intend to create any third party beneficiary rights or remedies with respect to any person, including without limitation any employees or former employees of Seller or other person or entity who is providing, or has provided services to Seller as a result of the provisions in this Agreement, and specifically hereby negate any such intention or construction.

Section 9.13 **Definitions; Interpretation.** For purposes of this Agreement, (a) the terms defined in this Agreement and in this Section 9.13 shall have the meanings assigned to them in this Agreement and this Section 9.13 and include the plural as well as the singular, (b) all accounting terms not otherwise defined herein have the meanings assigned under GAAP, (c) all references in this Agreement to designated Section or other subdivisions are to be designated Sections and other subdivisions of the body of this Agreement, (d) pronouns of either gender or neutral shall include, as appropriate, the other pronoun forms, and (e) the words herein, hereof and hereunder and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. Each of the parties has participated in the drafting and negotiation of this Agreement. If an ambiguity or question of intent or interpretation arises, this Agreement must be construed as if it is drafted by both parties, and no

presumption or burden of proof shall arise favoring or disfavoring any party by virtue of authorship of any of the provisions of this Agreement.

As used in this Agreement and the exhibits and schedules delivered pursuant to this Agreement, the following definitions will apply:

Action means any action, suit, claim, charge, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), controversy, assessment, arbitration, investigation, hearing, complaint, demand or other proceeding to, from, by or before any arbitrator, court, tribunal or other governmental entity.

Additional Product Delivery Payment means the *product of* (i) (A) the Excess Delivery Amount *divided by* (B) 58,300, rounded down to the nearest whole number *multiplied by* (ii) Two Million, Five Hundred Thousand Dollars ($2,500,000); provided, however, that in no event shall the Additional Product Delivery Payment exceed Seven Million, Five Hundred Thousand Dollars ($7,500,000).

Allowable Work in Process means the maximum total amount of Work in Process and Finished Inventory existing on the Manufacturing Closing Date which is reasonably necessary to support the sales forecasts provided by Purchaser to Seller.

Asset Acquisition Proposal means any proposal, inquiry or offer from any person (other than Purchaser) concerning the acquisition or license of all or any portion of the Transferred Assets.

Business Intellectual Property means any and all intellectual property and other intangible rights and property used in, held for use in, intended for use in, related to or necessary for the operation of the Business as presently conducted, including any or all of the following, and all rights in, arising out of, or associated therewith, including, but not limited to, all such rights used in the operation of the Business: (i) any and all Patent Rights; (ii) all inventions (whether patentable or not), invention disclosures, discoveries, improvements, trade secrets, proprietary information, technology, technical information, data (including data from scientific and clinical and pre-clinical studies and other research), customer, physician and supplier lists, procedures, processes, specifications, methods, techniques, ideas, results, marketing studies, plans and proposals, market research and all other information and know-how, whether or not patentable or protected as a trade secret, and all documentation relating to any of the foregoing; (iii) all trademarks, service marks, trade names, domain names, and registrations and applications relating to any of the foregoing, all logos, designs, brand names, trade dress and slogans, and all other rights corresponding thereto throughout the world (Trademark Rights); (iv) all copyrights, copyrights registrations and applications therefor, works of authorship and derivative works (including advertising, marketing and promotional materials, artwork, labels and other works of authorship) mask works, moral rights, and all other rights corresponding thereto throughout the world; (Copyright Rights) (v) all industrial designs and any registrations and applications therefor throughout the world; (vi) all software, including but not limited to source code, object, executable or binary code, templates, manuals and other items and documentation related thereto or associated therewith; (vii) all databases and data collections and all rights therein throughout the world; (viii) all Actions and rights to sue at law or in equity for any,

present or future infringement or other impairment thereto, including the right to receive all proceeds and damages therefrom, and all rights to obtain renewals, continuations, divisions or other extensions of legal protections pertaining thereto; and (ix) any similar or equivalent rights to any of the foregoing anywhere in the world, together with the goodwill and the business appurtenant thereto and any rights, claims or choses in action relating to or deriving from any of the foregoing.

Business Material Adverse Effect means any event, circumstance, development with respect to, change in or effect on the Business or the Transferred Assets that is, or would reasonably be expected to have, a material adverse effect on the business, assets, liabilities, financial condition or results of operations of the Business, taken as whole; provided, however, that any event, circumstance, development, change or effect arising out of or relating to the following shall not be taken into account in determining whether a Business Material Adverse Effect shall have occurred: (i) changes in general economic conditions which do not have a disproportionate impact on the Business, (ii) changes affecting generally the industry in which the Seller conducts the Business which do not have a disproportionate impact on the Business, (iii) the public announcement by Purchaser and Seller of the execution of this Agreement, (iv) any action taken or omitted to be taken by Seller pursuant to the express terms of this Agreement, (v) any change resulting solely from an action taken by Purchaser or its affiliates without the prior written consent of Seller, and (vi) any action taken at, and in accordance with, the written request of Purchaser.

Claims means, as the context dictates, any Purchaser Claim or Seller Claim.

Contract means any written or oral legally binding contract, agreement, instrument, commitment or undertaking of any nature (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts, letters of intent and purchase orders).

Code means the Internal Revenue Code of 1986, as amended, or as hereafter amended.

Excess Delivery Amount means the positive number, if any, by which the total number of cubic centimeters of Product that Seller shall have delivered to Purchaser prior to the Manufacturing Closing in accordance with the terms and provisions of, and subject to the specifications set forth in, the Manufacturing Agreement, exceeds the Second Delivery Threshold.

Finished Inventory means all finished goods inventory of Product.

GAAP means United States generally accepted accounting principals and practices in effect from time to time applied consistently throughout the periods involved.

Indemnified Party means, as the context dictates, any Purchaser Indemnified Party or Seller Indemnified Party.

Knowledge means, with respect to Seller, the actual knowledge of the individuals listed on Schedule 9.14 hereto or the knowledge that any such individual could obtain by reasonable inquiry.

Losses shall mean the amount of any loss, claim, Tax, demand, loss, deficiency, damage, liability, judgment, fine, penalty, fee, cost or expense (including, without limitation, reasonable attorneys , consultants and experts fees and expenses) incurred, paid, accrued or sustained by the Purchaser Indemnified Parties, including, without limitation, any costs of defending any Actions or enforcing the Purchaser Indemnified Party s rights under this Agreement. In determining the amount of any Loss (but, for avoidance of doubt, not in determining whether a breach of representation, warranty or covenant exists), any qualifications in the representations, warranties and covenants with respect to a Business Material Adverse Effect, materiality, material or similar terms shall be disregarded and will not have any effect with respect to the calculation of the amount of any Losses attributable to a breach of any representation, warranty or covenant of the Seller set forth in the Transaction Documents, and the exhibits, schedules or certificates delivered in connection therewith.

Net Sales means (i) the gross amount invoiced by Purchaser and its affiliates for Product sold in bona fide arms-length transactions to any non-affiliated third party customer or distributor and (ii) the gross royalties and license fees payable to Purchaser by licensees, sublicensees and distributors for Product sold in bona fide, arms-length transactions, in each case, less the following offsets and deductions: (a) quantity and/or cash discounts from the gross invoice price which are actually allowed and taken; (b) freight, postage and insurance included in the invoice price; (c) amounts repaid or credited by reasons of rejections or return of goods or because of retroactive price reductions specifically identifiable to such Product; (d) amounts payable resulting from government (or agency thereof) mandated rebate programs; (e) third party rebates or charge-backs to the extent actually allowed; and (f) invoiced customs duties and sales Taxes (excluding income, value-added and similar Taxes), if any, all as determined in accordance with GAAP. Where there is an initial disposal by Purchaser or any of its affiliates to Purchaser or any of its affiliates, as applicable, and a subsequent sale to a person or entity other than the Purchaser or its affiliates, the Net Sales shall be calculated by reference to the invoiced ex-work pertaining to the first sale or other disposal to a person or entity other than Purchaser or its affiliates.

Patent Rights means any and all (A) patents, (B) patent applications, including, without limitation, all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon, (C) all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation, supplementary protection certificates or the equivalent thereof, and (D) any other form of government-issued right substantially equivalent to any of the foregoing used in, necessary for or related to the Business.

Purchaser Common Stock Value means the average closing sales price of one share of Purchaser Common Stock on the principal exchange on which the Purchaser Common Stock is traded over the ten-day trading period ending on the second trading day preceding the date of issuance of such Purchaser Common Stock to the Seller.

Superior Proposal shall mean an unsolicited bona fide Asset Acquisition Proposal by a third party to enter into a sale, lease, exchange transfer, license, acquisition or disposition of all of the Business and the Transferred Assets in a single transaction or a series of related transactions that (a) was not obtained or made as a direct or indirect result of a failure to comply

with or breach of (or in violation of) the Agreement; and (b) is on terms and conditions that the Board of Directors of Seller determines, in its reasonable, good faith judgment, after obtaining and taking into account such matters that it deems relevant (taking into account all financial, regulatory, legal and other aspects thereof) following consultation with its outside legal counsel and regionally-recognized financial advisor: (x) is more favorable, from a financial point of view, to Seller s stockholders than the terms of this Agreement (taking into account any offer by the Purchaser to amend the terms of this Agreement,); and (y) is reasonably capable of being consummated on the terms proposed and on a timely basis (taking into account all financial, regulatory, legal and other aspects thereof); *provided*, *however*, that any such Asset Acquisition Proposal shall not be deemed to be a Superior Proposal if any financing required to consummate the transaction contemplated by such Asset Acquisition Proposal is not firmly committed and reasonably capable of being obtained by such third party, or if the consummation of such transaction is contingent on any such financing being obtained.

Taxes means (A) any and all foreign, and U.S. federal, state, local or other Taxes of any kind (together with any and all interest, penalties, additions to Tax and additional amounts imposed with respect thereto) imposed by any governmental entity, including Taxes on or with respect to income, franchises, windfall or other profits, gross receipts, property, sales, use, capital stock, payroll, employment, unemployment, social security, workers compensation or net worth, and Taxes in the nature of excise, withholding, ad valorem or value added; (B) any liability for the payment of any amounts of the type described in clause (A) as a result of being or ceasing to be a member of an affiliated, consolidated, combined or unitary group for any period; and (C) any liability for the payment of any amounts of the type described in clause (A) or (B) as a result of any express or implied obligation to indemnify any other Person or as a result of any obligations under any agreements or arrangements with any other Person with respect to such amounts and including any liability for Taxes of a predecessor or a transferor or otherwise by operation of law.

Tax Return means any return, report or similar filing (including the attached schedules) required to be filed with respect to Taxes, including any information return, claim for refund, amended return or declaration of estimated Taxes.

Technology Assets means all Transferred Assets other than the Manufacturing Assets.

WIP Value shall mean the positive or negative number equal to (i) with respect to Allowable Work in Process held by Seller as of the Manufacturing Closing Date that but for receipt of the documentation necessary for the Allowable Work in Process to constitute Finished Product, the product of (x) the aggregate cubic centimeters of such Allowable Work in Process, times (y) the then current Product Fee under the Manufacturing Agreement times (z) 0.7 *minus* (ii) the product of 17,500 times then current Product Fee under the Manufacturing Agreement.

Index of Other Defined Terms:

Defined Terms	Section Reference
510(k)	Section 2.18(d)
Affirmative Response Notice	Section 4.12(b)
Agreement	Preamble
Antitrust Laws	Section 4.15(b)
Applicable Milestone Payment	Section 1.5(a)
Assumed Contracts	Section 1.1(a)(x)
Assumed Liabilities	Section 1.2(a)
Audited Financial Statements	Section 4.3(c)
Balance Sheet	Section 2.7
Balance Sheet Date	Section 2.7
Basket Amount	Section 8.4(a)
Bill of Sale Manufacturing Assets	Section 6.1(g)
Bill of Sale Technology Assets	Section 5.2(g)
Business	Recital A
Change in Seller Board Recommendation	Section 4.20(c)
COBRA	Section 2.14
Competitive Business	Section 4.9(a)
Confidential Information	Section 4.5
Contested Claim	Section 8.5(c)
Corporate Event	Section 9.11
DGCL	Section 4.6(a)
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ERISA	Section 2.13(a)
Excluded Assets	Section 1.1(b)
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Fifth Milestone Payment	Section 1.5(a)(v)
Financial Information	Section 2.7
First Delivery Threshold	Section 1.5(a)(i)
First Milestone Payment	Section 1.5(a)(i)
Fourth Milestone Payment	Section 1.5(a)(iv)
General Cap Amount	Section 8.4(a)
Hazardous Material	Section 2.20(a)
HSR	Section 4.15(a)
Independent Contractors	Section 2.12(b)
Initial Purchaser Price	Section 1.4
Intellectual Property Rights	Section 4.7(a)
IP Assignment Agreement Patents	Section 5.2(h)
IP Assignment Agreement Trademark	Section 5.2(h)
JPA Opinions	Section 2.15(o)
License Agreement	Section 5.2(j)
Licensed Technology	Section 2.15(c)
Liens	Section 2.4
Manufacturing Agreement	Section 5.2(i)
Manufacturing Assets	Section 1.1(a)
Manufacturing Asset Transfer	Section 1.1(c)
Manufacturing Closing	Section 1.3
Manufacturing Closing Date	Section 1.3
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Milestone Assessment Notice	Section 1.5(b)(ii)

Milestone Dispute Notice	Section 1.5(b)(iii)
Milestone Expiration Date	Section 1.5(a)
Negotiation Notice	Section 4.12(b)
Net Sales Threshold	Section 1.5(b)(vi)
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Notice of Claim	Section 8.5
Notice of Superior Proposal	Section 4.6(a)
Osteocel XC	Section 4.12(a)
Osteocel XC Transaction	Section 4.12(b)
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Product Development	Section 1.1(a)(iv)
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Purchaser	Preamble
Purchaser Claim	Section 8.1
Purchaser Common Stock	Section 1.5(a)
Purchaser Indemnified Parties	Section 8.1
Purchaser Notice of Claim	Section 8.1
Purchaser Organizational Documents	Section 3.2(a)
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Restricted Period	Section 4.9(a)
Retained Liabilities	Section 1.2(b)
Rights of Set-Off	Section 1.5(c)
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SEC	Section 4.20(a)
Second Delivery Threshold	Section 1.5(a)(ii)
Second Milestone Payment	Section 1.5(a)(ii)
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Seller	Preamble
Seller Benefit Plan	Section 2.13(a)
Seller Board Recommendation	Section 4.20(b)
Seller Claim	Section 8.2
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Seller Indemnified Parties	Section 8.2
Seller Notice of Claim	Section 8.2
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Technology Closing Date	Section 1.3
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Transferred Assets	Section 1.1
Transferred Employee	Section 4.11(b)
Transferred Technology	Section 1.1(a)(i)
Work in Process	Section 1.1(a)(ii)

[Signature Page to Follow]

IN WITNESS WHEREOF, Seller and Purchaser have each caused this Agreement to be executed by their respective duly authorized officers, all as of the date first above written.

SELLER:

OSIRIS THERAPEUTICS, INC.

By:	C. RANDAL MILLS
Name:	C. Randal Mills
Title:	President & CEO

PURCHASER:

NUVASIVE, INC.

By:	ALEXIS V. LUKIANOV
Name:	Alexis V. Lukianov
Title:	CEO and Chairman of the Board

Appendix B

[FORM OF]

MANUFACTURING AGREEMENT

THIS MANUFACTURING AGREEMENT (the Agreement) is made and entered into as of , 2008 (the Effective Date), by and between Osiris Therapeutics, Inc. (Osiris), a Delaware corporation, and NuVasive, Inc. (NuVasive), a Delaware corporation.

RECITALS

WHEREAS, Osiris and NuVasive are parties to that certain Asset Purchase Agreement, dated , 2008 (the Asset Purchase Agreement), pursuant to which Osiris sold, and NuVasive purchased, technology related to manufacturing the Osteocel product line (as more specifically set forth therein); and

WHEREAS, NuVasive and Osiris desire to herein set forth an arrangement whereby Osiris shall manufacture and deliver to NuVasive, and NuVasive shall purchase, the Product (as defined below).

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1

DEFINED TERMS

As used herein, certain capitalized terms shall have the meanings ascribed to them as provided below:

1.1. AATB means the American Association of Tissue Banks.

1.2. Action shall have the meaning as such term is defined in Section 6.3 of this Agreement.

1.3. Affiliate means, with respect to a party, any person or entity which, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such party.

1.4. Certificate of Analysis means, for each Lot produced, a document prepared by Osiris setting forth the measured and observable characteristics of Product from the Lot, confirming that such Lot meets the Specifications, certifying that such Lot was manufactured and released in accordance with applicable Laws and cGTP.

1.5. cGTP means current Good Tissue Practice as defined in FDA rules and regulations, including the United States regulations set forth at 21 CFR Parts 1270 and 1271, subparts C and D, as in effect and as may be amended or replaced by the FDA from time to time.

1.6. Confidential Information means information which is disclosed by a party (the Disclosing Party) to the other party (the Receiving Party) in whatever media, and is marked, identified or otherwise acknowledged to be confidential at the time of disclosure; provided that information shall not be deemed Confidential Information which is (a) publicly known, through no fault of the Receiving Party, (b) received by the Receiving Party from a source having the right to

disclose such information, (c) known by the Receiving Party prior to disclosure of such information, or (d) independently developed by the Receiving Party without use of the Disclosing Party s information. Notwithstanding the foregoing and for the avoidance of doubt, the Confidential Information of NuVasive includes all Licensed Technology, whether or not marked, identified or otherwise acknowledged to be confidential and whether or not known or developed by Osiris, and the use and disclosure of Licensed Technology by Osiris (as the Receiving Party hereunder) shall be subject to Section 8.3.

1.7. CPI shall mean the Price Index for all Urban Consumers, U.S. city average, all items, for the then immediately preceding 12-month period as published by the US Government.

1.8. Damages shall have the meaning as such term is defined in Section 6.1 of this Agreement.

1.9. Deliver or Delivery with respect to Product means, and shall take place upon, the transfer of possession of Product to a carrier, FCA the Facility (Incoterms 2000).

1.10. Donor means a human tissue donor.

1.11. Donor Tissue means human musculoskeletal tissue, including bone and connective tissue.

1.12. Excess Quantities shall have the meaning as such term is defined in Section 3.3 of this Agreement.

1.13. Executives shall have the meaning as such term is defined in Section 9.8 of this Agreement.

1.14. Facility means the facility at which Osiris or its subcontractors set forth on Schedule 3.11, or otherwise approved by NuVasive in accordance with Section 3.11, will Process Product under this Agreement.

1.6. Confidential Information means information which is disclosed by a party (the Disclosing Party) to th

1.15. FDA means the U.S. Food and Drug Administration, and any successor or replacement agency thereto.

1.16. Inventions shall have the meaning as such term is defined in Section 8.2 of this Agreement.

1.17. Latent Defect means any defect in any Lot or other shipment of Product that could not reasonably be found by the exercise of ordinary care in an initial physical inspection by NuVasive, such as, but not limited to, the presence of a contaminant or Osiris failure to Process Product in accordance with cGTP.

1.18. Laws means all laws, rules, regulations, ordinances, standards and guidelines that apply to the Processing of Product or the performance of either party s obligations under this Agreement, as the context requires under this Agreement, including, without limitation, the Public Health Service Act, 42 U.S.C. §201 *et seq*., the United States National Organ Transplant Act, Title 21 of the Code of Federal Regulations Parts 1270 and 1271, Human Cells, Tissues, and Cellular and Tissue Based Products, other rules, regulations or standards promulgated by the FDA or any other applicable governmental agency, and of the AATB, as each may be amended from time to time.

1.15. FDA means the U.S. Food and Drug Administration, and any successor or replacement agency thereto

1.19. Licensed Technology means the intellectual property (including patents and patents pending of NuVasive), methods, technology, and know-how owned or licensed by NuVasive and used in, held for use in, intended for use in, related to or necessary for Processing the Product. Licensed Technology shall include all Transferred Technology as defined in and purchased by NuVasive under the Asset Purchase Agreement.

1.20. Lot means the Product, Processed in accordance with the Specifications, resulting from a single production run, traceable to a single source Donor.

1.21. Lot Records means manufacturing, packaging and test records, donor suitability determination documentation, cleaning, labeling and sterilization processes documentation and documentation relating to Processing and release of each Lot, including exception documentation, deviations/discrepancies, raw data or data worksheets and additional documentation generated and/or processed as part of the production record of the related Lot.

1.22. Minimum Performance Level shall have the meaning as such term is defined in Section 3.3 of this Agreement.

1.23. NuVasive Indemnitee shall have the meaning as such term is defined in Section 6.1 of this Agreement.

1.24. NuVasive Responsible Party shall have the meaning as such term is defined in Section 6.2 of this Agreement.

1.25. Order shall have the meaning as such term is defined in Section 3.2 of this Agreement.

1.26. Osiris Indemnitee shall have the meaning as such term is defined in Section 6.2 of this Agreement.

1.18. Laws means all laws, rules, regulations, ordinances, standards and guidelines that apply to the Proces

1.27. Osiris Product Warranty shall have the meaning as such term is defined in Section 3.7 of this Agreement.

1.28. Osiris Responsible Party shall have the meaning as such term is defined in Section 6.1 of this Agreement.

1.29. Parties shall mean Osiris and NuVasive; Party shall mean Osiris or NuVasive,

1.30. Process or Processing shall mean any or all of the acts of manufacturing (including procuring materials, Donor Tissue and Donors suitability for determination, for manufacturing), handling, storing, analyzing, testing, packaging, labeling and preparing for shipment Product by Osiris pursuant to this Agreement.

1.31. Product means osteobiologic allograft material containing cancellous bone (which contains viable mesenchymal stem cells) Processed by Osiris using the Licensed Technology and meeting the Specifications attached hereto as Exhibit A, and which has passed all required inspections and testing and has been released for distribution for human implantation.

1.32. Product Fees shall have the meaning as such term is defined in Section 4.1.

1.33. Product-Related Inspection shall have the meaning as such term is defined in Section 5.1 of this Agreement.

1.34. Product Withdrawal shall have the meaning as such term is defined in Section 5.7 of this Agreement.

1.35. Publication shall have the meaning as such term is defined in Section 8.4 of this Agreement.

1.36. Specifications means the Product specifications set forth in Exhibit A attached hereto, as the same may be amended in accordance with this Agreement.

1.37. Term shall have the meaning as such term is defined in Section 7.1 of this Agreement.

ARTICLE 2

PROCUREMENT AND SUPPLY OF DONORS

Donor Procurement Obligations. Osiris shall use its commercially reasonable best efforts to procure Donor Tissue as necessary to meet the Minimum Performance Levels and to Process Product in accordance with the terms of this Agreement.

ARTICLE 3

MANUFACTURING OF PRODUCT; TECHNOLOGY LICENSE

3.1. Manufacturing Obligations. Osiris shall Process for and supply to NuVasive Product in accordance with the terms of this Agreement. Osiris shall Process and supply the Product to NuVasive hereunder in conformity with the Specifications and in compliance with cGTP and all applicable Laws. If either party seeks a change to the Specifications or there is a change in applicable Laws that would necessitate a change in the Specifications, the parties will meet and confer in good faith to determine whether and what changes (if any) should be made thereto. Any and all amendments or modifications in the Specifications must be agreed upon in writing by both parties.

3.2. Forecasting and Orders. On or before sixty (60) days prior to each calendar quarter, NuVasive shall provide to Osiris a binding order (Order) for the quantity and size of Product to be delivered by Osiris to NuVasive in the following calendar quarter. Each Order shall be in writing, and shall specify the quantity of units of Product by size, the brand name of each unit of Product ordered, the requested Delivery date(s), the destination shipping address(es), and the Product Fees therefor. Osiris shall be required to supply to NuVasive all such quantities of Product as NuVasive orders pursuant to such Orders in accordance with the Product unit sizes and brand names specified in such Orders and shall use its commercially reasonable best efforts to conform to the requested Delivery date(s) set forth in such Orders, provided in each case such Orders do not exceed the Minimum Performance Levels during the applicable periods set forth in Section 3.3 below. Osiris shall deliver the Product to NuVasive pursuant to the Orders, subject to available Product being released for transplantation; provided, that the Parties understand and agree the final Delivery dates for Orders may vary from the requested dates based upon Donor Tissue procurement.

3.1. Manufacturing Obligations. Osiris shall Process for and supply to NuVasive Product in accordance with t

3.3. Performance Levels.

3.3.1. Minimum Performance Levels. Osiris shall use its commercially reasonable best efforts to Deliver Product to NuVasive at least in the quantities set forth below during the applicable periods (Minimum Performance Levels) and shall Deliver any such Product according to Product unit size and brand name specifications established by NuVasive and set forth in each Order. NuVasive shall provide Orders to purchase from Osiris Product in quantities of at least the Minimum Performance Level for the applicable period.

Applicable Period	Minimum Performance Level Delivered (cc)
Effective Date to April 15, 2009	125,000
April 16, 2009 to eighteen (18) months following the Technology Closing Date (as defined in the Asset Purchase Agreement)	125,000

3.3.2. Additional Product. Osiris shall have the right, in its discretion, to Process and Deliver Product hereunder in quantities that exceed NuVasive s Orders (the Excess Quantities), provided that Osiris gives advance written notice to NuVasive of its intent to Process and Deliver the Excess Quantities. Following receipt of such written notice, the Parties shall discuss and attempt in good faith to reach agreement on the unit sizes of the Excess Quantities. If the parties are unable to reach agreement on the unit sizes of any Excess Quantities within ten (10) days from the notice, Osiris shall Process and Deliver to NuVasive unit sizes of such Excess Quantities in the same proportion as the unit sizes of Product set forth in NuVasive s most recent Order. Subject to the notice and sizing provisions immediately above, in addition to NuVasive s requirement to purchase from Osiris Product in quantities of at least the Minimum Performance Level (provided that Osiris and/or its subcontractors Processes at least such quantities) for the applicable period, NuVasive shall purchase from Osiris the Excess Quantities that Osiris Processes in accordance with this Agreement during the Term; provided, however, that NuVasive shall have no obligation hereunder to purchase Product in quantities greater than cubic centimeters, and the Delivery and purchase of such greater quantities of Product, if any, shall be by mutual written agreement of both parties. For all Product Processed hereunder, Osiris shall provide NuVasive with a monthly forecast of projected Product manufacturing quantities for such month.

3.4. Shipment and Delivery. All Product shall be shipped to NuVasive or NuVasive s customers as directed by NuVasive using a shipping company designated by NuVasive. Osiris shall tender Product for Delivery, FCA the Facility, in accordance with the Specifications and addressed to the shipping address specified by NuVasive in the Orders or to such other address as NuVasive may provide to Osiris in writing in advance of any Delivery. NuVasive shall provide Osiris with standard shipping instructions prior to the first requested shipping date hereunder; thereafter, such shipping instructions may be changed upon written notice given to Osiris by NuVasive. Osiris shall not Deliver any Product prior to completion of quality control and release testing by Osiris. NuVasive shall be

3.2. Forecasting and Orders. On or before sixty (60) days prior to each calendar quarter, NuVasive shall prov

responsible for all shipping and insurance charges and risk of loss associated with the shipment of Product hereunder (from and after Delivery), provided that Osiris has complied with the shipping instructions of NuVasive and that the Product is tendered for Delivery in accordance

3.4. Shipment and Delivery. All Product shall be shipped to NuVasive or NuVasive s customers as directed b

with the Specifications. Title to Product shall pass to NuVasive upon Delivery of Product to the carrier selected by NuVasive.

3.5. Quality Control; Release Testing; Documentation. Osiris shall be responsible for quality control tests to ensure that each Lot conforms to the Specifications and is produced in accordance with applicable Laws and cGTP, and Osiris shall be responsible for all release testing. All quality control test results and release testing and other documents related to quality control and quality assurance and copies thereof shall be made available to NuVasive at Osiris s offices upon written request of NuVasive. Such information is considered NuVasive s Confidential Information in accordance with this Agreement and shall be transferred to NuVasive upon the termination of this Agreement. Any testing performed by or on behalf of Osiris (including tests to confirm that each Lot meets the Specifications) shall be performed at Osiris s sole cost and expense and may be used by NuVasive for final release of each Lot without additional testing by NuVasive; provided, however, that NuVasive may conduct its own release testing of each Lot in its discretion. NuVasive (in its sole discretion) shall determine the form and substance of any release testing information that is submitted to any regulatory authority. At the time of Delivery of each Lot, Osiris shall send to NuVasive a signed Certificate of Analysis with respect to such Lot. Within thirty (30) days following the Delivery of each Lot, Osiris shall provide NuVasive with properly completed copies of Lot Records for such Lot prepared in accordance with the Specifications and applicable Laws.

3.6. Rejection and Cure. Upon receipt of each shipment of Product, NuVasive or its customers shall perform an initial physical inspection of such Product and review any related documentation. If any Product (including without limitation any documentation related thereto) fails, in whole or in part, to conform to the applicable Specifications and the terms hereof, or if any Product is not Processed in accordance with cGTP or applicable Laws, then NuVasive shall have the right to reject such nonconforming Product. NuVasive shall give written notice to Osiris of its rejection hereunder as soon as possible, but no more than thirty (30) days after NuVasive s or its customer s receipt of such shipment, specifying the grounds for such rejection. If at any time thereafter NuVasive discovers a Latent Defect, NuVasive shall give written notice to Osiris of its rejection hereunder as soon as possible, but no more than ninety (90) days after NuVasive s receipt of the Product, specifying the grounds for such rejection. The nonconforming Product shall be held for Osiris s disposition, or shall be returned to Osiris, in each case at Osiris s expense, as directed by Osiris. Osiris shall use commercially reasonable best efforts to correct the root cause of the nonconformance in order to

comply with the requirements of the applicable Specification. In addition, Osiris shall, at its expense, promptly replace each nonconforming Product with conforming Product.

3.7. Warranty. With respect to Product supplied hereunder, Osiris warrants (Osiris Product Warranty) that the (a) Product shall conform with the applicable Specifications therefor, shall be free from defects in materials or workmanship, and shall not be adulterated, misbranded, contaminated, tampered with or otherwise altered or mishandled while in the custody and control of Osiris; and (b) Product shall be Processed in accordance with the applicable Specifications, and in compliance with cGTP and all applicable Laws. Osiris hereby represents, warrants and covenants that it will not, and has not, employed or otherwise used in any capacity the services of any person debarred under Section 21 U.S.C. 335a in performing any portion of the Processing of Product. EXCEPT AS PROVIDED HEREIN, OSIRIS MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

3.6. Rejection and Cure. Upon receipt of each shipment of Product, NuVasive or its customers shall perform a

3.8. Packaging; Labeling; Marketing. Osiris shall package and label the Product according to the Specifications and in compliance with cGTP and all applicable Laws, rules, regulations, and/or standards. Product supplied to NuVasive shall be labeled as determined by NuVasive, provided that NuVasive shall provide Osiris with at least thirty (30) days prior written notice of any labeling changes (including, but not limited to, brand names), and Osiris shall be entitled to recover, and NuVasive shall be responsible to pay to Osiris, all reasonable out of pocket costs that Osiris incurs associated with such labeling change. Each unit of Product shall have a unique identification number.

3.9. Regulatory Approvals. Product is currently regulated under 21 CFR parts 1270 and 1271 as a human cellular and tissue based tissue product. NuVasive shall obtain at its expense all regulatory approval by the FDA or other regulatory authority necessary or required for the distribution, sale and marketing of Product under current Laws as of the Effective Date. At NuVasive s request during the Term, Osiris will assist NuVasive in preparing the portions of NuVasive s regulatory filings that pertain to Processing and will make appropriate Osiris personnel reasonably available for meetings with regulatory authorities relating to Processing, provided that all such regulatory filings shall be the sole and exclusive property of NuVasive and NuVasive shall have sole authority and responsibility with respect to contacts and communications with regulatory authorities relating to the Product. In the event of changes in applicable Laws, or significant regulatory differences in foreign countries where NuVasive distributes Product, the Parties shall cooperate to determine what actions, if any, are required to meet any new or foreign regulations and shall negotiate in good faith changes to this Agreement including but not limited to, changes to Orders, Product Fees and Minimum Performance Levels to reflect any change in Product manufacturing costs. No change in Product-specific manufacturing processes, test methods, or other procedures or documentation relating to Processing shall be implemented by Osiris unless and until the parties have agreed in writing to such change.

3.10. Technology License. NuVasive hereby grants to Osiris during the Term, for the sole purpose of performing its duties and fulfilling its obligations under this Article 3, a non-exclusive and non-transferable license, without a right to sublicense, to use the Licensed Technology solely to the extent necessary to Process the Product under the terms and conditions of this Agreement. Notwithstanding the foregoing, NuVasive hereby consents to the sublicense by Osiris of the Licensed Technology to the Persons listed on Schedule 3.11 solely to the extent necessary for such subcontractor to provide processing services to Osiris, provided that the terms of any such sublicense arrangement shall either be pursuant to (i) the terms of those Contracts between Seller and such Persons which are identified on Schedule 3.11 hereto as such Contracts are in effect on the date hereof or (ii) require the prior written consent of NuVasive, which consent shall not be unreasonably withheld.

3.11. Subcontracting. Except as provided on Schedule 3.11, Osiris shall not assign, subcontract, or delegate any of its responsibilities under this Agreement without the prior written consent of NuVasive, which consent may be granted or withheld in NuVasive s sole discretion. Such subcontractors shall be subject to confidentiality obligations at least as stringent, when taken as a whole, as provided in this Agreement. No subcontractor may further subcontract any responsibilities under this Agreement without the prior written consent of NuVasive, which consent may be granted or withheld in NuVasive s sole discretion. Any approved subcontractor shall be subject to all of the terms and conditions applicable to Osiris under this Agreement. Osiris shall be responsible, and shall remain liable, for the performance of all of its obligations under this Agreement and for any breach by any subcontractor thereof. NuVasive shall have the right to audit

3.7. Warranty. With respect to Product supplied hereunder, Osiris warrants (Osiris Product Warranty) that

and inspect all subcontractors with whom Osiris may enter into agreements in the performance of its responsibilities under this Agreement. Such audit and inspection rights shall be substantially similar to the rights of NuVasive to audit and inspect Osiris under this Agreement.

ARTICLE 4
FEES

4.1. Product Fees. NuVasive shall pay to Osiris $ per cubic centimeter of Product (Product Fees) Delivered to NuVasive and that is not timely rejected by NuVasive pursuant to Section 3.6 above. All payments due hereunder shall be made in U.S. dollars, without set-off or counterclaim. For the avoidance of doubt, NuVasive shall be responsible for paying to Osiris the Product Fee for all conforming Product that is Delivered to NuVasive as a replacement of Product rejected in accordance with Section 3.6 to the extent that payment for such Product was not previously made.

4.2. Adjustments to Product Fees. The Product Fees shall be escalated on January 1, 2009 by the then current increase in CPI. Adjustments to Product Fees shall be effective January 1st and shall apply to all shipments of Product made on or after January 1st.

4.3. Billing. NuVasive shall pay to Osiris the Product Fees within thirty (30) days of Delivery of the conforming Product. In the event NuVasive fails to pay in accordance with this Section 4.3, Osiris may, in addition to any other remedies available to it, assess interest at a rate of one and one-half percent (1.5%) per month on all unpaid amounts.

4.4. Taxes. All payments required under this Agreement are exclusive of any applicable federal, state and local taxes. Each of the Parties shall be responsible for the payment of taxes and other assessments for which it is liable under Laws.

ARTICLE 5

ADDITIONAL OBLIGATIONS

5.1. Inspections. Upon reasonable prior written notice, NuVasive may, at its expense, audit Osiris during normal business hours for quality control and assurance, compliance with Laws, cGTP, and other applicable regulations or standards, and the terms hereof, and otherwise inspect facilities and records, each as related to the Processing of Product hereunder; provided, however, that such audits and inspections may be conducted no more than twice during the Term hereof, other than for cause audits, which NuVasive shall be entitled to conduct as necessary to address specific quality problems relating to Product, as well as in preparation for regulatory filings and in response to regulatory authority requirements. Any corrective action mutually agreed upon by the parties in response to NuVasive s audit or inspection shall be implemented by Osiris, at Osiris expense, prior to filling new or outstanding Orders. Osiris hereby agrees to advise NuVasive promptly (and, in any event, within thirty-six (36) hours) of any proposed or unannounced visit or inspection by any agent of a regulatory authority to the Facility where such visit or inspection is specifically related to the Product or its Processing (a Product-Related Inspection). Osiris agrees to permit, to the extent reasonably practical, one or more qualified representative(s) of NuVasive to be present during a Product-Related Inspection if requested by NuVasive. If NuVasive is not present during a Product-Related Inspection, Osiris shall promptly provide a summary report of the results of the Product-Related inspection to NuVasive. Osiris shall promptly notify NuVasive of the results of any inspection, comments, responses or notices received from the FDA, AATB, or other applicable regulatory authorities, which relate to the Processing of Product hereunder. With respect to the

5.1. Inspections. Upon reasonable prior written notice, NuVasive may, at its expense, audit Osiris during norm

forgoing, each Party shall provide the other Party at such other Party s request with copies of any notices or correspondence from or to such regulatory authorities that directly relate to Product. Such notices and correspondence are considered Confidential Information in accordance with this Agreement. The Parties will cooperate in the development and review of responses that are required to be submitted to any regulatory authority relating to the Processing of Product prior to submission to the regulatory authority.

5.2. Records; Safety. Osiris shall maintain accurate and complete records of its procurement, Processing and supply of Product hereunder for the longer of five (5) years after shipment of any such Product, or the period of time required by applicable Laws, regulations and/or standards, whichever is greater. No records required by this Agreement shall be discarded by Osiris without specific prior written notification of Osiris intent to discard to NuVasive. Those records (or copies of those records) that Osiris is unwilling to retain will be transferred to NuVasive for storage. Osiris shall promptly (and, in any event, within twenty four (24) hours) notify NuVasive of any information of which it becomes aware concerning Product supplied to NuVasive. Any such notification will include all related information in reasonable detail. Upon such notification, the parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either party to make a timely report of such matter to any regulatory authority or take other action that it deems to be appropriate or required by applicable Laws.

5.3. Regulatory Compliance. With respect to each Party s performance under this Agreement, Osiris and NuVasive shall each comply with all applicable Laws, regulations, and standards.

5.4. AATB Accreditation. The Parties agree that Osiris is actively pursuing AATB accreditation, and that NuVasive shall continue to perform its obligations under this Agreement despite the pendency of such AATB accreditation for so long as Osiris is using reasonable commercial efforts to obtain such accreditation. Once obtained, Osiris agrees to maintain its accreditation with the AATB and should Osiris accreditation lapse at any time or for any reason, it shall promptly communicate to the NuVasive the reasons for such lapse and the actions taken to cure the loss of AATB accreditation. In the event that Osiris fails to cure such loss within six months, notwithstanding any provision to the contrary contained in this Agreement, NuVasive shall be immediately and forever relieved of any

obligation to order Product or to pay any fees with respect thereto and shall have the right to cancel or amend, without liability, any Orders then pending; provided, however, NuVasive shall pay the Product Fees for all Orders shipped as long as such Orders are filled with Product Processed while Osiris was accredited.

5.5. Complaints. Osiris hereby agrees to advise NuVasive promptly (and, in any event, within thirty-six (36) hours) of any complaint information (including adverse event information) Osiris receives relating to Product. Osiris will assist NuVasive in investigating and resolving all complaints and adverse events related to the Processing of Product. NuVasive will be responsible for evaluating and investigating complaints and the Parties will cooperate in preparing communications to any regulatory authorities regarding Product complaints or adverse events. Osiris will take any corrective actions agreed to by the parties to avoid future occurrences of Product complaints or adverse events related to the Processing of the Product.

5.4. AATB Accreditation. The Parties agree that Osiris is actively pursuing AATB accreditation, and that NuVa

5.6. Product Tracking. NuVasive shall be responsible for maintaining trackability for all Products provided by Osiris. Tracking records shall be maintained by NuVasive in accordance with all applicable Laws.

5.7. Product Withdrawal. In the event Osiris or NuVasive believes it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to Product (a Product Withdrawal), NuVasive shall make all decisions as to such Product Withdrawal and Osiris shall cooperate with NuVasive in any Product Withdrawal. NuVasive shall bear all costs in connection with any such Product Withdrawal and NuVasive shall reimburse Osiris for all reasonable out-of-pocket expenses incurred by Osiris in connection with any such Product Withdrawal; provided, however, that if such Product Withdrawal is attributable to any breach, misrepresentation or non-fulfillment of any covenant, agreement, representation or warranty made or to be performed by Osiris under the Asset Purchase Agreement or this Agreement (including, without limitation, the failure of any Product supplied hereunder to meet the Osiris Product Warranty) or to the negligent act or omission or willful misconduct of Osiris, Osiris shall reimburse NuVasive for all costs reasonably incurred by NuVasive in connection with any such Product Withdrawal.

ARTICLE 6

INDEMNIFICATION AND INSURANCE

6.1. Osiris s Indemnity Obligations. Osiris shall defend, indemnify and hold harmless NuVasive, its Affiliates and their respective successors and permitted assigns (the NuVasive Indemnitees) from and against any and all losses, liabilities, claims, actions, proceedings, damages and expenses (including without limitation reasonable attorneys fees and expenses) (herein Damages) relating to or resulting from a claim that arises out of (a) any breach by Osiris or its Affiliates, sublicensees, contractors or subcontractors, or any of their respective officers, directors, employees, or agents (the Osiris Responsible Parties) of this Agreement, including without limitation, the failure of any Product supplied hereunder to meet or comply with the Specifications or Osiris Product Warranty, (b) the negligence or willful misconduct of any of the Osiris Responsible Parties, (c) any violation of Law by any of the Osiris Responsible Parties; or (d) the unauthorized use of Licensed Technology by any of the Osiris Responsible Parties; provided, however, this Section 6.1 shall not impose any obligation on Osiris to indemnify the NuVasive Indemnitees to the extent of any Damages for which NuVasive is obligated to indemnify the Osiris Indemnitees pursuant to Section 6.2.

6.2. NuVasive Indemnity Obligations. NuVasive shall defend, indemnify and hold harmless Osiris and its Affiliates, and their respective successors and permitted assigns (the Osiris Indemnitees) from and against any and all Damages relating to or resulting from a claim that arises out of (a) any breach by NuVasive or its Affiliates, sublicensees, contractors or subcontractors, or any of their respective officers, directors, employees, or agents (the NuVasive Responsible Parties) of this Agreement, (b) the negligence or willful misconduct of any of the NuVasive Responsible Parties, (c) any changes to the Specifications requested by NuVasive in writing, or (d) any violation of Law by any of the NuVasive Responsible Parties; provided, however, this Section 6.2 shall not impose any obligation on NuVasive to indemnify the Osiris Indemnitees to the extent of any Damages for which Osiris is obligated to indemnify the NuVasive Indemnitees pursuant to Section 6.1.

6.3. Notice of Claim. The indemnification obligations of the parties pursuant to this Agreement shall be proportional to the relative responsibility or fault of each party for the Damages

6.1. Osiris s Indemnity Obligations. Osiris shall defend, indemnify and hold harmless NuVasive, its Affiliates

incurred as a result of the actions or inactions of such party. Promptly after receipt by a NuVasive Indemnitee or Osiris Indemnitee of the commencement of any such claim, demand, action, suit or proceeding (collectively, Action) which is the subject of the other party s indemnification obligations hereunder, such Indemnitee shall notify the other party of the commencement of the Action. Any failure to provide such notice shall only relieve the other party of its indemnification obligations hereunder to the extent the indemnifying party has been materially prejudiced by such failure. The indemnifying party shall have sole right to select and retain attorneys (reasonably acceptable to the Indemnitee) to assert or negotiate, and sole right to control, the defense and any settlement of the Action, to the extent of the indemnifying party s corresponding indemnification and defense obligations, except that under no circumstances shall the indemnifying party enter into any settlement that involves an admission of liability, negligence or other culpability by the Indemnitee, or requires the Indemnitee to contribute to the settlement, without the Indemnitee s prior written consent. Without limiting the indemnifying party s foregoing right to select and retain attorneys and to sole control of the defense and settlement of such Action, the Indemnitee may, at its own expense, participate in the defense of, or otherwise consult with counsel of its own choice in connection with, an Action that is the subject of the other party s indemnification obligations.

6.4. Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE, WHETHER AS A RESULT OF CONTRACTUAL BREACH, TORT OR OTHERWISE, TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, SPECIAL, OR INCIDENTAL DAMAGES INCURRED BY SUCH OTHER PARTY, INCLUDING BUT NOT LIMITED TO INJURY TO GOODWILL, OR DIRECT, INDIRECT OR SPECULATIVE LOST PROFITS. The foregoing Limitation of Liability shall not apply to a party s liability for breach of its confidentiality obligations hereunder or to the extent such damages are paid to a third party in connection with a third party claim that is indemnified hereunder.

6.5. Insurance. Each party agrees to procure and maintain in full force and effect during the term of this Agreement, at its sole cost and expense, general liability and product liability insurance in amounts of not less than $2,000,000 per incident and $7,000,000 annual aggregate, which insurance shall be written on an occurrence basis policy form, or, in the alternative, shall continue for a period of ten (10) years following the termination or expiration of this Agreement, with a reputable insurance carrier and name the other party as an additional insured. Each party shall, on request, provide to the other party a copy of a certificate of coverage or other written evidence reasonably satisfactory to such requesting party of such insurance coverage.

ARTICLE 7

TERM AND TERMINATION

7.1. Term. Unless terminated earlier pursuant to the terms of this Agreement, this Agreement shall commence on the Effective Date and remain in effect for eighteen (18) months therefrom (the Term).

7.2. Termination.

7.2.1. This Agreement may be terminated, prior to the expiration of its Term, by either party immediately upon written notice to the other party after the material breach of any provision of this Agreement by the other party if the other party has not cured such breach within thirty (30) days after receipt of written notice thereof from the non-breaching party.

7.1. Term. Unless terminated earlier pursuant to the terms of this Agreement, this Agreement shall commenc

7.2.2. This Agreement may be terminated, prior to the expiration of its Term, immediately upon written notice by either party if the other party shall have become insolvent or bankrupt, or shall have made a general assignment for the benefit of its creditors, or any case or proceeding shall have been commenced by or against the other party in bankruptcy or seeking reorganization, liquidation, dissolution, or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law, and any such event shall have continued for sixty (60) days undismissed or undischarged.

7.2.3. This Agreement may be terminated, prior to the expiration of its Term, by NuVasive at any time and for any reason, immediately upon written notice to Osiris, after Osiris has Delivered to NuVasive an aggregate of cubic centimeters of Product hereunder.

7.3. Effect of Termination or Expiration. After either party provides notice of termination under Section 7.2.1 or 7.2.2 and pending termination of this Agreement under such Sections, the Parties shall continue to perform their respective obligations hereunder. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. The provisions of Sections 3.7, 5.2, 6.1, 6.2, 6.3, 6.4, 6.5, 8.1, 8.2, and 8.3 and the applicable provisions of Article 9 shall survive any expiration or termination of this Agreement. Each party agrees to return upon the expiration or termination of this Agreement all Confidential Information acquired from the other party, except as to such information it may be required to retain under applicable Laws, and except for one copy of such information may be retained by such party s legal department; provided, that if Osiris elects not to retain a copy of any such Confidential Information provided to NuVasive pursuant to Section 3.5 hereof, then NuVasive shall, upon reasonable notice to NuVasive and during NuVasive s normal business hours, provide Osiris with access to such Confidential Information as is reasonably necessary for purposes of Osris compliance with applicable Laws or in connection with Osiris defense of any third party claims related thereto.

ARTICLE 8

INTELLECTUAL PROPERTY AND CONFIDENTIALITY

8.1. Intellectual Property. Subject to the license expressly granted by this Agreement, NuVasive is the sole and exclusive owner of all right, title and interest in and to the methods of Processing Product and all of NuVasive s patents, trademarks, inventions, copyrights, know-how, and trade secrets.

8.2. Other Inventions. The parties do not contemplate that any inventions, discoveries, improvements, modifications, derivations, information, know-how and the like that arise out of the performance of this Agreement (collectively, the Inventions), including those related to processes, compositions of matter and methods of use, whether protectable by patent or as a trade secret, shall by Osiris. Accordingly, any and all Inventions made by either party individually or jointly hereunder, including any Inventions hereunder pertaining to Processing of Product, shall be owned solely by NuVasive, and Osiris hereby assigns to NuVasive all right, title and interest in and to all Inventions. Osiris shall, upon NuVasive s request, execute such documents, including any and all applications, assignments or other instruments, give any testimony and take such other actions as NuVasive deems necessary for NuVasive to obtain such ownership and to apply for, secure, and maintain patent or other proprietary protection in the United States or any other country with respect to Product or Inventions, provided that NuVasive shall compensate Osiris for its reasonable out of pocket costs and expenses associated with such actions. All Inventions and any information with respect thereto shall be the Confidential Information of NuVasive.

8.1. Intellectual Property. Subject to the license expressly granted by this Agreement, NuVasive is the sole ar

8.3. Confidentiality. The Receiving Party shall ensure the confidentiality of the Disclosing Party s Confidential Information it receives by taking substantially the same precautions as the Receiving Party does with its own Confidential Information, but not less than a reasonable standard of care. The Receiving Party shall not use the Disclosing Party s Confidential Information for any purpose other than to carry out the Receiving Party s obligations hereunder. The obligations of confidentiality shall not apply to information that the Receiving Party is required by applicable Laws to disclose; provided, however, that the Receiving Party shall so notify the Disclosing Party of the Receiving Party s intent to disclose and shall cooperate with the Disclosing Party at the Disclosing Party s expense on reasonable measures to protect the confidentiality of the Disclosing Party s Confidential Information. The Receiving Party may not disclose the Disclosing Party s Confidential Information received pursuant to this Agreement except to the Receiving Party s directors, officers, employees, consultants, attorneys and accountants who reasonably require disclosure of such Confidential Information for the Receiving Party to exercise its rights or perform its obligations under this Agreement, provided that such persons and entities are obligated to hold the Confidential Information in confidence in accordance with restrictions and procedures no less stringent than provided for herein and such persons enter into a written confidentiality agreement whereunder they agree not to disclose such information. The fact that general information may be in or become part of the public domain, in and of itself, does not exclude any specific Confidential Information from the obligations of this Agreement. The Parties hereto understand and agree that this Section 8.3 is reasonable and necessary to protect NuVasive s and Osiris respective business interests. The Parties further agree that the other may suffer irreparable harm from a breach of this Section 8.3. Thus, in addition to any other rights or remedies, all of which shall be deemed cumulative, a party shall be entitled to pursue injunctive relief to enforce the terms of this Section 8.3.

8.4. Publications. No announcement, news release, public statement, publication, or presentation relating to this Agreement or either party s performance hereunder (collectively, a Publication) shall be made without the other party s prior written approval, except as required by Law. Each party agrees to submit each Publication it proposes to make to the other party for purposes of such other party s

8.2. Other Inventions. The parties do not contemplate that any inventions, discoveries, improvements, modific

review, comment and approval. Each party further agrees to respond as promptly as reasonably possible.

ARTICLE 9
MISCELLANEOUS

9.1. No Assignment. Except as otherwise set forth herein, neither Party shall transfer, assign or cede any rights or delegate any obligations hereunder, in whole or in part, whether voluntarily or by operation of law, without the prior written consent of the other Party, which consent may be withheld at the other Party s reasonable business discretion, provided, that (a) Osiris may transfer this Agreement without prior written consent of NuVasive to an Affiliate or in connection with a merger or sale of all or substantially all of the stock or assets of Osiris to any party that NuVasive does not reasonably deem to be a competitor, and (b) NuVasive may transfer this Agreement without prior written consent of Osiris to an Affiliate of NuVasive or in connection with a merger or sale of all or substantially all of the assets of NuVasive.

9.2. Notices. All notices or other communications given pursuant hereto shall be in writing and deemed given (a) when delivered by messenger, (b) when sent by facsimile, (with receipt confirmed), (c) when received by the addressee, if sent by Federal Express or other express delivery service (receipt requested), or (d) five days after being mailed in the U.S., first-class

postage prepaid, registered or certified, in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a party may designate as to itself by notice to the other party):

If to Osiris:	**If to NuVasive**
Osiris Therapeutics, Inc.	NuVasive, Inc.
7015 Albert Einstein Drive	7473 Lusk Boulevard
Columbia, MD 21046	San Diego, CA 92121
Attention: Chief Executive Officer	Attention: General Counsel
Fax No.: 443-545-1701	Fax No.: [*]
With a copy to:	With a copy (which shall not constitute notice) to:
McKenna Long & Aldridge LLP	DLA Piper US LLP
303 Peachtree St., NE, Suite 5300	4365 Executive Drive
Atlanta, GA 30308	Suite 1100
Attention: Michael Cochran, Esq.	San Diego, CA 92122
Fax No.: 404-527-4198	Attention: Michael Kagnoff
	Fax No.: 858-638-5022

9.3. Force Majeure. Nonperformance by either party hereto shall be excused to the extent that performance is rendered impossible by strike, fire, explosion, flood, acts of God, terrorism, war or civil commotion, governmental acts or orders or restrictions, failure of suppliers, public utilities or common carriers, or any other reason where failure to perform is beyond the reasonable control of and is not caused by the negligence of the non-performing party. Such non-performing party shall exercise best efforts to eliminate the force majeure event and to resume performance of its affected obligations as soon as practicable. In the event that, as a result of such force majeure event, a party does not perform all of its obligations hereunder for any period of ninety (90) consecutive days, in addition to any other rights hereunder, the other party may terminate this Agreement on thirty (30) days prior written notice to the non-performing party.

9.4. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

9.2. Notices. All notices or other communications given pursuant hereto shall be in writing and deemed given

9.5. Partial Invalidity. If any provision of this Agreement is held to be invalid, the remaining provisions shall nevertheless remain in full force and effect. In addition, the Parties shall renegotiate in good faith any term held to be invalid, and be bound by the mutually agreed upon substitute provision.

9.6. Entire Agreement; Inconsistent Terms; Waiver. This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and may not be amended, modified, waived or cancelled except by a writing signed by each of the Parties or, in case of a waiver, by the party effecting such waiver. If any terms or conditions of any standard form

9.5. Partial Invalidity. If any provision of this Agreement is held to be invalid, the remaining provisions shall ne

(e.g., purchase order, order acknowledgment, etc.) of Osiris or NuVasive conflict or are inconsistent with any terms or conditions of this Agreement, the terms and conditions of this Agreement shall govern. Failure to require performance of any provision hereof shall in no manner affect the right of such party at a later time to enforce the same, and no waiver in any one instance shall be deemed to be a further or continuing waiver of the same or any other provision.

9.7. Governing Law; Consent to Jurisdiction. This Agreement shall be governed by the laws of the State of Delaware, without regard to conflicts of laws principles.

9.8. Dispute Resolution. In the event of a dispute arising under this Agreement, each party agrees to notify the other party of the specific complaints or points of disagreement, and to use its good faith efforts to resolve such dispute, without legal action, by referring such dispute to the [Title] of Osiris and [Title]of NuVasive (collectively, Executives) for resolution. The Executives shall meet promptly after such referral to attempt to resolve such dispute through good faith discussions. In the event the Executives cannot resolve such dispute within fifteen (15) days of such initial meeting, either party may request that such dispute be resolved by binding arbitration before one (1) neutral arbitrator in accordance with the then-current Commercial Arbitration Rules of the American Arbitration Association, applying the substantive law specified in Section 9.7. The parties shall jointly select the arbitrator. Within three (3) months of the conclusion of an arbitration proceeding, the arbitration decision shall be rendered in writing and shall specify the basis on which the decision was made. Any award rendered by the arbitrator shall be final and binding upon the parties, and judgment upon any such award may be entered in any court having jurisdiction thereof. Arbitration shall be conducted in Chicago, Illinois. The parties agree that, any provision of applicable law notwithstanding, they will not request, and the arbitrator shall have no authority to award, punitive or exemplary damages against either party. The costs of the arbitration, including administration fees, shall be shared by the parties in proportion to their fault, as determined by the arbitrator. Notwithstanding the foregoing, the parties agree that

if any breach or threatened breach of this Agreement would necessarily result in immediate, irreparable injury to a party, that party, in addition to any other remedies available under this Agreement, shall have the right to seek injunctive relief in any court of competent jurisdiction. Notwithstanding anything to the contrary in this Agreement, this Section 9.8 shall not apply to any disputes arising under Section 8.3 (Confidentiality) or to any disputes relating to a party s intellectual property (including, without limitation, disputes relating to ownership or inventorship of inventions, validity or infringement of patents, or scope of patent claims).

9.9. Independent Contractor. The relationship between NuVasive and Osiris established by this Agreement is that of independent contractors. Neither party shall have authority to conclude contracts or otherwise to act for or bind the other party in any manner, whatsoever, as agent or otherwise.

9.10. Further Actions. Each party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purpose and intent of this Agreement.

9.11. Representations and Warranties. Each of the Parties represents and warrants that (i) it is fully authorized to enter into this Agreement; (ii) its entering into and performance under this Agreement does not violate or breach it Certificate of Incorporation or corporate bylaws or any agreement or contract to which it is a party; (iii) there is no claim, demand, action, suit or proceeding or investigation pending or currently threatened against it or any of its Affiliates involving or relating to the subject matter hereof, or which, if adversely determined, would restrict it from

9.8. Dispute Resolution. In the event of a dispute arising under this Agreement, each party agrees to notify th

entering into this Agreement and carrying out its obligations under this Agreement; and (iv) it has no legal obligations which would prevent this Agreement from being fully implemented in accordance with its terms.

IN WITNESS WHEREOF, the undersigned caused this Agreement to be executed as of the Effective Date.

OSIRIS THERAPEUTICS, INC.	**NUVASIVE, INC.**
By:	By:
Name:	Name:
Its:	Its:

9.11. Representations and Warranties. Each of the Parties represents and warrants that (i) it is fully authorized

Exhibit A Product Specifications

Osiris Materials Specifications numbers 90055, 90067, 90080, 90081, 90103, 9012, 90129, 90149, and 90188, as may be amended by mutual written agreement of the parties.

Appendix C

[FORM OF]

Company Voting and Support Agreement

COMPANY VOTING AND SUPPORT AGREEMENT, dated as of May 8, 2008, (this Agreement), by and between Nuvasive, Inc. (Nuvasive), a Delaware corporation, and (the Stockholder). Capitalized terms used but not defined herein shall have the meanings given to such terms in the Asset Purchase Agreement, dated as of the date hereof (the Purchase Agreement), by and between Nuvasive and Osiris Therapeutics, Inc. (the Company).

W I T N E S S E T H:

WHEREAS, Nuvasive and the Company are entering into the Purchase Agreement concurrently with the execution and delivery of this Agreement, which Purchase Agreement sets forth the terms and conditions on which Nuvasive will acquire certain assets of the Company (the Acquisition).

WHEREAS, as of the date hereof, the Stockholder is the beneficial and record owner of shares of Company Common Stock (the Existing Shares).

WHEREAS, Nuvasive has required, as a material inducement to Nuvasive s willingness to enter into the Purchase Agreement, that the Stockholder enter into this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual representations, warranties, covenants and agreements contained herein, and intending to be legally bound hereby, the parties hereto hereby agree as follows:

ARTICLE I

VOTING

1.1 Agreement to Vote. The Stockholder agrees that, from and after the date hereof and until this Agreement is terminated pursuant to Section 4.1, at the Stockholder Meeting and any other meeting of the stockholders of the Company, however called relating to any proposed action by the stockholders of the Company

with respect to the matters set forth in Section 1.1(b) below (each, a Voting Event), the Stockholder shall:

(a) appear at each such Voting Event or otherwise cause the Existing Shares and any voting securities of the Company acquired by the Stockholder after the date hereof and prior to the record date of such Voting Event (together with the Existing Shares, the Voting Shares) owned beneficially or of record by the Stockholder to be counted as present thereat for purposes of calculating a quorum; and

(b) vote (or cause to be voted), in person or by proxy, all the Voting Shares (i) in favor of adoption of the Purchase Agreement and any other transactions and other matters specifically contemplated by the Purchase Agreement and (ii) against any action or agreement submitted for adoption of the stockholders of the Company that, to the Stockholder s knowledge, would result in a breach of any covenant, representation or warranty or any other obligation or

agreement of the Company contained in the Purchase Agreement or of the Stockholder contained in this Agreement.

1.2 Fiduciary Duties. Each party hereto acknowledges and agrees that the Stockholder is not making any agreement or understanding herein in any capacity other than in its capacity as a stockholder of the Company. If the Stockholder or any affiliates, employees or agents of the Stockholder is an officer or member of the Board of Directors of the Company, nothing herein shall in any way limit or affect actions taken by them in such capacity, and no action taken in their capacity as such an officer or director in furtherance of their fiduciary duties as an officer or director of the Company shall be deemed to be a breach of the provisions of this Agreement.

ARTICLE II

REPRESENTATIONS AND WARRANTIES

2.1 Representations and Warranties of the Stockholder. The Stockholder hereby represents and warrants to Nuvasive as follows:

(a) Authorization; Validity of Agreement; Necessary Action. This Agreement has been duly and validly executed and delivered by the Stockholder and, assuming this Agreement constitutes the valid and binding agreement of Nuvasive, constitutes the valid and binding agreement of the Stockholder, enforceable against the Stockholder in accordance with its terms, subject to (i) laws of general application relating to bankruptcy, insolvency and the relief of debtors, and (ii) rules of law governing specific performance, injunctive relief and other equitable remedies.

(b) Ownership. As of the date hereof, the number of shares of Company Common Stock beneficially owned by the Stockholder is noted in the Recitals to this Agreement. The Existing Shares are, and the Voting Shares will be, owned beneficially by the Stockholder. As of the date hereof, the Existing Shares are the only shares of Company Common Stock held of record or beneficially owned by the Stockholder. Subject to Section 3.1, the Stockholder has and will have at all times through the time of any Voting Event sole voting power, sole power of disposition, sole power to issue instructions with respect to the matters set forth in Article I or Section 3.1 hereof, and sole power to agree to all of the matters set forth in this Agreement, in each case with respect to all of the Existing Shares and with respect to all of the Voting Shares at the time of any Voting Event, with no limitations, qualifications or restrictions on such rights, subject to applicable federal securities laws and the terms of this Agreement. The Stockholder has good title to the Existing Shares, free and clear of any Liens and the Stockholder will have good title to such Voting Shares as of the time of any Voting Event, free and clear of any Liens. The Stockholder further represents that any proxies heretofore given in respect of the shares of Company Common Stock owned beneficially and of record by such Stockholder, if any, are revocable, and have been revoked.

(c) No Violation. The execution and delivery of this Agreement by the Stockholder does not, and the performance by the Stockholder of its obligations under this Agreement will not, (i) contravene or conflict with the organizational or governing documents of

the Stockholder, (ii) contravene or conflict with or constitute a violation by Stockholder of any provision of any Law binding upon or applicable to the Stockholder or any of its properties or assets, or (iii) result in any violation of, or default (with or without notice or lapse of time, or both) under, or give rise to a right of termination, cancellation or acceleration of any material obligation or to the loss of a material benefit under any loan, guarantee of indebtedness or credit agreement, note, bond, mortgage, indenture, lease or agreement binding upon the Company or any of its subsidiaries or result in the creation of any Lien (other than Permitted Liens) upon any of the properties or assets of the Stockholder, except for any of the matters set forth in the foregoing clause (iii) as would not reasonably be expected to materially impair the ability of the Stockholder to perform its obligations hereunder or to consummate the transactions contemplated hereby on a timely basis.

2.2 Representations and Warranties of Nuvasive. Nuvasive hereby represents and warrants to the Stockholder as follows:

(a) Authorization; Validity of Agreement; Necessary Action. This Agreement has been duly and validly executed and delivered by Nuvasive and, assuming this Agreement constitutes the valid and binding agreement of the Stockholder, constitutes the valid and binding agreement of Nuvasive, enforceable against Nuvasive in accordance with its terms, subject to (i) laws of general application relating to bankruptcy, insolvency and the relief of debtors, and (ii) rules of law governing specific performance, injunctive relief and other equitable remedies.

(b) No Violation. The execution and delivery of this Agreement by Nuvasive does not, and the performance by Nuvasive of its obligations under this Agreement will not, (i) contravene or conflict with the organizational or governing documents of Nuvasive, (ii) contravene or conflict with or constitute a violation by Nuvasive of any provision of any Law binding upon or applicable to Nuvasive or any of its properties or assets or (iii) result in any violation of, or default (with or without notice or lapse of time, or both) under, or give rise to a right of termination, cancellation or acceleration of any material obligation or to the loss of a material benefit under any loan, guarantee of indebtedness or credit agreement, note, bond, mortgage, indenture, lease or agreement binding upon Nuvasive or result in the creation of any Lien (other than Permitted Liens) upon any of the properties or assets of Nuvasive, except for any of the matters set forth in the foregoing clause (iii) as would not reasonably be expected to materially impair the ability of Nuvasive to perform his obligations hereunder or to consummate the transactions contemplated hereby on a timely basis.

ARTICLE III

OTHER COVENANTS

3.1 Further Agreements of the Stockholder. (a) The Stockholder hereby agrees, while this Agreement is in effect, and except as expressly contemplated hereby, not to sell, transfer, pledge, encumber, assign, distribute, gift or otherwise dispose of (collectively, a Transfer) or enter into any contract, option, put, call or other arrangement or understanding with respect to any Transfer (whether by actual disposition or effective economic disposition due to hedging, cash settlement or otherwise) of, any of the Voting Shares, or any interest therein, provided, that

notwithstanding the foregoing, the Stockholder may Transfer any Voting Shares to

any transferee or transferees (including, for avoidance of doubt, any member of Stockholder s immediate family, a trust for the benefit of the Stockholder or any member of the Stockholder s immediate family or upon the death of the Stockholder) if either (i) Stockholder retains direct or indirect sole voting control over such Transferred Voting Shares through the term of this Agreement; or (ii) as a condition to such Transfer, such transferee or transferees shall execute an agreement that contains the same substantive covenants regarding voting and transfer as are contained in this Agreement.

(a) In case of a stock dividend or distribution of voting securities of the Company, or any change in the Company Common Stock by reason of any stock dividend or distribution, split-up, recapitalization, combination, exchange of shares or the like, the term Voting Shares shall be deemed to refer to and include the Voting Shares as well as all such stock dividends and distributions of voting securities of the Company and any voting securities into which or for which any or all of the Voting Shares may be changed or exchanged.

(b) The Stockholder agrees, while this Agreement is in effect, not to, nor to permit any investment banker, financial adviser, attorney, accountant or other representative or agent of the Stockholder to, directly or indirectly, engage in any activity which would be prohibited pursuant to Section 4.7 of the Purchase Agreement if engaged in by the Company.

(c) The Stockholder agrees, while this Agreement is in effect, not to take or agree or commit to take any action that would make any representation and warranty of the Stockholder contained in Section 2.1 of this Agreement inaccurate in any material respect. The Stockholder further agrees that it shall use its commercially reasonable efforts to cooperate with the Company to effect the transactions contemplated hereby including the Acquisition.

ARTICLE IV

MISCELLANEOUS

4.1 Termination. This Agreement shall terminate upon the earlier to occur of (a) the receipt of the Stockholder Approval (as defined in the Purchase Agreement) and (b) the termination of the Purchase Agreement pursuant to its terms. In the event of such termination of this Agreement, this Agreement shall forthwith become void and have no effect, without any liability or obligation on the part of any party; provided, however that nothing herein shall relieve any party from liability for any fraud, intentional misrepresentation or willful breach of any of its representations, warranties, covenants or agreements set forth in this Agreement prior to such termination.

4.2 Further Assurances. From time to time, at the other party s request and without further consideration, each party shall execute and deliver such additional documents and take all such further action as may be reasonably necessary or desirable to consummate the transactions contemplated by this Agreement.

4.3 No Ownership Interest. Nothing contained in this Agreement shall be deemed to vest in Nuvasive any direct or indirect ownership or incidence of ownership of or with respect to any Voting Shares. All rights, ownership and economic benefits of and relating to the

Voting Shares shall remain vested in and belong to the Stockholder, and Nuvasive shall have no authority to manage, direct, superintend, restrict, regulate, govern or administer any of the policies or operations of the Company or exercise any power or authority to direct the Stockholder in the voting of any of the Voting Shares, except as otherwise provided herein.

4.4 Notices. Except for notices that are specifically required by the terms of this Agreement to be delivered orally, all notices, requests, claims, demands and other communications hereunder shall be in writing and shall be deemed given if delivered personally, faxed (with confirmation) or sent by overnight courier (providing proof of delivery) to the parties at the following addresses (or at such other address for a party as shall be specified by like notice)

(a) **(a) if to Nuvasive:**

NuVasive, Inc.

7473 Lusk Boulevard

San Diego, California 92121

Attention: General Counsel

Facsimile: (858) 909-2479

with a copy (which shall not constitute notice) to:

DLA Piper US LLP

4365 Executive Drive, Suite 1100

San Diego, California 92122

Attention: Michael Kagnoff

Facsimile: (858) 456-3075

and (b) if to the Stockholder:

4.5 Interpretation. When a reference is made in this Agreement to an Article or Section, such reference shall be to an Article or Section of this Agreement unless otherwise indicated. Whenever the words include, includes or including are used in this Agreement, they shall be deemed to be followed by the words without limitation. The words hereof, herein and hereunder and words of similar import when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. All terms defined in this Agreement shall have the defined meanings when used in any certificate or other document made or delivered pursuant thereto unless otherwise defined therein. Whenever the context of this Agreement requires, the gender of all words herein shall include the masculine, feminine and neuter, and the number of all words herein shall include the singular and plural. Any agreement, instrument or statute defined or referred to herein or in any agreement or

instrument that is referred to herein means such agreement, instrument or statute as from time to time amended, modified or supplemented, including (in the case of agreements or instruments) by waiver or consent and (in the case of statutes) by succession of comparable successor statutes and references to all attachments thereto and instruments incorporated therein. Each of the parties has participated in the drafting and negotiation of this Agreement. If an ambiguity or question of intent or interpretation arises, this Agreement must be construed as if it is drafted by all the parties, and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of authorship of any of the provisions of this Agreement.

4.6 Counterparts. This Agreement may be executed in two or more consecutive counterparts (including by facsimile), each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and shall become effective when one or more counterparts have been signed by each of the parties and delivered (by telecopy or otherwise) to the other parties.

4.7 Entire Agreement; Third-Party Beneficiaries. This Agreement (including the exhibits and schedules hereto) constitutes the entire agreement, and supersedes all other prior agreements and understandings, both written and oral, between the parties, or any of them, with respect to the subject matter hereof and thereof and is not intended to and shall not confer upon any person other than the parties hereto any rights or remedies hereunder; provided, however, that the Company shall be deemed to be a third-party beneficiary of the Stockholder s obligations under Sections 1.1 and 3.1 and shall be entitled to enforce the terms of this Agreement in respect thereto as if it were a party hereto.

4.8 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of Delaware.

4.9 Jurisdiction; Enforcement. The parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement. Each of the parties hereto irrevocably agrees that any legal action or proceeding with respect to this Agreement and the rights and obligations arising hereunder, or for recognition and enforcement of any judgment in respect of this Agreement and the rights and obligations arising hereunder brought by the other party hereto or its successors or assigns, shall be brought and determined exclusively in the Delaware Court of Chancery and any state appellate court therefrom within the State of Delaware (or, only if the Delaware Court of Chancery declines to accept jurisdiction over a particular matter, any state or federal court within the State of Delaware). Each of the parties hereto hereby irrevocably submits with regard to any such action or proceeding for itself and in respect of its property, generally and unconditionally, to the personal jurisdiction of the aforesaid courts and agrees that it will not bring any action relating to this Agreement or any of the transactions contemplated by this Agreement in any court other than the aforesaid courts. Each of the parties hereto hereby irrevocably waives, and agrees not to assert as a defense, counterclaim or otherwise, in any action or proceeding with respect to this Agreement, (a) any

claim that it is not personally subject to the jurisdiction of the above named courts for any reason other than the failure to serve in accordance with this Section 4.9, (b) any claim that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise) and (c) to the fullest extent permitted by the applicable Law, any claim that (i) the suit, action or proceeding in such court is brought in an inconvenient forum, (ii) the venue of such suit, action or proceeding is improper or (iii) this Agreement, or the subject mater hereof, may not be enforced in or by such courts.

4.10 Amendment. Any provision of this Agreement may be amended or waived if, and only if, such amendment or waiver is in writing and signed, in the case of an amendment, by each of the parties hereto, or in the case of a waiver, by the party against whom the waiver is to be effective. Notwithstanding the foregoing, no failure or delay by any party hereto in exercising any right hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise of any other right hereunder.

4.11 Severability. Any term or provision of this Agreement which is invalid or unenforceable in any jurisdiction shall, as to that jurisdiction, be ineffective to the sole extent of such invalidity or unenforceability without rendering invalid or unenforceable the remainder of such term or provision or the remaining terms and provisions of this Agreement in any jurisdiction. If any provision of this Agreement is so broad as to be unenforceable, such provision shall be interpreted to be only so broad as is enforceable.

4.12 Assignment. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by any of the parties hereto (whether by operation of law or otherwise) without the prior written consent of the other parties, and any assignment without such consent shall be null and void. Subject to the preceding sentence, this Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered as of the date first above written.

NUVASIVE, INC.

By:
Name:
Title:

Name:
Title:

Received and acknowledged as of
the date first above written:

OSIRIS THERAPEUTICS, INC.

By:
Name:
Title:

Signature Page to Voting and Support Agreement

APPENDIX D

FINANCIAL STATEMENTS

OSTEOCEL BUSINESS UNIT

A Wholly Owned Business Unit of Osiris Therapeutics, Inc.

Unaudited Carve Out Balance Sheets

Amounts in thousands

	March 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Accounts receivable	$ 3,955	$ 4,324
Inventory	4,622	3,983
Prepaid expenses	72	138
Total current assets	8,649	8,445
Property and equipment, net	5,539	4,596
Total assets	$ 14,188	$ 13,041
LIABILITIES AND PARENT COMPANY S NET INVESTMENT		
Current liabilities:		
Accounts payable	$ 2,931	$ 2,447
Accrued vacation and bonuses	79	34
Other current liabilities	58	70
Total current liabilities	3,068	2,551
Parent company s net investment	11,120	10,490
Total liabilities and parent company s net investment	$ 14,188	$ 13,041

The accompanying notes are an integral part of these carve out financial statements.

OSTEOCEL BUSINESS UNIT

A Wholly Owned Business Unit of Osiris Therapeutics, Inc.

Unaudited Carve Out Statements of Operations

Amounts in thousands

	Three Months Ended March 31, 2008	Year Ended December 31, 2007
Product sales	$ 7,511	$ 15,240
Cost of goods sold	3,781	6,955
Gross profit	3,730	8,285
Operating expenses:		
Research and development expense		3,711
General and administrative expense	99	431
Corporate allocation	82	206
Total operating expenses	181	4,348
Net income	$ 3,549	$ 3,937

The accompanying notes are an integral part of these carve out financial statements.

OSTEOCEL BUSINESS UNIT

A Wholly Owned Business Unit of Osiris Therapeutics, Inc.

Unaudited Carve Out Statements of Changes in

Parent Company s Net Investment

Amounts in thousands

Balance at January 1, 2007	$	3,494
Intercompany transfers, net		3,059
Net income		3,937
Balance at December 31, 2007		10,490
Intercompany transfers, net		(2,919)
Net income		3,549
Balance at March 31, 2008	$	11,120

The accompanying notes are an integral part of these carve out financial statements.

OSTEOCEL BUSINESS UNIT

A Wholly Owned Business Unit of Osiris Therapeutics, Inc.

Unaudited Carve Out Statements of Cash Flow

Amounts in thousands

	Three Months Ended March 31, 2008	Year Ended December 31, 2007
Cash flows from operating activities:		
Net income	$ 3,549	$ 3,937
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	62	105
Non-cash Share-based payments	41	69
Changes in operating assets and liabilities:		
Accounts receivable	369	(2,855)
Inventory	(639)	(2,090)
Prepaid expenses	66	(138)
Accounts payable and accrued expenses	517	1,817
Net cash provided by operating activities	3,965	845
Cash flows from investing activities:		
Purchases of property and equipment	(881)	(3,834)
Cash flows from financing activities:		
Net transfers (to) from parent	(3,084)	2,989
Net change in cash		
Cash at beginning of period		
Cash at end of period	**$**	**$**

The accompanying notes are an integral part of these carve out financial statements.

OSTEOCEL BUSINESS UNIT

A Wholly Owned Business Unit of Osiris Therapeutics, Inc.

NOTES TO UNAUDITED CARVE OUT FINANCIAL STATEMENTS

Amounts in Thousands

1. Nature of Business and Basis of Presentation

The Osteocel Business Unit is a division of Osiris Therapeutics, Inc. (the Company) and manufactures and distributes Osteocel, a human cell and tissue based allograft material containing cancellous bone product for the regeneration of bone in orthopedic indications. Osteocel XO is a similar formulation under development, also using cancellous bone. Osteocel was launched in July 2005 and is sold pursuant to written agreements, primarily to two customers.

Osteocel XC is the name we use to refer to our second generation mesenchymal stem cell product candidate for bone repair, which would utilize culture expanded mesenchymal stem cells to create a synthetic version of Osteocel. We are not currently engaged in an active product development program focused specifically on Osteocel XC. Osteocel XC is not considered to be part of the Osteocel Business Unit.

In May 2008, we announced that we had signed a definitive agreement to sell the Osteocel Business Unit to NuVasive, Inc. The sale will be effected at two closings a technology assets closing which is expected to occur as soon as practicable following the satisfaction of various conditions precedent; and a manufacturing assets closing which is expected to occur within approximately eighteen months following the technology assets closing. The Company will receive $35.0 million in cash upon the technology assets closing and $12.5 million in cash upon the manufacturing assets closing. During the period between the technology assets closing and the manufacturing assets closing, the Company will continue to manufacture or have manufactured, and supply, Osteocel to NuVasive. We are entitled to milestone payments of up to $37.5 million based upon certain manufacturing and sales thresholds and up to $52 million from the manufacture and supply of Osteocel under the manufacturing agreement.

The accompanying carve out financial statements and related notes thereto represent the carve out balance sheets and statements of operations, changes in parent company investment and cash flows of the Osteocel Business Unit. The carve out financial statements have been prepared in accordance with Regulation S-X, Article 3, *General instructions as to the financial statements* and Staff Bulletin Topic 1-B, *Allocation of Expenses and Related Disclosure in Financial Statements of Subsidiaries, Divisions or Lesser Business Components of Another Entity*. Certain assumptions and estimates were made in order to allocate a reasonable share of such expenses to the Osteocel Business Unit so that the accompanying carve out financial statements reflect substantially all costs of doing business.

Certain corporate overhead expenses have been allocated to the Osteocel Business Unit as a corporate allocation. These overhead charges include personnel costs for support functions such as accounting, finance, human resources, procurement, security and senior management. They also include non-personnel costs such as insurance, professional fees and other costs. The corporate overhead charges were allocated to the Osteocel Business Unit based upon estimated relative time and resources dedicated to the business unit. Management believes the basis of the allocations are reasonable.

Certain corporate non-operating transactions of ours have not been allocated to the Osteocel Business Unit. These items include interest income on our cash and short-term investment and interest expense on our debt and capitalized leases.

2. Summary of Significant Accounting Policies

The accompanying carve out financial statements were derived from the historical accounting records of Osiris Therapeutics, Inc.

Use of Estimates

The preparation of carve out financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in carve out financial statements and accompanying notes. Due to the inherent uncertainty involved in making those assumptions, actual results could differ from those estimates. Also, certain amounts in the accompanying carve out financial statements have been allocated in a way that management believes is reasonable and consistent in order to depict the historical financial position, results of operations, and cash flows of the Osteocel Business Unit on a stand-alone basis. Actual results could differ materially from those estimates. We believe that the most significant estimate that affect our financial statements are those that related to inventory valuation and share-based compensation.

OSTEOCEL BUSINESS UNIT

A Wholly Owned Business Unit of Osiris Therapeutics, Inc.

NOTES TO UNAUDITED CARVE OUT FINANCIAL STATEMENTS

Amounts in Thousands

Revenue Recognition

We recognize revenue on Osteocel sales when legal title to the product has passed to the customer, which occurs when the product is shipped from our Baltimore, Maryland manufacturing facilities or placed in designated freezers at the request of the customer. We have agreements with our customers that specify the terms of sale, including price. During the three months ended March 31, 2008 and the year ended December 31, 2007, sales of our Osteocel product were primarily to two customers. Historically, we have not incurred any sales returns.

Cost of Goods Sold

Costs of goods sold of Osteocel consist primarily of the costs to obtain the tissue and other chemical and supplies, quality and sterility testing, plus labor and allocated overhead costs and the costs of operating the clean-room facilities.

Research and Development Costs

Prior to 2008, we incurred research and development costs to launch and improve Osteocel and to develop Osteocel XO, and during 2007, we incurred development costs to expand our Baltimore, Maryland Osteocel manufacturing facilities, including production qualification runs. Research and development costs are expensed as incurred.

Concentration of Risk and Accounts Receivable

Our accounts receivable at both March 31, 2008 and December 31, 2007 consist of amounts due from commercial customers and we expect these receivables to be collected. Since the launch of Osteocel in July 2005, we have incurred $3 in bad debt expense related to the sale of Osteocel.

Inventory

Inventory consists of tissue products in process and available for distribution. We determine our inventory values using the first-in, first-out method. Due to the nature of our Osteocel product, we incur all of the costs to manufacture the product prior to completing the extensive testing and evaluation necessary to determine if the product can be released. We estimate the reserve for work-in-process inventory based upon our historical experience. Historically, we have nominal amounts of finished goods inventory.

Property and Equipment

The Asset Purchase Agreement calls for the transfer of the equipment used in the manufacture and storage of Osteocel to be transferred to NuVasive upon the manufacturing asset closing. The Agreement also calls for the transfer of the leasehold improvements and rights we have in the lease to our Columbia, Maryland administrative, research and development and manufacturing facilities. Our Baltimore, Maryland facilities will close by September 2008 and all our business activities, including the manufacture and storage of Osteocel will take place in our Columbia, Maryland facilities. Until the closing of our Baltimore facilities, no Osteocel activities took place in Columbia.

Since the Asset Purchase Agreement requires the transfer of the Columbia, Maryland facilities to NuVasive, these assets are included in the carve out balance sheets of the Osteocel Business Unit.

We record property and equipment, including improvements that extend useful lives, at cost, while maintenance and repairs are charged to operations as incurred. We calculate depreciation using the straight-line method based on the estimated useful lives ranging from three to seven years for furniture, equipment and internal use software. We amortize leasehold improvements over the shorter of the estimated useful life of the asset or the original term of the lease.

Share-Based Compensation

Employees of the Osteocel Business Unit participate in the Company s stock compensation plans. We recognize all share-based payments to employees in our financial statements based on their grant date fair values, using prescribed option-pricing models. We use the Black-Scholes option pricing model to value share-based payments. Compensation expense related to share-based awards is recognized on a straight-line basis based on the value of share awards that are scheduled to vest during the requisite service period. Share-based compensation expense is based on awards ultimately expected to vest and is reduced for estimated forfeitures.

OSTEOCEL BUSINESS UNIT

A Wholly Owned Business Unit of Osiris Therapeutics, Inc.

NOTES TO UNAUDITED CARVE OUT FINANCIAL STATEMENTS

Amounts in Thousands

3. Property and Equipment

Property and equipment consist of the following for the periods presented:

	March 31, 2008	December 31, 2007
Osteocel manufacturing assets	$ 1,038	$ 810
Leasehold improvements	4,151	4,151
Construction in process	771	14
	5,960	4,975
Accumulated depreciation and amortization	(421)	(379)
Property and equipment, net	$ 5,539	$ 4,596

At March 31, 2008, we estimate that we will invest an additional $2.1 million in our Columbia, Maryland Osteocel manufacturing facilities and purchase approximately $600 of additional manufacturing equipment and freezers. These assets will be transferred to NuVasive upon the manufacturing asset closing.

4. Income Taxes

The Osteocel Business Unit is an entity not directly subject to income taxes. The results of the Osteocel Business Unit operations are included in the Company s federal and state income tax returns. As of March 31, 2008, the Company had approximately $223 million in net operating loss carryforwards. The Company s deferred tax assets have been fully reserved in both 2008 and 2007.

5. Share-Based Compensation

Information with respect to stock options and warrants can be found in Note 6 to Osiris Therapeutics, Inc. financial statements for the year ended December 31, 2007, that are filed as part of our Annual Report on Form 10-K.

6. Facility Lease

The future minimum lease payments due under the operating lease for our Columbia, Maryland facility at March 31, 2008, are as follows:

		Columbia Facility
2008	$	660
2009		978
2010		1,056
2011		1,082
2012		1,109
2013 - 2016		3,999
	$	8,884

This lease will be assigned to NuVasive upon the manufacturing asset closing.

APPENDIX E

Reports filed by Osiris

- Annual Report on Form 10-K for the fiscal year ended December 31, 2007
- Quarterly Report on Form 10-Q (as modified by Form 10-Q/A) for the quarterly period ended March 31, 2008
- Current Report on Form 8-K filed with the SEC on June 10, 2008
- Current Report on Form 8-K filed with the SEC on June 17, 2008

[SEE PAGES FOLLOWING]

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934:**

For the fiscal year ended December 31, 2007

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934:**

For the transition period from to

Commission file number 001-32966

Osiris Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**71-0881115**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
7015 Albert Einstein Drive, Columbia, Maryland	**21046-1707**
(Address of principal executive offices)	(Zip Code)

443-545-1800

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class		**Name of Each Exchange on with Registered**

Common Stock, $0.001 par value		NASDAQ Global Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to *Item 405* of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x

On June 30, 2007, the last business day of the registrant s most recently completed second fiscal quarter, the aggregate market value of voting Common Stock held by non-affiliates of registrant, based upon the last sale price of the Common Stock reported on the NASDAQ Global Market was approximately $201,789,000.

The number of shares of the registrant s Common Stock outstanding as of March 9, 2008 is 31,652,561.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our definitive Proxy Statement for our 2008 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2007 fiscal year are incorporated by reference into Part III of this Annual Report on Form 10-K.

OSIRIS THERAPEUTICS, INC.

Annual Report on Form 10-K

Fiscal Year Ended December 31, 2007

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PART I

Item 1. Business.

Forward-Looking Information

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Forward-looking statements include statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, compensation arrangements, financing needs, plans or intentions relating to collaborations or business combinations, business trends and other information that is not historical information and, in particular, may appear under the headings Risk Factors in this Part I Item 1A, Part II Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and the other documents we file with the Securities and Exchange Commission, or SEC, including, among others, our quarterly reports on Form 10-Q and any amendments thereto.

When used in this Annual Report, the words *estimates, expects, anticipates, projects, plans, intends, believes, forecasts* and variations of such words or similar expressions are intended to identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements regarding the following: our product development efforts; our clinical trials and anticipated regulatory requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for Mesenchymal Stem Cells (MSCs) and biologic drug candidates; our cash needs; patents, trademarks and other proprietary rights; ability of our potential products to treat disease; our ability to supply a sufficient amount of our products to meet regular and repeated demand; our costs to comply with governmental regulations; our relationship with collaborating partners; our ability to benefit from government contracts; our plans for sales and marketing; our plans regarding facilities; types of regulatory frameworks we expect will be applicable to our potential products; and results of our scientific research.

All forward-looking statements, including, without limitation, management s examination of historical operating trends, are based upon our current expectations and various assumptions. Our expectations, beliefs and projections are expressed in good faith and we believe there is a reasonable basis for them. However, there can be no assurance that management s expectations, beliefs and projections will result or be achieved.

There are a number of risks and uncertainties that could cause our actual results to differ materially from the forward-looking statements contained in this Annual Report. Important factors that could cause our actual results to differ materially from the forward-looking statements we make in this Annual Report are set forth in this report, including Risk Factors. There may be other factors that may cause our actual results to differ materially from the forward-looking statements.

All forward-looking statements attributable to us or persons acting on our behalf apply only as of the date of this Annual Report and are expressly qualified in their entirety by the cautionary statements included herein. We undertake no obligation to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances and do not intend to do so.

When we use the terms Osiris, we, us, and our we mean Osiris Therapeutics, Inc., a Delaware corporation.

Company Overview

We are a leading stem cell therapeutic company headquartered in Columbia, Maryland and focused on developing and marketing products to treat medical conditions in the inflammatory,

orthopedic, and cardiovascular areas. We were incorporated in Delaware in April 2002. Our predecessor company was organized in 1992. We currently manufacture, market and sell Osteocel® for regenerating bone in orthopedic indications. It is the only commercially available product in the U.S. containing viable stem cells. Our lead biologic drug candidate, Prochymal , is being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease (GvHD) and Crohn s disease, and is the only stem cell therapeutic currently granted both Orphan Drug and Fast Track status by the Food and Drug Administration (FDA). Prochymal is also being developed for the repair of heart tissue following a heart attack and for protection of pancreatic islet cells in patients with type 1 diabetes. Our pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen for osteoarthritis in the knee. We have also partnered with Genzyme Corporation to develop Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies.

Osiris is a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. We have developed an extensive intellectual property portfolio to protect our technology in the United States and a number of foreign countries including 47 U.S. and 253 foreign patents owned or licensed.

Osteocel and our two biologic drug candidates utilize human mesenchymal stem cells, or MSCs. MSCs can selectively differentiate, based on the tissue environment, into various tissue lineages, such as muscle, bone, cartilage, marrow stroma, tendon or fat. In addition, MSCs have anti-inflammatory properties and can prevent fibrosis or scarring. These characteristics give MSCs the potential to treat a wide variety of medical conditions. We believe that our biologic drug candidates have advantages over other stem cell therapeutics in development for the following reasons:

- **Stem Cell Source.** Our stem cells are obtained from adult bone marrow, a readily available source. The cells are drawn from the hips of volunteer donors between the ages of 18 and 30 years, using a simple needle and syringe aspiration. Because the cells are obtained from consenting adult donors, we are able to largely avoid the ethical controversy surrounding embryonic and fetal stem cell research.

- **Ability to Mass Produce.** Through our proprietary manufacturing methods, we can grow MSCs in a controlled fashion to produce up to 10,000 treatments of our biologic drug candidates from a single bone marrow donation. Our ability to produce a large quantity of treatments from one donation provides us with manufacturing efficiencies and product consistency that are essential to commercialization.

- **Universal Compatibility.** Many stem cell therapies under development can elicit a rejection response in the recipient and therefore require donor-to-recipient matching or potentially harmful immunosuppression. This greatly reduces manufacturing efficiencies and creates a risk of mismatch which can result in an acute inflammatory response and, potentially, in death. Based on our clinical experience, we believe that our biologic drug candidates are not rejected by the patient s immune system and so, like type O negative blood, do not require matching. This universal compatibility allows us to produce a standardized product available to all patients in almost any medical setting.

- **Treatment on Demand.** Our biologic drug candidates can be stored frozen at end-user medical facilities until they are needed. We anticipate that medical facilities will be able to prescribe and dispense these products in much the same way as conventional drugs. In contrast, other stem cell technologies under development require weeks to prepare after a patient s need is identified. This is a key feature of our technology, as many patients in the critical care setting require prompt treatment.

The following table summarizes key information about Osteocel and our biologic drug candidates.

Product/Candidate	Indication	Status
Osteocel	Spinal Procedures	Marketing
	Orthopedics	Marketing
Prochymal	Steroid Refractory Acute GvHD	Phase III
	First Line Treatment of Acute GvHD	Phase III
	Biologics Refractory Crohn s Disease	Phase III
	Type I Diabetes	Phase II
	Acute Myocardial Infarction	Phase II
	Acute Radiation Syndrome	Preclinical
Chondrogen	Osteoarthritis & Cartilage Protection	Phase I/II

Osteocel consists of a matrix of cancellous bone containing mesenchymal stem cells and is used in spinal fusion and other orthopedic surgical procedures. Cancellous bone is the porous and spongy inner structure accounting for approximately 20% of total bone mass. Osteocel is the only commercially available product containing viable stem cells in the United States. We launched Osteocel in July 2005 and to date it has been used in over 15,000 surgical procedures. We produce Osteocel from the marrow-rich bone of organ and tissue donors, and we believe that it is properly characterized, and regulated by the FDA, as a human cell, tissue, and cellular and tissue-based product, or HCT/P, under section 361 of the Public Health Service Act. Unlike our biologic drug candidates, our ability to supply Osteocel is limited by the amount of marrow-rich bone that we are able to obtain from organ and tissue donors. Osteocel is currently distributed non-exclusively by us and by Blackstone Medical (a subsidiary of Orthofix International NV) for orthopedic indications, and jointly by us and Blackstone Medical for spinal procedures. We are party to a multi-year agreement with AlloSource, a non-profit tissue procurement organization for the supply by AlloSource to us of tissue for use in the manufacture of Osteocel. Under the terms of the agreement, AlloSource has committed to provide bone matrix to us for use in the production of Osteocel, and to ensure that the technology is made available to the communities from which it is sourced, the agreement also enables AlloSource to act as a non-exclusive distributor of Osteocel in AlloSource s local donor communities. Recently, we entered into a multi-year agreement with Tissue Banks International (TBI), a non-profit tissue procurement organization for the supply by TBI to us of tissue for use in the manufacture of Osteocel. Under the terms of the agreement, TBI has committed to provide bone matrix to us for use in the production of Osteocel, and to ensure that the technology is made available to the communities from which it is sourced, the agreement enables TBI also to act as a non-exclusive distributor of Osteocel in TBI s local donor communities.

Prochymal is our lead biologic drug candidate and is being evaluated in Phase III clinical trials for three indications, including the first line treatment of acute GvHD, steroid refractory acute GvHD and biologics refractory Crohn s disease and is the only stem cell therapeutic currently designated by the FDA as both an Orphan Drug and Fast Track product.

Phase III Clinical Trial Steroid Refractory Acute GvHD

We are currently enrolling patients in a pivotal Phase III trial for the treatment of steroid refractory acute GvHD. GvHD is a life threatening immune system reaction that commonly affects the skin, gastrointestinal tract, and liver in patients who have received a bone marrow transplant. Although in the U.S. there are no drugs approved for treating GvHD, the disease is commonly treated off-label with steroids. GvHD that does not respond to this treatment is known as steroid refractory GvHD. A large majority of steroid refractory GvHD patients die within six months. In our Phase II trial for treatment refractory GvHD, we enrolled patients that did not respond to treatment with steroids and at least one second line therapy. Of these patients, 59% responded to Prochymal.

Our Phase III trial to evaluate Prochymal as a treatment for steroid refractory GvHD is a randomized, double blind, placebo controlled study designed to enroll up to 240 patients. The trial is investigating patient response to eight infusions of Prochymal administered twice per week for four consecutive weeks. The primary trial endpoint is complete resolution of GvHD for at least 28 day duration. Each patient will also be monitored for safety for up to 180 days after their first treatment with Prochymal. Six-month survival is a key secondary endpoint. This trial is being conducted in approximately 80 centers in the United States, Canada, Europe and Australia.

Phase III Clinical Trial First Line Treatment of Acute GvHD.

We are also enrolling patients in a Phase III trial evaluating Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD. Our Phase II trial for treatment of newly diagnosed acute GvHD, found that patients were twice as likely to have total clinical resolution of their disease when Prochymal was added to steroid therapy, compared to reported results for steroid only treatment. Twenty-nine of 31 patients, or 94% responded after receiving two infusions of Prochymal, with 24 patients, or 77% achieving a complete response, meaning the patients had experienced total clinical resolution of the disease. At six months, 61% of all patients treated with Prochymal still had a durable response requiring no additional immunosuppressive therapy, clinical intervention, or increased steroid use. Furthermore, 95% of patients achieving a durable response were alive at six months.

Our Phase III trial to evaluate Prochymal as a first line treatment for GvHD is a randomized, double blind, placebo controlled study designed to enroll up to 184 patients. The trial is investigating patient response to a total of six infusions during the first four weeks of the study. The primary trial endpoint is the proportion of patients who achieve a complete response at day 28 and who survive to day 90 without the addition of a second line therapy. The study is being conducted at approximately 50 centers in the United States and Canada.

Phase III Clinical Trial Biologics Refractory Crohn s Disease.

Based on our clinical observations of the effects of Prochymal on the gastrointestinal symptoms of patients with GvHD, we are developing Prochymal for the treatment of Crohn s disease. Crohn s disease is a chronic condition that results in inflammation of the gastrointestinal tract. We have completed patient enrollment in a Phase II trial for Crohn s disease under a separate Investigational New Drug application (IND). We received Fast Track designation from the FDA, for the development of Prochymal for moderate to severe Crohn s disease patients that are refractory to standard therapies, including biologics.

We are currently enrolling patients in a Phase III trial evaluating Prochymal for the treatment of moderate to severe Crohn s disease that is refractory to biological therapy. The study is designed to enroll up to 258 patients and is double blind, placebo controlled, and includes patients, 18 to 70 years of age, with a Crohn s Disease Activity Index (CDAI) greater than 250. The primary endpoint of this trial is the proportion of patients with CDAI of less than 150 (clinical remission) at day 28. The study is being conducted at 50 leading centers in the United States and Canada.

Phase II Clinical Trial Acute Myocardial Infarction.

Prochymal is also being evaluated for the repair of heart muscle in patients who have suffered a heart attack. Based on statistics published in 2005 by the American Stroke Association and the American Heart Association, approximately 700,000 individuals in the United States each

year experience their first heart attack. According to these same statistics, approximately 20% of these patients suffer extensive damage to their heart muscle leading to heart failure within six years. In preclinical studies in animal models, Prochymal targeted the damaged area of the heart following a single intravenous infusion. These studies also indicate that Prochymal prevents scar formation that

typically occurs after a heart attack and improves cardiac function eight to ten weeks after its administration.

We completed enrollment in a Phase I clinical trial for Prochymal to evaluate its safety and efficacy to restore heart function in patients experiencing a first time myocardial infarction (MI). In March 2007, we reported six-month results in this trial. In a 53-patient, double-blind, placebo- controlled study evaluating the safety and preliminary efficacy of the intravenous administration of Prochymal, MI patients receiving the therapy had significantly lower rates of adverse events, such as cardiac arrhythmias, as well as significant improvements in heart, lung and global function. Administration of Prochymal was found to be well tolerated at all dose levels. Based on these positive findings, we have received approval from the FDA to initiate a Phase II trial.

Phase II Clinical Trial Type 1 Early Onset Diabetes.

We have recently initiated a Phase II, 60 patient, placebo controlled study in the United States for the treatment of early onset type 1 diabetes in individuals 18 to 30 years old. We believe that based upon their mechanism of action, MSCs may home to the pancreas and inhibit the local immune and inflammatory responses, preventing the destruction of pancreatic islets and promoting the repair of pancreatic tissue damage. Patients must be enrolled within 2 to 16 weeks of being diagnosed with type-1 diabetes and will receive three infusions of Prochymal over the course of 60 days. Primary efficacy will be measured at six months and the primary endpoint is the marker of insulin response in response to glucose stimulation. We have entered into a collaborative agreement with the Juvenile Diabetes Research Foundation (JDRF) for this study. This agreement provides for JDRF to fund $4.0 million of clinical study costs during 2008 and 2009.

Preclinical Study Acute Radiation Syndrome.

In 2007, we partnered with Genzyme Corporation to develop Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies. In January 2008, we were awarded a contract from the United States Department of Defense (DoD) for the development and stockpiling of Prochymal for the treatment of acute radiation syndrome (ARS). Under the terms of the contract, DoD will provide funding to us in two stages, with an initial amount of $4.2 million expected to be earned in 2008. The fully funded value of the contract, assuming FDA approval of Prochymal for ARS and exercise by DoD of all of its purchase options for up to 20,000 doses of Prochmal at current prices ($10,000 per dose) is up to $224.7 million. We will carry out this contract in collaboration with Genzyme.

Chondrogen is our biologic drug candidate for the treatment of osteoarthritis and the reduction of pain in the knee. According to a 2005 article in the *American Journal of Sports Medicine*, approximately 1.0 million people have surgery to remove damaged or torn meniscus in the United States each year. As noted in a 1999 article in the journal *Sports Medicine*, patients who have had this procedure are 10 to 15 times more likely to develop osteoarthritis, a highly debilitating orthopedic condition. There are currently no FDA approved products available to regenerate meniscal tissue. In several preclinical studies, Chondrogen regenerated meniscal tissue and prevented osteoarthritis in animal models. We recently completed enrollment in a Phase I/II clinical trial for Chondrogen to evaluate its safety and efficacy in patients following surgery to remove torn meniscus. A total of 55 patients were treated in the Phase I/II, double-blind study evaluating the safety and exploratory effectiveness of Chondrogen, a preparation of adult stem cells formulated for direct injection into the knee. At the twelve month time point, Chondrogen met its primary endpoint, demonstrating product safety. The data also showed improvements in joint condition that correlated with a clinically and statistically significant improvement in pain in patients with osteoarthritis (OA) who received Chondrogen as compared to those treated with the control, hyaluronic acid (HA). Patients will be followed for safety and additional

preliminary efficacy, such as cartilage damage and changes in the meniscus for two years under the current study protocol.

We expended approximately $50.9 million in fiscal 2007, $37.6 million in fiscal 2006, and $16.9 million in fiscal 2005, on research and development. Our research and development expenditures in 2007 and 2006 were entirely sponsored by us. In 2005, we were reimbursed for $1.4 million of research and development expenditures through grants with the U.S. government. For more detailed financial information, including information regarding our revenues, profit and loss, and total assets and research and development costs and expenses for the past three fiscal years, see our Financial Statements included in Item 8 to this Annual Report on Form 10-K for fiscal year 2007.

Scientific Background

Stem cells are a special class of cells that can self-replicate and differentiate into multiple tissue types. Different populations of stem cells, also called progenitor or precursor cells, reside within the body. These cells are generally classified according to their differentiation potential, or ability to become distinct cell types. Embryonic stem cells are recognized as being totipotent, or unlimited, in terms of the number of different cell types they can become. Other stem cells are either multipotent, meaning capable of becoming two or more cell types, or unipotent, meaning preprogrammed for a single final cell type. Multipotent stem cells include the hematopoietic stem cells responsible for generating cells associated with the circulatory and immune systems, mesenchymal stem cells responsible for the formation of connective tissue cells, and neuronal stem cells dedicated to producing the different nervous system cell types. Stem cells participate in embryological and fetal development and orchestrate tissue repair following disease or injury in the adult. Though the precise mechanism of their activity has not yet been determined, experimental work has provided empirical evidence of the therapeutic benefit of various types of stem cells administered to animal and human subjects.

The embryonic stem cell, or ESC, has the greatest differentiation potential and is capable of developing into all cell types found within the human body. ESCs must be harvested from human embryos, giving rise to ethical controversies surrounding the procurement of ESCs, which have hindered progress in ESC research. The United States government has significantly restricted the funding of ESC research. Also, technical difficulties in purifying and growing ESCs have prevented widespread experimental work capable of withstanding academic or regulatory scrutiny.

In the adult, two major classes of stem cells exist in bone marrow, hematopoietic stem cells and mesenchymal stem cells. Throughout life, hematopoietic stem cells, or HSCs, located within the bone marrow give rise to most types of blood cells. HSC transplantation has served as the basis for a number of aggressive treatments for various types of cancer. However, therapies based on HSCs are largely limited to hematological disorders because HSCs can only differentiate into blood cells.

In contrast to HSCs, mesenchymal stem cells, or MSCs, are progenitor cells that differentiate into various connective tissues, such as bone, muscle, fat, tendon, ligament, cartilage and bone marrow stroma when they receive appropriate biochemical and biomechanical signals. Other biochemical stimuli cause MSCs to mobilize to areas of injury or inflammatory disease. Once there, MSCs coordinate tissue regeneration at a local level by producing tissue growth factors and by interacting with local cells to reduce inflammation and scarring. Importantly, MSCs do not express markers on the surface of cells, known as HLA class II antigens, which are responsible for recognition of the cells by the immune system. Also, the cell surface markers, CD40, CD80 and CD86, which are essential for activation of immune cells, are not present on MSCs. These characteristics allow MSCs to:

- be transplanted into an unrelated patient without giving rise to an immune response;
- regenerate connective tissues like bone and cartilage;
- act as a potent anti-inflammatory agent; and
- exhibit anti-fibrotic activity to limit tissue damage.

MSCs and HSCs are most readily isolated from bone marrow. Because MSCs represent a small fraction of bone marrow cells, they require amplification to be clinically useful. We have developed and optimized a proprietary process for isolating and expanding these cells using standardized cell culture methodologies. We can grow MSCs in a controlled fashion to produce up to 10,000 treatments of our biologic drug candidates from a single bone marrow donation.

Stem cells can be derived from either the patient, referred to as an autologous source, or from a donor, referred to as an allogeneic source. For many cell therapies, allogeneic sourcing is not possible due to the immune response that typically occurs following the injection of unrelated cells. The non-immunogenic nature of MSCs permits allogeneic cell sourcing and carries significant advantages over autologous sourcing. Allogeneic cell sourcing from a healthy donor population allows for specific quality control measures to select therapeutically optimal stem cells. For example, if a patient s cells are of poor quality due to advanced age, disease or metabolic state, the product to be re-infused will likely be of similar poor quality. We believe that allogeneic sources used in large scale production will enable us to utilize quality control practices to ensure that product potency is reproducible from treatment to treatment. We have developed and continue to develop quality standards for our biologic drug candidates, including potency assays directed to the specific indications for use. To our knowledge, no patients participating in our clinical trials or who have used Osteocel to date have experienced an immunogenic response.

Strategy

We are striving to be the first company to receive FDA marketing approval and to commercialize a stem cell drug therapy and become the world s leading provider of stem cell therapies.

Successfully commercialize our lead stem cell therapy, Prochymal. We are currently enrolling patients in three Phase III clinical trials for Prochymal. Assuming marketing approval, we plan to develop a sales and marketing force to promote Prochymal initially for the first line treatment of acute GvHD and steroid refractory acute GvHD, followed by moderate to severe Crohn s disease. Based on the small number of bone marrow transplantation hospitals in the United States and the lack of effective treatments for this population, we believe we can successfully market Prochymal with a specialized sales force for the treatment of GvHD.

Expand our pipeline of biologic drug candidates where our stem cell technology has a therapeutic potential. We are continuously investing in our biologic drug candidate pipeline by evaluating our therapies in additional diseases and disorders where we believe MSCs have potential therapeutic benefit. This will allow us to maintain our position as the leader in cellular therapeutics.

Exploit our MSC technology, manufacturing ability and proprietary know-how to advance our pipeline. We intend to leverage our preclinical research, safety data and manufacturing ability to rapidly and efficiently grow our biologic drug candidate pipeline. Because we utilize MSCs as the active agent for all of our biologic drug candidates, we believe the accumulated safety data will reduce the time and cost associated with early stage clinical trials for new indications.

Internally develop and commercialize future biologic drug candidates. We believe that we have the requisite experience to develop and commercialize our unpartnered biologic drug candidates and any future biologic drug candidates without the help of a strategic partner. Due to our experience with Osteocel and our current pipeline candidates, we believe we have gained the clinical, regulatory, manufacturing and commercial capabilities to successfully develop and commercialize biologic drug candidates.

Marketed Product

Osteocel®

Osteocel consists of a matrix of cancellous bone containing mesenchymal stem cells and is used in spinal fusion and other orthopedic surgical procedures. It is the only commercially available product in the United States containing viable stem cells. We launched Osteocel in July 2005 and to date it has been used in over 15,000 surgical procedures. Osteocel is currently distributed non-exclusively by us, Blackstone Medical, AlloSource and TBI for orthopedic indications, and by us jointly with Blackstone Medical for spinal procedures.

According to data published by the Centers for Medicare and Medicaid Services, over 900,000 surgeries are performed in the United States each year that require the reconstruction or replacement of bone. The standard of care is a procedure known as autograft, in which bone is harvested from another site within the same patient and transferred to the site of injury. The harvested bone contains stem cells and is often an effective agent for regenerating bone. However, this procedure has significant disadvantages. An additional surgery is required to obtain the autograft bone, resulting in increased time under anesthesia, additional blood loss, and the costs associated with an additional surgery. These patients also face an increased risk of infection and may experience chronic post-operative pain from the harvest procedure. As noted in an article published by the University of California, Los Angeles (UCLA) Department of Orthopaedic Surgery, complications from the autograft harvest occur in up to 35% of patients having the procedure. As such, we believe there is a significant medical need for a product that can promote bone formation reliably and eliminate the need for autograft.

Spinal fusion is a surgical procedure used to correct problems in the spine bones, or vertebrae, and is one of the most common and expensive surgeries in orthopedics. Based on data published by the Centers for Medicare and Medicaid Services, there were 450,000 spine fusion surgeries in 2003, associated with multi-billion dollar health care costs. All spinal fusion surgeries require autograft or other material to support bone formation. Non-viable bone sourced from cadavers, synthetic materials, and recombinant growth factors are used as alternatives to autograft. Each has significant limitations and none has the same regenerative characteristics of autograft. While Osteocel contains the same bone forming properties as autograft, it has several distinct advantages:

- Osteocel avoids the potential complications and expense of an additional surgical procedure;

- the availability of Osteocel during surgery is limited only by the in-house supply, while autograft availability is limited to the amount harvested from the patient in the prior surgical procedure;

- every lot of Osteocel is tested to ensure consistent quality, while the quality of the autograft is dependent upon the health of the patient; and

- ease of use, storage characteristics, and shelf life allow Osteocel to be used in virtually any surgical setting where bone formation is needed.

Osteocel works in three ways. The cancellous bone matrix of Osteocel is osteoconductive, meaning it encourages new bone growth by providing a scaffold to support bone formation. Osteocel is also inductive. Osteoinduction is the indirect promotion of bone formation by recruiting the patient s cells to the site through signaling mechanisms. Lastly, the stem cells contained in Osteocel make it osteogenic. Osteogenesis is the ability of certain cells to form bone directly. Only two current treatments contain all three of these necessary components for new bone growth: autograft and Osteocel. Over the past 10 years our scientists have published over 20 peer reviewed journal articles demonstrating the consistent osteogenic capabilities of the MSCs in Osteocel.

We produce Osteocel from the marrow-rich bone of organ and tissue donors. Since its introduction in July 2005, we have been unable to produce quantities of Osteocel sufficient to meet surgeon demand. During 2006, we were constrained by our manufacturing facility and limitations on the supply of marrow-rich bone obtainable from adult organ and tissue donors. To increase our ability to supply

our customers, we expanded our manufacturing capacity and increased the number of organ and tissue agencies that supply us with tissue. We are party to a multi-year agreement with AlloSource, a non-profit tissue procurement organization, for the supply by AlloSource to us of tissue for use in the manufacture of Osteocel. AlloSource has committed to to provide bone matrix to us for use in the production of Osteocel, and to ensure that the technology is made available to the communities from which it is sourced, the agreement enables AlloSource to act as a non-exclusive distributor of Osteocel in AlloSource s donor communities. Recently, we entered into a multi-year agreement with Tissue Banks International (TBI), a non-profit tissue procurement organization for the supply by TBI to us of tissue for use in the manufacture of Osteocel. Under the terms of the agreement, TBI has committed to provide bone matrix to us for use in the manufacture of Osteocel, and to ensure that the technology is made available to the communities from which it is sourced, the agreement enables TBI also to act as a non-exclusive distributor of Osteocel in TBI s local donor communities.

We believe that Osteocel is properly characterized, and regulated by the FDA, as a HCT/P under section 361 of the Public Health Service Act.

We are in the process of developing a second generation MSC product for bone repair, Osteocel-XC , as a long-term strategy to relieve supply constraints. Unlike Osteocel, Osteocel-XC will utilize culture-expanded MSCs like our other biologic drug candidates. Based on our clinical and preclinical experience with Osteocel and MSCs, we are preparing to submit an Investigational New Drug application to FDA to study Osteocel-XC.

Revenues from sales of Osteocel were $15.2 million in fiscal 2007, $8.3 million in fiscal 2006 and $1.0 million in fiscal 2005.

Clinical Programs

Prochymal

Prochymal is our biologic drug candidate that is being used to treat medical conditions in a variety of indications. Prochymal is being evaluated in Phase III clinical trials for three indications, including first line and steroid refractory acute Graft versus Host Disease (GvHD) and Crohn s disease, and is the only stem cell therapeutic currently designated by the FDA as both an Orphan Drug and Fast Track product. Prochymal is also being developed for the repair of heart tissue following a heart attack and for the protection of pancreatic islet cells in patients with type 1 diabetes. We are also developing Prochymal as a medical countermeasure to nuclear terrorism and other radiological countermeasures.

Graft versus Host Disease

GvHD is a life threatening immune system reaction that commonly affects the skin, gastrointestinal tract, and liver in patients who have received a bone marrow transplant. We estimate that there are approximately 3,000 instances of GvHD in the United States each year.

Bone marrow transplantation is a treatment of last resort for patients with certain cancers and some genetic diseases. This procedure can result in a particularly serious type of rejection referred to as acute GvHD. This condition gets its name because the bone marrow transplant, or the graft, begins to attack the recipient, or the host. As noted in an article published in the journal *Biology of Blood and Marrow Transplantation* in 2005,

acute GvHD is one of the most common complications of allogeneic bone marrow or hematopoietic stem cell transplantation, affecting approximately 50% of transplant patients. Acute GvHD is graded for prognostic and treatment purposes on a four grade scale, with Grade I considered mild, Grade II moderate, and Grades III-IV considered severe and life-threatening. The onset of GvHD in patients who have received a bone marrow transplant leads to a poor prognosis because of the already weakened state of such patients. According to a 2002 article published in *Biology*

of Blood and Marrow Transplantation, the estimated one-year survival rate for patients with acute GvHD decreases drastically with increasing disease severity, as illustrated below:

Acute GvHD	Estimated One Year Survival
Grade I	65%
Grade II	60%
Grade III	39%
Grade IV	22%

Typically, patients are treated aggressively with steroids when their GvHD reaches Grade II. A 2001 article published in the journal *Blood* noted that approximately 50% of these patients will not respond to treatment with steroids and approximately 50-80% of steroid refractory GvHD patients die of the disease.

The current treatments available for acute GvHD are inadequate in several ways. First, mortality in patients with acute GvHD is unacceptably high. Second, most treatments for acute GvHD work by suppressing or destroying the immune system. This leads to a number of debilitating side effects, including severe and life threatening infection. Unlike steroids or other immunosuppressant drugs, which have a systemic effect, Prochymal s mechanism of action is designed to specifically target areas of inflammation. Therefore, we believe the use of Prochymal will result in a lower rate of life threatening infection.

We are currently enrolling patients in two Phase III pivotal trials for acute GvHD and have been granted Fast Track status by FDA for both. The first Phase III trial is investigating Prochymal in patients with steroid refractory GvHD. Approximately 80 sites in the United States, Canada, Europe and Australia are participating in this trial. The second Phase III trial is evaluating Prochymal as a first line treatment for acute GvHD and is taking place in approximately 50 leading centers in the United States and Canada.

A program is also ongoing to provide Prochymal in a compassionate use setting for pediatric patients with severe treatment refractory acute GvHD and no remaining treatment options. At the end of 2007, data was reported for a total of twelve pediatric patients between five months and fifteen years of age suffering from severe (Grade III/IV) acute GvHD. These patients had failed, on average, 3.2 lines of therapy prior to treatment with Prochymal. Patients received a median of eight infusions of Prochymal (range 3-21) at a dose of 2 million cells per kilogram of body weight. All patients (12/12) experienced an objective clinical response to therapy, with 58% (7/12) of patients achieving a complete resolution of their GvHD. The 100 day survival was also 58% (7/12) and directly correlated with response rate. There were no infusional toxicities associated with the administration of Prochymal. This pediatric compassionate use program for Prochymal is ongoing.

We completed a Phase II trial evaluating Prochymal as a first-line treatment in combination with steroids, for patients diagnosed with Grade II through Grade IV acute GvHD. A total of 32 patients were treated with two infusions of Prochymal, administered 72 hours apart. The treatment commenced within 48 hours of GvHD diagnosis. In this study, we were evaluating safety, dose and response to treatment by day 28. When Prochymal was added to steroid therapy, patients were twice as likely to have total clinical resolution of their disease compared to reported results for steroid only treatment. Twenty-nine of 31 patients, or 94% responded after receiving two infusions of Prochymal, with 24 patients, or 77% achieving a complete response, meaning the patients had experienced total clinical resolution of the disease. At six months, 61% of all patients treated with Prochymal still had a durable response requiring no additional use. Furthermore, 95% of patients achieving a durable response were alive at six months.

Beginning in 2004, several requests were made by physicians to use Prochymal in a compassionate use setting for patients with acute severe treatment refractory GvHD and no remaining treatment

options. Both pediatric and adult patients that had failed to respond to steroids and other immunosuppressive agents were treated on an emergency-use basis, and clinical improvements were seen in gastrointestinal and skin GvHD. Patients were treated with Prochymal every 72 hours as needed for response, for a maximum of eight treatments. Fourteen patients were treated and had failed to respond to an average of 4.4 other drug therapies prior to treatment with Prochymal. A 59% Prochymal response rate was observed in this treatment refractory population, defined as an improvement in at least one affected organ by at least one full GvHD stage without disease progression in any other organ. Because the patients in this trial had previously not responded to multiple lines of therapy and their condition was immediately life threatening, for ethical reasons the use of a placebo control was not possible. Therefore, further analysis of the statistical significance of our results was not performed.

In 2003 we completed a Phase I trial to determine the safety of Prochymal in patients who received hematopoietic stem cell transplants. The trial investigated patient response to three different doses of Prochymal. No safety concerns related to the use of Prochymal were observed in the 46 subjects who were evaluated.

We obtained both Fast Track and Orphan Drug designation in 2005 for the use of Prochymal in GvHD patients. The FDA grants Fast Track designation to investigational drugs that have the potential to treat life-threatening diseases with unmet medical needs. Our Biologic License Application will be eligible for an expedited review process by the FDA as a result of this designation. Orphan Drug designation offers several benefits including eligibility for grants to fund studies,, up to seven years of marketing exclusivity and a waiver of the Biologic License Application fee of approximately $900,000. Prochymal is the only stem cell therapeutic currently designated by the FDA as both an Orphan Drug and Fast Track product candidate.

Crohn s Disease

Based on our clinical observations of the effects of Prochymal on the gastrointestinal symptoms of patients with GvHD, we are developing Prochymal for the treatment of Crohn s disease. Crohn s disease is a chronic, life-long condition that features relapsing inflammation of the gastrointestinal tract. Severe Crohn s disease can cause intractable diarrhea and abdominal pain, undesirable changes in lifestyle, hospitalization, and unwanted side effects from required medications. Approximately 60% of Crohn s disease patients require at least one surgery to remove an affected portion of their intestine at some time during their lifetime, according to a 2002 article in the journal *Alimentary Pharmacology & Therapeutics*. This article further notes that there are over 500,000 cases of diagnosed Crohn s disease in the United States, and at any given time approximately 10% of these cases have a severe exacerbation or relapse that does not respond to traditional immunosuppressive treatments. Standard treatments of steroids and other immune suppressants often cause secondary health problems. According to a 2003 article in the *British Journal of Clinical Pharmacology*, with current medical therapies about 50% of patients with severe Crohn s disease will relapse within one year.

We completed a Phase II trial studying Prochymal as a treatment for moderate to severe Crohn s disease that is refractory to steroids and other immune suppressants. We enrolled ten patients in this study and communicated the results during the October 2006 annual meeting of the American College of Gastroenterology. The trial was a prospective, randomized, open label trial, conducted at 4 leading centers in the United States. Patients with moderate to severe Crohn s disease, defined as having a Crohn s Disease Activity Index (CDAI) of at least 220, who had previously failed treatment with steroids and other immunosuppressive agents, were given two infusions of Prochymal seven days apart. A total of ten patients were treated and nine patients were evaluated through the 28 day follow-up. One patient elected to exit the trial prior to completion. Patients were assigned to one of two treatment groups and received Prochymal on an outpatient basis. In addition to safety parameters, patients were evaluated for changes in CDAI and improvement in the Inflammatory Bowel Disease

Questionnaire (IBDQ). Prior to entering the trial, patients who had been treated with infliximab or other biological agents were required to complete a washout period of 90 days to preclude the possibility that response was the result of a previous treatment.

Entering the trial, the average CDAI score at baseline was 341. Patients entering this study had suffered from Crohn s disease for an average of 14.2 years, and 80% of the patients required prior surgical intervention to treat their Crohn s disease. In the study, one-third of the patients had a reduction of CDAI of greater than 100 points within 14 days of treatment. Each of these responders had failed previous treatment with infliximab (Remicade(R)). Mean IBDQ scores improved significantly from baseline to day 28 (113 to 146, p=0.008). One-third of the patients reported IBDQ scores of at least 170, indicating they had achieved clinical remission of their disease. Although not reaching statistical significance, there appeared to be correlation between dose and response. Patients receiving the high dose had a 72-point greater reduction in CDAI than those receiving low dose (CDAI reduction of 137 vs. 65). There were no infusional toxicities, and no treatment-related severe adverse events.

As a result of the encouraging data, we are enrolling patients in a Phase III trial evaluating Prochymal for the treatment of moderate to severe Crohn s disease that is refractory to biological therapy. The study is designed to enroll up to 258 patients and is double blind, placebo controlled, and includes patients, 18 to 70 years of age, with a Crohn s Disease Activity Index (CDAI) greater than 250. The primary endpoint of this trial is the proportion of patients with CDAI of less than 150 (clinical remission) at day 28. The study is being conducted at 50 leading centers in the United States and Canada. We have received Fast Track designation from the FDA, which makes us eligible for expedited FDA review of Prochymal for this indication.

Acute Myocardial Infarction

We are also evaluating Prochymal for the repair of heart muscle in patients who have suffered a heart attack. Preclinical studies indicate that Prochymal prevents scar formation that typically occurs after a heart attack and improves cardiac function eight to ten weeks after its administration. As discussed further below, we completed enrollment in a Phase I clinical trial for Prochymal in March, 2006. This trial is designed to evaluate the safety and efficacy of Prochymal to restore heart function in patients experiencing a first time heart attack.

A heart attack, or acute myocardial infarction (AMI), occurs when coronary arteries become blocked with fatty deposits, depriving the heart muscle of oxygen and nutrients. Based on statistics published in 2005 by the American Stroke Association and the American Heart Association, in the United States approximately 700,000 individuals each year experience their first heart attack. According to these same statistics, approximately 20% of patients experiencing their first heart attack suffer extensive damage to their heart muscle, leading to heart failure within six years. Furthermore, we believe the statistics indicate that despite improvements in the standard of care, this progression from myocardial infarction to heart failure remains largely unavoidable in patients with AMIs.

Prochymal is being developed for the treatment of heart muscle damage following AMI. Its primary indication is to treat post-AMI complications and prevent the formation of scar tissue and associated cardiac dysfunction. Our preclinical studies indicate that the mechanism by which Prochymal improves myocardial function includes the prevention of pathological scarring of the heart muscle and the formation of new blood vessels. We are developing Prochymal as a therapy to be delivered through a standard intravenous line up to 10 days post-myocardial infarction.

In preclinical studies, Prochymal selectively targeted the damaged area of the heart when a single infusion was administered. These studies also indicated that Prochymal has the effect of retarding or stopping the progression of further cardiac tissue deterioration and limiting the damage caused by an AMI. Significant improvements in cardiac function as demonstrated by increased ejection fraction, reduced end diastolic pressures,

and reduced wall stress were observed eight to ten weeks after

administration of Prochymal. A preclinical study was performed to determine if an intravenous infusion of MSCs following myocardial infarction would result in an improvement in cardiac function. Significant improvement in cardiac function as indicated by left ventricular ejection fraction was observed three months after infarct in those animals receiving intravenous delivery of MSCs compared to control animals. MSCs were detected in the damaged area of the heart muscle of Prochymal treated animals, but not in the remote, undamaged regions.

In March 2006, we completed enrollment of a 53-patient Phase I randomized, double blind, placebo controlled clinical study to evaluate Prochymal in patients following AMI. The trial was designed to investigate patient response to three different doses of Prochymal or placebo. Exploratory efficacy endpoints included overall improvement in the function and remodeling of the heart muscle six months after treatment. A safety evaluation for each subject will be conducted two years after the subject is enrolled in the trial.

In March 2007, we reported six-month results in this trial. Heart attack patients receiving Prochymal had significantly lower rates of adverse events, such as cardiac arrhythmias, as well as significant improvements in heart, lung and global function. Administration of Prochymal was found to be well tolerated at all dose levels. Patients in the Prochymal group were four times less likely to experience an arrhythmic event compared to those receiving placebo (9% vs. 37%, p=0.025). Fewer patients experienced clinically significant premature ventricular contractions after receiving Prochymal as compared to placebo at the one month (6% vs. 32%, $p < 0.05$) and two month (9% vs. 38%, $p < 0.05$) time points. Patients with anterior wall myocardial infarctions had a statistically significant 7.0 point (24%) improvement in ejection fraction at three months and a 7.3 point (25%) improvement at six months over baseline ($p<0.05$). In comparison, placebo patients in this group did not have a significant increase. Patients receiving Prochymal had significantly improved pulmonary function as measured by improvement in FEV1% predicted values (17 point Prochymal vs. 6 point placebo, $p<0.05$). Significantly more patients who received Prochymal experienced improvement in their overall condition at six months as compared to those receiving placebo (42% vs. 11%, p=0.027).

In February 2008, we reported interim results at the one-year time point in the Phase I trial. The trial continued to demonstrate Prochymal s strong safety profile as well as continued statistically significant improvement in heart function. One year magnetic resonance imaging (MRI) data on left ventricular ejection fraction (LVEF) was collected and patients treated with Prochymal showed a statistically significant 5.2 point increase over baseline (p=0.021). Patients receiving placebo showed only a 1.8-point improvement over baseline, which was not statistically significant. Patients with more severe myocardial infarction, defined as a baseline LVEF of 45 or less, demonstrated even greater effects. The Prochymal treatment group showed a 6.5-point improvement one year post-treatment, compared to a 1.9-point increase in the placebo group. Prochymal treated patients continued to experience fewer adverse events at a rate of 6.1 per patient, compared to 8.0 per patient in the placebo group. This one-year interim analysis was performed as a part of the full two-year follow-up, and as a result, contains only limited data.

Based upon the positive results from the Phase I trial, we received approval from the FDA to initiate a Phase II trial.

Type 1 Diabetes

We are also investigating Prochymal as a treatment for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus. Type 1 diabetes, commonly known as juvenile diabetes or insulin-dependent diabetes, is an autoimmune disorder that attacks and destroys insulin producing islet cells in the pancreas causing glucose accumulation in the blood. As a result, those suffering from type 1 diabetes must take insulin to regulate blood sugar levels. Over time, poorly controlled diabetes can lead to serious health conditions, including heart disease, stroke, blindness, amputations, kidney disease and nerve damage. Currently, there are no preventative measures for

type 1 diabetes. In preclinical research, both animal and human bone marrow-derived mesenchymal stem cells (MSCs) were shown to preserve beta cell function in animal models of diabetes.

In October 2007, we reported the initiation of a Phase II trial evaluating the safety and efficacy of Prochymal in conjunction with standard of care in preserving insulin production in patients recently diagnosed with type 1 diabetes mellitus. The trial is double-blind, placebo-controlled and will target the enrollment of 60 patients. Patients in the study will receive three intravenous infusions of Prochymal over the course of sixty days. The primary endpoint of the trial is the measurement of C-peptide produced during a Mixed Meal Tolerance Test in patients treated with Prochymal, compared to those receiving placebo. This test is frequently used in diabetic patients to determine how much insulin is being produced by the pancreas in response to glucose stimulation. The patients in the trial will be followed for safety and efficacy for two years

Chondrogen

Chondrogen is our biologic drug candidate for regeneration of meniscus, a type of cartilage that cushions the knee joint. There are currently no FDA approved products available to regenerate meniscal tissue. In several preclinical studies, Chondrogen, a preparation of adult stem cells formulated for direct injection into the knee, regenerated meniscus and prevented osteoarthritis in animal models. As described further below, at the end of the first quarter of 2006 we completed enrollment in a Phase I/II clinical trial for Chondrogen, designed to evaluate the safety and preliminary efficacy in patients following surgery to remove torn meniscus.

The meniscus is a crescent-shaped cushion in the knee joint that protects cartilage and enables the knee to move smoothly. Injury and tears to the meniscus are common and can be traumatic, arising from sports injury for example, or degenerative, due to daily wear and tear. An injured or torn meniscus is painful and typically requires surgical intervention. The current standard of care for significant injuries is partial meniscectomy surgery, in which the damaged portion of the meniscus is permanently removed. According to a 2005 article in the *American Journal of Sports Medicine*, approximately 1.0 million people have surgery to remove damaged or torn meniscus in the United States each year. As noted in a 1999 article in the journal *Sports Medicine*, patients who have had this procedure are 10 to 15 times more likely to develop osteoarthritis, a highly debilitating orthopedic condition. As a result, a significant medical need exists for a product that can regenerate the meniscal tissue removed during surgery and prevent cartilage degeneration.

At the end of the first quarter of 2006, we completed a randomized double-blind, placebo controlled Phase I/II clinical trial evaluating Chondrogen for safety and preliminary efficacy based upon regeneration of meniscus at six-months. We plan on evaluating each patient for safety two years after the patient enrolled in the trial. Participants in the trial received one of two doses of Chondrogen or placebo, and a total of 55 patients were treated. At the six-month time point, Chondrogen met its primary endpoint, demonstrating product safety. An initial review of the data showed that Chondrogen was well tolerated, was not associated with serious adverse events, did not result in any adverse hematological events, and did not result in the formation of any unwanted or ectopic tissue. There was no significant change in the volume of meniscus on MRI at six-months in patients that received Chondrogen compared to those patients receiving placebo. However, about 30% of patients treated with Chondrogen demonstrated an improvement in their baseline cartilage or joint condition, while no patients in the placebo group demonstrated similar improvement.

In November 2007, we reported one-year data for the Phase I/II Chondrogen trial. The data continued to show improvements in joint condition that correlated with a clinically and statistically significant improvement in pain in patients with osteoarthritis (OA) who received Chondrogen as compared to those treated with the control, hyaluronic acid (HA). Patients receiving the control were 3.5 times more likely to experience degenerative bone changes associated with OA as compared to those receiving Chondrogen. The effects were dose dependent and pain scores improved from six

15

months to one year following treatment, suggesting Chondrogen caused a biological modification of patients OA. Patients will be followed for safety and additional preliminary efficacy, such as cartilage damage and changes in the meniscus for two years under the current study protocol.

Collaborations

JCR Pharmaceuticals Co., Ltd. License Agreement

In August 2003, we entered into a license agreement with JCR Pharmaceuticals Co., Ltd. (JCR), pursuant to which we granted to JCR an exclusive right in Japan to our MSC technology for use in connection with the use of hematopoietic stem cells derived from peripheral blood, cord blood or bone marrow in the treatment of hematological malignancies.

The license agreement provided for a payment by JCR to us of an up-front license fee of $3.0 million and payment of an additional $0.5 million upon certain technology transfer. In addition, if and when marketing approval is obtained in Japan, JCR is required to pay up to $7.0 million in pre-commercialization milestones per product and certain amounts for pre-determined thresholds of cumulative net sales. Lastly, JCR has an obligation to pay royalties to us, with such amount dependent upon the cumulative net sales. We received a $0.5 million milestone payment in 2007 when JCR filed an IND in Japan.

Under the terms of the collaborative arrangement, JCR will bear all costs associated with bringing the drug to market in Japan. JCR is obligated to use its reasonable best efforts to develop and commercialize in Japan products covered under the terms of the license, including conducting clinical trials and procuring regulatory and other approvals. The license expires with respect to specific products on the later of 15 years from the date of the first sale of the product in Japan or the date on which our last patent in Japan covering that product expires. Also, the license and the collaboration can be terminated unilaterally by JCR upon 180 days notice to us or by mutual agreement between us and JCR.

In conjunction with this collaboration, JCR made a $3.0 million investment in our preferred stock, which converted at the closing of our initial public offering into 136,363 shares of our common stock.

Genzyme Corporation Collaboration Agreement

In July, 2007, we entered into an agreement with Genzyme Corporation for collaboration in the preparation and execution of development and purchase agreements with United States and Allied government agencies for countermeasures to nuclear terrorism and other radiological emergencies. In January 2008, we were awarded a contract from the United States Department of Defense (DoD) for the development and stockpiling of Prochymal for the treatment of Acute Radiation Syndrome (ARS). Under the terms of the contract, the DoD will provide technology and product development funding to us in two stages, with an initial amount of $4.2 million expected to be earned in 2008. The contract further provides for additional funding for activities leading to FDA approval of Prochymal for ARS and the scaling up of manufacturing processes, and provides the DoD with successive options for the purchase of up to 20,000 doses of Prochymal in the aggregate. The total value of the contract, assuming FDA approval and the exercise by the DoD of all of its options to purchase doses of Prochymal at current prices ($10,000 per dose), is up to $224.7 million. We will carry out this contract in partnership with Genzyme, with us contributing Prochymal and our corresponding safety and advocacy database to the effort, and with Genzyme lending its mass product development and large scale commercialization expertise. Our agreement with Genzyme provides for Genzyme to receive a royalty of 15% of net product sales, limited

to those sales made under contracts with United States or Allied government agencies for emergency preparedness.

Juvenile Diabetes Research Foundation Collaborative Agreement

In October 2007, we entered into a collaborative agreement with the Juvenile Diabetes Research Foundation (JDRF) for the development of Prochymal as a treatment for the preservation of insulin production in patients with newly diagnosed type 1 diabetes. Under the terms of the agreement, JDRF has agreed to fund $4.0 million of the research costs, payable to us based upon the achievement of established milestones. We expect to earn $2.0 million during 2008 from the agreement, and $2.0 million during 2009.

Blackstone Medical, Inc. Distribution Agreement

In November 2005, we entered into a distribution and supply arrangement for Osteocel with Blackstone Medical, Inc., or Blackstone. Blackstone has since been acquired and now operates as a division of Orthofix International, N.V. Blackstone has the right to distribute Osteocel in the United States for the treatment of spinal injuries or diseases. In addition, we granted Blackstone an exclusive distribution right with regard to spinal implant manufacturers provided that it commits to purchase at least 80% of the quarterly production forecast of Osteocel at a stipulated price per unit.

Blackstone markets Osteocel under the Trinity name. We have also retained the right to directly market and distribute Osteocel under the Osteocel brand.

Blackstone is required to use its best efforts to distribute Osteocel. Unless earlier terminated, the agreement terminates on December 31, 2008; however, it can be renewed for one-year periods so long as Blackstone achieves certain predetermined performance objectives.

Either party may terminate the agreement immediately upon written notice to the other party of the occurrence of certain bankruptcy events or failure to remedy a material breach that continues for more than 30 days.

Boston Scientific Corporation Research, Development and Commercialization Collaboration

In March 2003, we entered into a collaboration agreement with Boston Scientific Corporation, or Boston Scientific, to develop applications of our MSC technology to treat acute myocardial infarction and chronic ischemia. In connection with this collaboration, we granted to Boston Scientific a worldwide, exclusive license to develop, market and distribute MSC products in the covered field.

Boston Scientific paid a $5.0 million licensing fee to us upon the effectiveness of the license, and lent us $5.0 million under a line of credit that was established in connection with the collaborative agreement. In conjunction with this collaboration, Boston Scientific made a $10.0 million investment in our preferred stock, which converted at the closing of our initial public offering into 500,000 shares of our common stock.

In December 2007, we terminated the research, development and commercialization collaborative agreements with Boston Scientific and regained the worldwide rights to cardiac indications. Upon termination of the agreements, the outstanding amounts due under the line of credit, together with accrued interest were converted into a one-year 8% promissory note which is payable in quarterly installments beginning in January 2008.

Intellectual Property

We have established a considerable patent position in adult stem cell technology. We currently own or have exclusive licenses to approximately 47 issued U.S. patents. Foreign counterparts to these patents, including composition of matter claims, have been filed, and we own or hold licenses to approximately 253 issued patents in Europe, Canada, Australia and other countries. The patents and patent licenses included in our portfolio address the composition and therapeutic use of mesenchymal

stem cells. We are committed to protecting our intellectual property position and to aggressively pursue our patent portfolio, and have approximately 13 additional U.S. patent applications pending and approximately 59 foreign patent applications on file but not yet allowed. For most of our biologic drug candidates, we rely on multiple patents in combination.

Through our experience with MSCs and MSC-based product development, we have developed expertise and know-how in this field. We manufacture clinical grade MSCs in-house and contract for the production through contract manufacturers. To protect this non-patentable know-how, our policies require confidentiality agreements with our employees, consultants, contractors, manufacturers, outside collaborators, sponsored researchers, and advisors. These agreements generally provide for protection of confidential information, restrictions on the use of materials and assignment of inventions conceived during the course of performance for us. These agreements might not effectively prevent disclosure of our confidential information.

We were founded on the basis of MSC technology obtained from Case Western Reserve University, or CWRU. In January 1993, we entered into a Technology Transfer and License Agreement with CWRU, which was subsequently amended in October 1999 and twice in October 2003. Pursuant to this license agreement certain patents were assigned to us and others were exclusively licensed to us, with the right to grant sublicenses.

The exclusive license is subject to any rights of a governmental agency based on research funding by such an agency, and to CWRU s retained rights under the patents for non-clinical research, testing or educational purposes of CWRU.

With respect to the patents licensed to us, we are obligated to pay royalties to CWRU based on sales of products covered by granted licensed patents, and such royalties commence with respect to each such product on the third anniversary of the initial sale thereof. We are also obligated to pay minimum royalties under the agreement with CWRU. We are responsible for patent costs and along with CWRU have the right to enforce licensed patents. The license is terminable by CWRU in the event that there is a material breach by us. Otherwise the license is for the life of the patents. Under certain circumstances, we are obligated to negotiate in good faith with a third party a sublicense under patents licensed from CWRU and under patents and know-how owned by us that are reasonably required by the third party to exercise the granted sublicense. We are not obligated to grant such a sublicense where it would have a potential adverse effect on a product being researched, developed or commercialized by us or by a licensee or sub licensee of ours.

Under terms of a Marketing, Collaboration and License Agreement with Lonza, we have licensed our MSC technology to Lonza to sell MSCs, the MSC descendants, cells produced from MSCs and materials used with MSCs for commercial and non-commercial research purposes. Under the terms of this agreement, Lonza is specifically precluded from selling the licensed products for use in humans. We receive royalties on any sales under this agreement.

Patent life determination depends on the date of filing of the application or the date of patent issuance and other factors as promulgated under patent law. The United States Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, permits a patent extension of up to five years as compensation for patent term lost during the FDA regulatory review process. The patent term restoration period is generally one-half the time between the effective date of an Investigational New Drug Application or IND and the submission date of a New Drug Application or NDA, plus the time between the submission date of an NDA and the approval of the drug. Only the earliest patent applicable to an approved drug is eligible for the extension. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves applications for patent term extension. We expect to apply for patent term extensions for eligible patents to add patent life beyond the expiration date, depending on the expected length of clinical trials and other factors involved in the filing of a new drug application.

Manufacturing

Production of Biologic Drug Candidates

We believe that we have differentiated ourselves from other stem cell companies through proprietary manufacturing methods that allow for the controlled growth of MSCs to produce up to 10,000 treatments of our biologic drug candidates from a single bone marrow donation. This is in contrast to most other stem cell technologies that are able to make only a single treatment from each donation.

We have been manufacturing mesenchymal stem cells for over nine years. The first material manufactured in-house was released in 1999. Since that time manufacturing has continued to improve in support of clinical trials. The current manufacturing process utilizes cell factories, a closed system of surfaces on which the cells adhere, for stem cell expansion. We have developed this technology into a reproducible process that can be scaled up at additional sites. A second manufacturing site was successfully qualified in 2003. In addition, JCR Pharmaceuticals, our partner in Japan, has successfully implemented our manufacturing technology in Japan. We believe that we perform all of our manufacturing activities in compliance with the FDA s current Good Manufacturing Practice requirements.

Our manufacturing process begins with the collection of bone marrow aspirate from qualified volunteer donors, 18-30 years of age. Prior to donation, these individuals are screened and tested for a battery of diseases including HIV and hepatitis according to the FDA s donor suitability guidance. We purchase bone marrow aspirate from commercial sources. Since the mesenchymal stem cell is extremely rare, accounting for only one in every 100,000 cells in bone marrow, an initial purification process is required. Upon arrival at our facilities, MSCs are isolated and selectively removed from the bone marrow through a multi-step process. A beneficial feature of our stem cells is that they adhere to the surface of the cell factory and the other remaining cell populations do not adhere and are washed away throughout the process. Our stem cells are then expanded, harvested, packaged and cryopreserved as an in-process intermediate, and we conduct a second battery of quality testing. Each packaged intermediate is further expanded and formulated to produce the final product. Sterility and quality testing completes the process. This well-defined process has allowed for the development of a supply chain where material specifications have been established and vendors have been qualified.

The final product will be configured to allow for ease of storage, distribution and use in the clinic. We expect the product will be provided in ready-to-use patient dose quantities, shipped from the distribution center on dry ice, and stored in the freezer at the pharmacy.

Production of Osteocel

Osteocel is a matrix of viable cancellous bone containing primary or unexpanded MSCs. Unlike our biologic drug candidates, the stem cells and cancellous bone used in Osteocel are obtained from organ and tissue donors. Additionally, the production of Osteocel is different from our biologic drug candidates in that it does not feature the expansion of MSCs.

Since its introduction into the marketplace in July 2005, we have been unable to produce Osteocel in quantities sufficient to meet our customer demand due to constraints in our manufacturing facility and the lack of sufficient quantities of marrow-rich bone. We contract with tissue recovery agencies for Osteocel source tissue. We currently have ten agencies under contract, including Allosource as discussed above. These agencies in turn have contracts with federally designated Organ Procurement Organizations who notify the agencies of donor candidates in their

areas. Once an initial qualification of the donor is performed, a surgical team is deployed to remove the tissue and send it to our processing center via overnight delivery. The agencies also compile the donor s medical records, perform a medical and social history evaluation, collect serum samples for serological testing and

perform other donor screening services. These agencies operate on a fee-for-service basis, which varies depending upon the tissue type and transplant suitability. We intend to enter into contracts with additional tissue recovery agencies in the future in order to fulfill product demand. We expect to continue to increase manufacturing capacities in line with tissue supply, and believe we will eventually be limited by available donor material regardless of manufacturing capacity.

The processing of Osteocel is in many ways more like the process of organ donation than standard tissue processing. This is because it is essential that the stem cells contained within Osteocel are kept in a living, healthy state. We overcome this challenge through a proprietary process that is designed to preserve the material, particularly the stem cells. Sterility cultures are performed on the final product from every lot according to United States Pharmacopeia standards. Following completion of quality control testing and quality assurance review, the product is released for distribution.

Sales, Marketing and Distribution

Our current sales network consists of approximately 45 independent sales representatives and a distribution agreement with Blackstone Medical, Inc., and its affiliates, for the distribution of Osteocel. In addition, to ensure that Osteocel is made available to the communities from which it is sourced, our agreements with AlloSource and Tissue Banks International enables these agencies to act as a non-exclusive distributor of Osteocel in their local donor communities.

To increase Osteocel s market penetration, we intend to further expand our network of sales professionals in the United States. We intend to self commercialize all of our biologic drug candidates in the United States upon FDA approval through the creation of additional sales and marketing capabilities in existing and new indications and the leverage of Osteocel s sales and marketing infrastructure for orthopedic indications. We have entered into a collaborative arrangement with JCR Pharmaceuticals Co., Ltd. for the distribution of Prochymal for GvHD in Japan following marketing approval.

Both our Osteocel product and our biologic drug candidates have long-term storage requirements within specific frozen temperature ranges, -80 degrees Centigrade and -140 degrees Centigrade, respectively. Generally, we do not believe this will pose a significant problem for end-users as most hospitals and medical centers have freezers with these storage capabilities readily available. However, some facilities may not have this type of storage available and this may limit product and biologic drug candidate distribution. In an effort to mitigate potential issues with product and biologic drug candidate storage, we are performing studies to develop less restrictive storage temperatures. For example, we have implemented temporary -50 degree Centigrade storage of Osteocel for up to two weeks, which opens distribution to a wider hospital base.

Osteocel

Our marketing of Osteocel is targeted to orthopedic surgeons and neurosurgeons practicing in the United States. The most rapid adoption rates to date have been for spinal fusion procedures. Osteocel is currently distributed by our corporate partner, Blackstone Medical, Inc., and its affiliates, and is also distributed by AlloSource, Tissue Banks International and for us by an independent network of approximately 45 sales representatives. Blackstone is a designer and manufacturer of spinal instruments and implants located in Massachusetts. In the field of orthopedics, we intend to continue to develop a network of sales professionals for the distribution of Osteocel.

Prochymal

Upon FDA approval of Prochymal for GvHD indications, we expect to focus our sales and marketing efforts on the approximately 210 transplantation hospitals in the United States that are registered with the International Bone Marrow Transplantation Registry. We expect to employ a

number of sales representatives, initially targeting the most active transplantation centers in a region. An important component of the sales strategy will be to gain the support of key opinion leaders, facilitating the adoption of Prochymal as the treatment strategy for GvHD. We have entered into a license agreement with JCR Pharmaceuticals that grants it the exclusive right to distribute Prochymal for the treatment of GvHD in Japan when it has been approved for marketing in that country.

Competition

Our industry is subject to rapid and intense technological change. We face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery activities or funding, both in the U.S. and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we target in our commercial, clinical and preclinical programs.

Many of the companies competing against us have financial and other resources substantially greater than our own. In addition, many of our competitors have significantly greater experience in testing pharmaceutical and other therapeutic products, obtaining FDA and other regulatory approvals of products, and marketing and selling those products. Accordingly, our competitors may succeed more rapidly than we will in obtaining FDA approval for products and achieving widespread market acceptance. If we obtain necessary regulatory approval and commence significant commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited or no commercial-scale experience.

Our commercialized product, Osteocel, currently competes with established treatment options such as autograft bone and Medtronic s INFUSE® and potentially may compete with other products currently in development for the same indications. Our two biologic drug candidates, if approved, would compete with several marketed products and other future biologic drug candidates. For our existing product and each of our clinical-stage biologic drug candidates, the primary competitors include:

- *Osteocel.* Our commercialized bone regeneration product competes with autograft bone, synthetic biomaterials, growth factors and allograft bone. Competing products include Medtronic s INFUSE®, Stryker s OP-1, numerous bone void filler products such as Zimmer s CopiOs and autologous bone marrow products such as DePuy Spine s CELLECT®.

- *Prochymal.* If approved, Prochymal will likely be the first drug indicated for the treatment of acute GvHD. The competitive landscape in Crohn s disease is more crowded and if approved, Prochymal will compete with Johnson & Johnson s Remicade®, Abbott s HUMIRA® and Biogen s Tysabri®

- *Chondrogen.* If approved, Chondrogen will compete with products such as allograft menisci from cadavers, Conmed Linvatec s meniscal fixation system of screws and arrows and if approved, Regen Biologics Collagen Meniscus Implant.

We may face competition in the future from other companies that are researching and developing stem cell therapies. We are aware of many companies working in this area, including: Aastrom Biosciences, Advanced Cell Technology, Athersys, Cellerant Therapeutics, Cognate Therapeutics, Cytori Therapeutics, Gamida Cell, Geron, Mesoblast, MultiCell Technologies, Neuronyx, Theradigm, ViaCell and StemCells.

We expect to compete based upon, among other things, our intellectual property portfolio and the efficacy of our products. Our ability to compete successfully will depend on our continued ability to attract and retain skilled and experienced scientific, clinical development and executive personnel, to

identify and develop viable biologic drug candidates and to exploit these products and compounds commercially before others are able to develop competitive products.

In addition, our stem cell therapies may be expensive as compared to other therapies and this may make it more difficult for us to compete with other pharmaceuticals

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in the development, manufacture, commercialization and reimbursement of our products and services. Virtually all of the products we develop will require marketing approval, or licensure, by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical testing and other approval procedures of the U.S. Food and Drug Administration, or FDA, and similar regulatory authorities in other countries. Various governmental statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage and record keeping related to such products and their marketing. State, local and other authorities may also regulate pharmaceutical manufacturing facilities. The process of obtaining these approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and money, and there can be no guarantee that approvals will be granted.

FDA Approval Process

We believe that Osteocel is appropriately characterized as a product regulated by the FDA as a human cells, tissues and cellular and tissue-based product, for which the FDA does not require premarket approval. See the discussion below under the caption Human Cellular and Tissue-Based Product. Our biologic drug candidates will require approval from the FDA and corresponding agencies in other countries before they can be marketed. The FDA regulates human therapeutic products in one of three broad categories: biologics, drugs, or medical devices. Our biologic drug candidates will be regulated as biological products. The FDA generally requires the following steps for premarket approval or licensure of a new biological product or new drug product:

- preclinical laboratory and animal tests conducted in compliance with the FDA s Good Laboratory Practice, or GLP, requirements to assess a drug s biological activity and to identify potential safety problems, and to characterize and document the product s chemistry, manufacturing controls, formulation, and stability;

- submission to the FDA of an Investigational New Drug or IND application, which must become effective before clinical testing in humans can begin;

- obtaining approval of Institutional Review Boards, or IRBs, of research institutions or other clinical sites to introduce the biologic drug candidate into humans in clinical trials;

- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication conducted in compliance with the FDA s Good Clinical Practice, or GCP, requirements;

- compliance with current Good Manufacturing Practices, or cGMP regulations and standards;

- submission to the FDA of a Biologics License Application, or BLA, or New Drug Application, or NDA, for marketing that includes adequate results of preclinical testing and clinical trials;

- FDA review of the marketing application in order to determine, among other things, whether the product is safe, effective and potent for its intended uses; and

- obtaining FDA approval of the BLA or NDA, including inspection and approval of the product manufacturing facility as compliant with cGMP requirements, prior to any commercial sale or shipment of the pharmaceutical agent.

Typically, clinical testing involves a three-phase process although the phases may overlap. In Phase I, clinical trials are conducted with a small number of healthy volunteers or patients and are designed to provide information about product safety and to evaluate the pattern of drug distribution and metabolism within the body. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In some cases, an initial trial is conducted in diseased patients to assess both preliminary efficacy and preliminary safety and patterns of drug metabolism and distribution, in which case it is referred to as a Phase I/II trial. Phase III clinical trials are generally large-scale, multi-center, comparative trials conducted with patients afflicted with a target disease in order to provide statistically valid proof of efficacy, as well as safety and potency. In some circumstances, the FDA may require Phase IV or post-marketing trials if it feels that additional information needs to be collected about the drug after it is on the market. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. An agency may, at its discretion, re-evaluate, alter, suspend, or terminate the testing based upon the data which have been accumulated to that point and its assessment of the risk/benefit ratio to the patient. Monitoring all aspects of the study to minimize risks is a continuing process. All adverse events must be reported to the FDA.

The results of the preclinical and clinical testing on a non-biologic drug and certain diagnostic drugs are submitted to the FDA in the NDA or BLA. In the case of vaccines or gene and cell therapies, the results of clinical trials are submitted as a BLA. In responding to the submission of a BLA or NDA, the FDA may grant marketing authority, request additional clinical data or deny approval if the FDA determines that the application does not satisfy its regulatory approval criteria. FDA review of a BLA or NDA typically takes one to three years, but may last longer, especially if the FDA asks for more information or clarification of information already provided. Further clinical trials may be required to gain approval to promote the use of the product for any additional indications. Such additional indications are obtained through the approval of a supplemental BLA or NDA.

The process of obtaining regulatory approval is lengthy, uncertain, and requires the expenditure of substantial resources. Each NDA or BLA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA s fee schedule, effective through September 30, 2007, the user fee for an application requiring clinical data, such as an NDA or BLA, is $896,200. PDUFA also imposes an annual product fee for prescription drugs and biologics ($49,750), and an annual establishment fee ($313,100) on facilities used to manufacture prescription drugs and biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the drug also includes a non-orphan indication, and if a contract manufacturer is used, the contract manufacturer is responsible for the establishment fee.

Before approving an NDA or BLA, all facilities and manufacturing techniques used for the manufacture of products must comply with applicable FDA regulations governing cGMP. A local field division of the FDA is responsible for completing this inspection and providing recommendation for or against approval. This effort is intended to assure appropriate facility and process design to avoid potentially lengthy delays in product approvals due to inspection deficiencies. Similarly, before approving a new drug or biologics application, the FDA may also conduct pre-licensing inspections of a company, its contract research organizations and/or its clinical trial sites to ensure that clinical, safety, quality control and other regulated activities are compliant with GCP. To assure such cGMP and GCP

compliance, the applicants must incur significant time, money and effort in the area of training, record keeping, production, and quality control. Following approval, the manufacture, holding, and distribution of a product must continue to devote significant resources to maintain full compliance in these areas.

After FDA approval has been obtained, the FDA will require post-marketing reporting to monitor the side effects of the drug. Further studies may be required to provide additional data on the product s risks, benefits, and optimal use, and will be required to gain approval for the use of the product as a treatment for clinical indications other than those for which the product was initially tested. Results of post-marketing programs may limit or expand the further marketing of the product. Further, if there are any modifications to the drug, including changes in indication, labeling, or a change in the manufacturing process or manufacturing facility, an NDA or BLA supplement may be required to be submitted to the FDA.

Additionally, after the FDA has authorized a drug product to enter commercial distribution, numerous regulatory requirements apply. These include, among others, the cGMPs, which require manufacturers to follow extensive design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA s general prohibition against promoting drug products for unapproved or off-label uses; and adverse event reporting regulations, which require that manufacturers report to the FDA if their drug may have caused or contributed to a death or serious injury. The FDA has broad post-market and regulatory and enforcement powers. Failure to comply with the applicable U.S. drug regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, refunds, recalls or seizures of products (which would result in the cessation or reduction of production volume), total or partial suspension of production, withdrawals or suspensions of current product applications, and criminal prosecution. Adverse events related to a drug product in any existing or future markets could cause regulatory authorities to withdraw market approval for such product.

Fast Track and Orphan Drug Designations

Congress enacted the Food and Drug Administration Modernization Act of 1997 in part to ensure the availability of safe and effective drugs, biologics, and medical devices by expediting the FDA review process for new products. The Modernization Act establishes a statutory program for the approval of Fast Track products, including biologics. A Fast Track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Under the Fast Track program, the sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. This designation assures access to FDA personnel for consultation throughout the development process and provides an opportunity to request priority review of a marketing application providing a six-month review timeline for the designated product. If a preliminary review of the clinical data suggests that a Fast Track product may be effective, the FDA may initiate review of sections of a marketing application for a Fast Track product before the sponsor completes the application. This rolling review is available if the applicant provides a schedule for submission of remaining information and pays applicable user fees. However, the time periods specified under PDUFA concerning timing goals to which the FDA has committed in reviewing an application do not begin until the sponsor submits the complete application. During the first quarter of 2005 the FDA designated Prochymal as a Fast Track product for the treatment of GvHD. Prochymal also received Fast Track designation from the FDA in January 2007 for the treatment of refractory Crohn s disease. We cannot predict whether this designation will impact the timing or likelihood of FDA approval of Prochymal.

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for Orphan Drug designation. The first developer to receive FDA marketing approval for

an Orphan Drug is entitled to a seven year exclusive marketing period in the United States for that product as well as a waiver of the BLA user fee. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven year exclusive marketing period. The FDA granted Orphan Drug designation for Prochymal during the last quarter of 2005.

Legislation similar to the Orphan Drug Act has been enacted in countries other than the United States, including the European Union. The orphan legislation in the European Union is available for therapies addressing conditions that affect five or fewer out of 10,000 persons. The marketing exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Human Cellular and Tissue-Based Product

Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient is regulated by the FDA as human cells, tissues, and cellular and tissue-based product, or HCT/Ps. We believe that Osteocel is appropriately characterized as an HCT/P and not as a biologic or drug. HCT/Ps are regulated differently from drug or biologic products due to the fact they are minimally manipulated tissues intended for homologous use in the patient s body, are not combined with a drug, device or biologic, and do not have systemic or metabolic effects on the body. The FDA does not require premarket approval for HCT/Ps, however, it does require strict adherence to federally mandated current Good Tissue Practice, or cGTP, regulations. These regulations are analogous to the GMP regulations described above in terms of manufacturing standards. In addition, the FDA s regulations include other requirements to prevent the introduction, transmission and spread of communicable disease. Specifically, the FDA s regulations require tissue establishments to register and list their HCT/Ps with the FDA and to evaluate donors through screening and testing.

We maintain state licensure as a human tissue bank in Maryland, California, Florida, Illinois and New York. These are the only states in which such licensure is required for us.

Privacy Law

Federal and state laws govern our ability to obtain and, in some cases, to use and disclose data we need to conduct research activities. Through the Health Insurance Portability and Accountability Act of 1996, or HIPAA, Congress required the Department of Health and Human Services to issue a series of regulations establishing standards for the electronic transmission of certain health information. Among these regulations were standards for the privacy of individually identifiable health information. Most health care providers were required to comply with the Privacy Rule as of April 14, 2003.

HIPAA does not preempt, or override, state privacy laws that provide even more protection for individuals health information. These laws requirements could further complicate our ability to obtain necessary research data from our collaborators. In addition, certain state privacy and genetic testing laws may directly regulate our research activities, affecting the manner in which we use and disclose individuals health information, potentially increasing our cost of doing business, and exposing us to liability claims. In addition, patients and research collaborators may have contractual rights that further limit our ability to use and disclose individually identifiable health information. Claims that we have violated individuals privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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Other Regulations

In addition to privacy law requirements and regulations enforced by the FDA, we also are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. These laws include, but are not limited to, the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, we cannot assure you that accidental contamination or injury to employees and third parties from these materials will not occur. We may not have adequate insurance to cover claims arising from our use and disposal of these hazardous substances.

Foreign Regulation

We will most likely have to obtain approval for the manufacturing and marketing of each of our products from regulatory authorities in foreign countries prior to the commencement of marketing of the product in those countries. The approval procedure varies among countries, may involve additional preclinical testing and clinical trials, and the time required may differ from that required for FDA approval or licensure. Although there is now a centralized European Union approval mechanism in place, this applies only to certain specific medicinal product categories. In respect of all other medicinal products, each European country may impose certain of its own procedures and requirements in addition to those requirements set out in the appropriate legislation, many of which could be time-consuming and expensive. Although data requirements presently exist for gene therapy and somatic cell therapy medicinal products, additional European approval standards for cellular therapy are still under development, and consequently approval of cell therapy products in Europe may require additional data that we may not be able to satisfy.

Employees

As of December 31, 2007, our headcount was 133 individuals, comprising 107 full-time employees and 26 full-time contract employees. Of this total, 70 were engaged in manufacturing and operations, 46 were engaged in research and development and clinical trials and 17 were engaged in administration, facilities and finance. All of our employees have entered into non-disclosure agreements with us regarding our intellectual property, trade secrets and other confidential information. None of our employees are represented by a labor union or covered under a collective bargaining agreement, nor have we experienced any work stoppages.

Executive Officers of the Registrant

Executive officers are appointed annually by the Board of Directors and, subject to the terms of any applicable employment agreement, serve at the discretion of the Board of Directors. Information regarding our executive officers is as follows:

Name	Age	Position	Other Offices or Positions Held During the Past Five Years
C. Randal Mills, Ph.D.	36	President and Chief Executive Officer (since July 2004)	Dr. Mills is also a member of the Board of Directors. Prior to joining Osiris, Dr. Mills was an executive officer of Regeneration Technologies, Inc. (NASDAQ RTIX). Dr. Mills served in several leadership positions at RTI from its formation in 1998 until 2004, including Vice President of Business Development and Vice President of Operation and R&D and is credited with several key initiatives including the development and commercialization of RTI s core technology, BioCleanse®.
Philip R. Jacoby, Jr.	55	Interim Chief Financial Officer and Corporate Secretary (since November 2007)	Mr. Jacoby has over 30 years of financial and management experience with public and privately held companies. Mr. Jacoby joined Osiris in April 2005 as our Corporate Controller and principal accounting officer in preparation for our initial public offering. Prior to joining Osiris, Mr. Jacoby was the Vice President and Corporate Controller for FTI Consulting, Inc. (NYSE FCN) from 1999 through the first quarter of 2005.
Harry E. Carmitchel	57	Chief Operating Officer (since September 2004)	Mr. Carmitchel has over 25 years of general management and operations experience in the medical field. Prior to joining Osiris, Mr. Carmitchel was a Principal with the Pacific Consulting Group for four years, where he specialized in corporate turnarounds. Prior to this time, Mr. Carmitchel was a General Manager with McQuay International, running a $410 million group, and spent eight years as President of the Medical Division for Stryker Corporation.
Michelle LeRoux Williams, Ph.D.	33	Vice President of Development (since May 2007)	Dr. Williams joined Osiris in 2001 as the Director of Orthopedics and was responsible for the development of Osteocel from the initial concept through product launch in 2005. Dr. Williams also advanced the Chondrogen program from preclinical testing through the Phase I/II clinical trial. Prior to joining Osiris, Dr. Williams completed an NIH postdoctoral fellowship in tissue engineering at Columbia University, evaluating cellular constructs for the repair and regeneration of cartilage in arthritis patients.

Earl R. Fender	60	Vice President and General Manager of Orthopedics (since June 2006)	Prior to joining Osiris, Mr. Fender served for over ten years with DePuy Spine, a Johnson & Johnson company, holding positions as Vice President, Sales, U.S. President, and finally as Worldwide President. Under his direction, DePuy Spine became the second largest spinal implant manufacturer in the world.
Lode Debrabandere, Ph.D.	43	Vice President and General Manager, Inflammatory Diseases (since July 2006)	Prior to joining Osiris, Dr. Debrabandere served for over four years with Bristol-Myers Squibb as Vice President for Strategic Marketing for Neuroscience and Infectious Diseases. He led the Neuroscience Unit and was the Global Brand Leader for Abilify . Previously, Dr. Debrabandere led the Marketing department of UCB Pharma Inc., focusing in the areas of allergy/respiratory (Zyrtec) and neurology (Keppra).

Available Information

Our website address is *www.osiris.com*. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available on our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission, or SEC. The public may read and copy these materials at the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains such reports, proxy and information statements and other information, and the Internet address is *http://www.sec.gov*. Information contained on our website is not and should not be deemed a part of this annual report or any other report or filing filed with the SEC.

Item 1A. Risk Factors.

Risks Related To Our Business

We have a history of operating losses and may not achieve or sustain profitability.

We have incurred losses in each year since our inception and expect to experience losses over the next several years. As of December 31, 2007, we had an accumulated deficit of $241.4 million. These losses resulted principally from costs incurred in our research and development programs and from our general and administrative expenses. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets and working capital.

We expect to continue to incur significant operating expenses and anticipate that our expenses and losses will increase in the foreseeable future as we seek to:

- complete our Phase III clinical trials for Prochymal for GvHD and Crohn s disease;
- complete our Phase I/II clinical trial for Chondrogen, and, if supported by the Phase I/II clinical trial, initiate additional clinical trials;
- complete our Phase I clinical trial for Prochymal for cardiac indications, and, if supported by the Phase I clinical trial, initiate Phase II clinical trials;
- complete our Phase II clinical trial for Prochymal for type 1 diabetes, and, if supported by the Phase II clinical trial, initiate Phase III clinical trials;
- complete our preclinical studies for Prochymal for acute radiation syndrome, and, if supported by the preclinical studies, initiate further studies;
- maintain and expand our network of sales professionals for the distribution of Osteocel, and further expand and train our sales network in anticipation of the approval of our biologic drug candidates for commercial sale;

- expand our manufacturing capacity, which will require that we obtain additional administrative and manufacturing space and build-out a portion of that space as a Food and Drug Administration, or FDA, compliant and validated product manufacturing facility;

- complete the relocation of all of our business operations to our Columbia, Maryland leased facility;

- maintain, expand and protect our intellectual property portfolio;

- hire additional clinical, quality control, scientific and management personnel; and

- add operational, financial, accounting, facilities engineering and information systems personnel, consistent with expanding our operations and our status as a public company.

In addition, Osteocel is our only commercially available product. While revenue from Osteocel has increased since its commercial introduction in July 2005, our ability to scale up our production capabilities for commercial quantities of this product are limited, and our costs in marketing and distributing this product will also increase as production increases.

The extent of our future operating losses or profits is highly uncertain, and we may not achieve or sustain profitability. If we are unable to achieve and then maintain profitability, the market value of our common stock will decline and you could lose part or all of your investment.

If we are not able to recruit and retain qualified management and scientific personnel, we may fail in developing our technologies and biologic drug candidates.

Our future success depends to a significant extent on the skills, experience and efforts of the principal members of our scientific, management and sales personnel. These members include C. Randal Mills, Ph.D., Harry E. Carmitchel, Michelle L. Williams, Ph.D., Philip R. Jacoby, Jr., Earl R. Fender and Lode Debrabandere Ph.D. The loss of any or all of these individuals could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. We have entered into employment agreements with Dr. Mills, Messrs. Carmitchel, Fender and Dr. Debrabandere. The existence of an employment agreement does not, however, guarantee retention of these employees, and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. Except for Dr. Mills, Messrs. Carmitchel, Fender and Dr. Debrabandere, none of our employees is employed for a specified term. Competition for personnel is intense. We may be unable to retain our current personnel or attract or integrate other qualified management and scientific personnel in the future.

We may not be able to raise additional capital necessary to fund our operations.

Our future capital requirements will depend on many factors, including:

- the level of cash flows from Osteocel sales;
- the scope and results of our research and preclinical development programs;
- the scope and results of our clinical trials, particularly regarding the number of patients required for our Phase III trials for Prochymal;
- the timing of and the costs involved in obtaining regulatory approvals for our biologic drug candidates, which could be more lengthy or complex than obtaining approval for a new conventional drug, given the FDA s limited experience with late-stage clinical trials and marketing approval for stem cell therapeutics;
- the costs of building and operating our manufacturing facilities, both in the near term to support Osteocel sales and our clinical activities and also in anticipation of expanding our commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;

- our debt repayment obligations; and

- the costs of enlarging our work force consistent with expanding our business and operations and status as a public company, and as necessary to enhance and train our sales network in anticipation of the approval of our biologic drug candidates for commercial sale.

As a result of these factors, we may need or choose to seek additional funding prior to our becoming cash flow positive on an operational basis. We would likely seek such funding through public or private financings or some combination of them. We might also seek funding through collaborative arrangements if determined to be necessary or appropriate. Additional funding may not be available to us on acceptable terms, or at all. If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our technologies or biologic drug candidates. If we raise additional capital through the incurrence of debt, we would likely become subject to covenants restricting our business activities, and holders of debt instruments would have rights and privileges senior to those of our equity investors. In addition, servicing the interest and repayment obligations under these borrowings would divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we are unable to obtain adequate financing on a timely basis, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our business, financial condition and results of operations.

If the potential of our stem cell therapies to treat diseases is not realized, the value of our technology and our development programs could be significantly reduced.

The potential of our stem cell therapies to treat diseases is currently being explored by us. We have not proven in clinical trials that our stem cell therapy will be a safe and effective treatment for any disease. Our stem cell therapies are susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their marketing approval or commercial use. We have not treated a sufficient number of patients to allow us to make a determination that serious unintended consequences will not occur. If the potential of our stem cell therapies to treat disease is not realized, the value of our technology and our development programs could be significantly reduced. Because our biologic drug candidates are based on MSCs, any negative developments regarding the therapeutic potential or side effects of MSCs could have a material adverse effect on our business, financial condition and results of operations.

Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our therapeutics creates significant challenges in regards to product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, the FDA has relatively limited experience with stem cell therapies. None has been approved by the FDA for commercial sale, and the pathway to regulatory approval for our biologic drug candidates may accordingly be more complex and lengthy. Additionally, stem cells are subject to donor-to-donor variability, which can make standardization more difficult. As a result, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

There are no FDA approved treatments for some of the disease indications we are pursuing. This could complicate and delay FDA approval of our biologic drug candidates.

There are no drugs or therapies currently approved with stated indications for the first-line treatment of acute GvHD or the treatment of steroid refractory GvHD. As a result, the clinical efficacy endpoints, or the criteria to measure the intended results of treatment, for our biologic drug candidate Prochymal for the treatment of GvHD may be difficult to determine. In addition, patients battling GvHD and who, therefore, are candidates for treatment with Prochymal, are typically very ill as a result of an underlying genetic or oncologic condition. Due to the graveness of their underlying disease and the very serious complications and disorders that often accompany acute GvHD, many of these patients will die from causes other than GvHD prior to the completion of the study even if their GvHD responds favorably to treatment with Prochymal. The resulting reduction in the number of patients available for evaluation at the end of the study may make it more difficult for us to demonstrate efficacy, as necessary to obtain FDA approval to market Prochymal for commercial sale.

There are also no drugs or therapies currently approved with stated indications for the regeneration of meniscal tissue or the repair of heart muscle following heart attack. As a result, the clinical endpoints for our biologic drug candidates Prochymal and Chondrogen may be difficult to determine. In the case of Prochymal for the treatment of Crohn s disease, there are other products approved for the treatment of this disease, so it is expected that the clinical efficacy endpoints for Prochymal for this indication will be established by comparison with these already approved treatments. In order to obtain FDA approval for this indication, we will have to demonstrate, among other things,

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that our biologic drug candidate is safe and effective. The results of our clinical trials must be statistically significant, meaning that there must be sufficient data to indicate that it is unlikely the outcome occurred by chance. These challenges may prevent us from developing and commercializing products on a timely or profitable basis, or at all.

Our biologic drug candidates represent new classes of therapy that the marketplace may not understand or accept.

Even if we successfully develop and obtain regulatory approval for our biologic drug candidates, the market may not understand or accept them. We are developing biologic drug candidates that represent novel treatments and will compete with a number of more conventional products and therapies manufactured and marketed by others, including major pharmaceutical companies. The degree of market acceptance of any of our developed and potential products will depend on a number of factors, including:

- the clinical safety and effectiveness of Osteocel and our biologic drug candidates and their perceived advantage over alternative treatment methods;

- our ability to demonstrate that Prochymal can have a clinically significant effect on steroid refractory GvHD;

- our ability to separate ourselves from the ethical controversies associated with stem cell drug candidates derived from human embryonic or fetal tissue;

- ethical controversies that may arise regarding the use of stem cells or human tissue of any kind, including adult stem cells, adult bone marrow and other adult tissues derived from donors, in the manufacture and sale for profit of Osteocel and our biologic drug candidates;

- adverse events involving our biologic drug candidates or the products or product candidates of others that are stem cell based;

- our ability to supply a sufficient amount of our product to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our products; and

- the cost of our products and the reimbursement policies of government and third-party payors.

If the health care community does not accept Osteocel or our potential products for any of the foregoing reasons, or for any other reason, it could affect our sales, having a material adverse effect on our business, financial condition and results of operations.

The successful commercialization of our biologic drug candidates, or any of our other potential stem cell therapeutics, will depend on obtaining reimbursement from third-party payors.

If we successfully develop and obtain necessary regulatory approvals, we intend to sell our biologic drug candidates initially in the United States and Europe. In the United States, the market for any pharmaceutical product is affected by the availability of reimbursement from third-party payors, such as government health administration authorities, private health insurers, health maintenance organizations and pharmacy benefit management companies. Stem cell therapies like Prochymal, and Chondrogen may be expensive compared with standard pharmaceuticals, due to the higher cost and complexity associated with the research, development and production of stem cell therapies, the small size and large geographic diversity of the target patient population for some indications, and the complexity associated with distribution of stem cell therapies which require special handling and shipment procedures and protocols. This, in turn, may make it more difficult for us to obtain adequate reimbursement from third-party payors, particularly if we cannot demonstrate a favorable cost-benefit relationship. Third-party payors may also deny coverage or offer inadequate levels of reimbursement

for our potential products if they determine that the product has not received appropriate clearances from the FDA or other government regulators or is experimental, unnecessary or inappropriate. For example, patients battling GvHD and who, therefore, are candidates for treatment with Prochymal, are typically very ill as a result of an underlying genetic or oncologic condition. Because these patients have a low probability of survival (whether or not their GvHD is successfully treated), third-party payors may resist reimbursing the cost of treatment.

In the countries of Europe and in some other countries, the pricing of prescription pharmaceutical products and services and the level of government reimbursement are subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct one or more clinical trials that compares the cost effectiveness of our biologic drug candidates or products to other available therapies. Conducting one or more clinical trials would be expensive and result in delays in commercialization of our products.

Managing and reducing health care costs has been a general concern of federal and state governments in the United States and of foreign governments. Although we do not believe that any recently enacted or presently proposed legislation should impact our business, we might be subject to future regulations or other cost-control initiatives that materially restrict the price we receive for our products. In addition, third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and many limit reimbursement for newly approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price for products that we may develop, which would result in lower product revenues to us.

Our dependence upon a limited supply of adult marrow-rich bone necessary to produce Osteocel may impact our ability to produce Osteocel on a large scale.

The production of Osteocel does not involve an expansion of MSCs and is therefore limited by the amount of adult human marrow-rich bone donations that are available to us. Since the introduction of Osteocel into the marketplace in July 2005, we have been unable to obtain quantities of adult human marrow-rich bone sufficient to meet the demand for Osteocel. Osteocel consists of primary, or unexpanded, MSCs in a matrix of viable cancellous bone. Cancellous bone is the porous and spongy inner structure of bones accounting for approximately 20% of total bone mass. The bone and cells are derived from human organ and tissue donors. We rely on the efforts of not-for-profit donor procurement agencies to educate the public and foster an increased willingness to donate bone tissue. These organizations may not be able to provide us with sufficient amounts of viable cancellous bone to meet present or future demand for Osteocel. Our inability to secure enough viable cancellous bone to meet our Osteocel demands could limit our ability to successfully market and drive market acceptance of Osteocel and may limit our potential revenues from Osteocel.

Our dependence upon a limited supply of bone marrow donors may impact our ability to produce sufficient quantities of our biologic drug candidates as necessary to complete our clinical trials, and if our trials are successful, to meet product demand.

The population of acceptable bone marrow donors is limited to volunteers between the ages of 18 and 30. In addition, potential donors are prescreened for a variety of health conditions and are only allowed to donate bone marrow a total of six times in their lifetime, further limiting the total number of potential donors. The amount of bone marrow donated may be insufficient for us to mass produce our biologic drug candidates. Future government regulation or health concerns may also reduce the number of donors or otherwise limit the amount of bone marrow available to us. If we cannot secure quantities of bone marrow sufficient to meet the manufacturing demands for our clinical trials, we

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might not be able to complete our clinical trials and obtain marketing approval for our biologic drug candidates. Moreover, even if our clinical trials are successful and we obtain marketing approval for our biologic drug candidates, our inability to secure enough bone marrow to meet product demand would limit our potential revenues.

Osteocel and our biologic drug candidates are derived from human tissue and bone marrow sources and therefore have the potential for disease transmission.

The utilization of donated adult human cancellous bone and bone marrow creates the potential for transmission of communicable disease, including but not limited to human immunodeficiency virus, or HIV, viral hepatitis, syphilis, Creutzfeldt- Jakob disease, or the human form of mad cow disease, and other viral, fungal or bacterial pathogens. Although we are required to comply with federal and state regulations intended to prevent communicable disease transmission, and our suppliers of adult human bone and bone marrow are also required to comply with such regulations in connection with their collection, storage and supply to us:

- we or our suppliers may fail to comply with such regulations;
- even with compliance, our products might nevertheless be viewed by the public as being associated with transmission of disease; and
- a patient that contracts an infectious disease might assert that the use of our products resulted in disease transmission, even if the patient became infected through another source.

Any actual or alleged transmission of communicable disease could result in patient claims, litigation, distraction of management s attention and potentially increased expenses. Further, any failure in screening, whether by us or other manufacturers of similar products, could adversely affect our reputation, the support we receive from the medical community and overall demand for our products. As a result, such actions or claims, whether or not directed at us, could have a material adverse effect on our reputation with our customers and our ability to market our products, which could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to manufacture Osteocel in quantities sufficient to expand our market for the product and may not be able to manufacture our biologic drug candidates in quantities sufficient for later stage clinical studies or for commercial sale.

We may encounter difficulties in the production of Osteocel and our biologic drug candidates due to our manufacturing capabilities. This difficulty could reduce sales of our products, increase our costs or cause production delays, any of which could damage our reputation and hurt our profitability. Even if we were to obtain access to quantities of adult marrow-rich bone sufficient to allow us otherwise to expand our Osteocel manufacturing capabilities, we may not be able to produce sufficient quantities of the product at an acceptable cost, or at all.

If we successfully obtain marketing approval for one of our biologic drug candidates, we may not be able to produce sufficient quantities of the product at an acceptable cost. Commercial-scale production of therapies made from live human mesenchymal stem cells involves production in

small batches and strict adherence to complex manufacturing and storage protocols and procedures. Our biologic drug candidates are inherently more difficult to manufacture at commercial-scale than chemical pharmaceuticals, which are manufactured using precise chemical formulations and operational methods.

We use third-party collaborators to help us develop and commercialize our products, and our ability to commercialize such products may be impaired or delayed if collaborations are unsuccessful.

We have arrangements in place with third-party collaborators as a means to help us with research and development efforts or marketing and distribution. For example:

- we currently sell a large majority of our Osteocel product through a distribution arrangement with Blackstone Medical, Inc., which sells this product under the Blackstone brand Trinity ;

- we have a collaboration with JCR Pharmaceuticals Co., Ltd. granting to JCR an exclusive right to Prochymal for the treatment of GvHD in Japan; and

- we have a collaboration with Genzyme Corporation to develop effective countermeasures to nuclear terrorism and other radiological emergencies. The initial focus of the collaboration will be to develop Prochymal to treat the potentially lethal complications of acute radiation syndrome.

We may enter into additional collaborations in the future. We are dependent upon the success of our current and any future collaborators in performing their responsibilities and their continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development and commercialization of our potential products will be delayed if collaborators fail to conduct their responsibilities in a timely manner or if they breach or terminate their collaboration agreements with us. Disputes with our collaborators could result in product development delays, decreased revenues and litigation expenses. In addition, because our products may be marketed under a different brand name by our collaborators, as is the case in our relationship with Blackstone, should the relationship be terminated for any reason, our product recognition could be adversely impacted, affecting our product and potentially causing brand confusion in the market.

We are dependent upon third-party suppliers for services and raw materials needed for the manufacture, and we are dependent upon third parties for the distribution, of Osteocel and our biologic drug candidates. If any of these third parties fail or are unable to perform in a timely manner, our ability to manufacture and deliver will be compromised.

In order to produce our biologic drug candidates for use in clinical studies, and to produce Osteocel and any other of our biologic drug candidates that may be approved for commercial sale, we require biological media, reagents and other highly specialized materials. This is in addition to the adult marrow-rich bone donations used in the manufacture of Osteocel, and the bone marrow aspirate used in the manufacture of our biologic drug candidates. These items must be manufactured and supplied to us in sufficient quantities and in compliance with current Good Manufacturing Practices, or cGMP. To meet these requirements, we have entered into supply agreements with firms that manufacture these components to cGMP standards. Our requirements for these items are expected to increase if and when we transition to the manufacture of commercial quantities of our biologic drug candidates.

In addition, as we proceed with our clinical trial efforts, we must be able to demonstrate to the FDA that we can manufacture our biologic drug candidates with consistent characteristics. Accordingly, we are materially dependent on these suppliers for supply of cGMP-grade components of consistent quality. Our ability to complete ongoing clinical trials may be negatively affected in the event that we are forced to seek and validate a replacement source for any of these critical components. If we are not able to obtain adequate supplies of these items of consistent quality from our third-party suppliers, it

will also be more difficult to manufacture commercial quantities of Osteocel or any of our current biologic drug candidates that may subsequently be approved for commercial sale.

In addition, we rely on third parties to distribute Osteocel and, if approved, our biologic drug candidates. Proper shipping and distribution requires compliance with specific storage and shipment procedures. For example, our products must be placed in a freezer within 72 hours of shipment. Failure to comply with these procedures or the occurrence of inadvertent damage to the shipping container will necessitate return and replacement, potentially resulting in additional cost and causing us to fail to meet supply requirements.

Use of third-party manufacturers may increase the risk that we will not have adequate quantities of our biologic drug candidates.

We use third-party manufacturers to supply our biologic drug candidates for clinical trials. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured such components ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;

- the possible breach of the manufacturing agreement by the third party; and

- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Our contract manufacturers are subject to all of the risks and uncertainties that we have when we manufacture on our own. Similar to us, they are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP regulations and other governmental regulations and corresponding foreign standards. However, we do not control compliance by our contract manufacturers with these regulations and standards. Our present or future manufacturers might not be able to comply with these regulatory requirements. If our third-party manufacturers fail to comply with applicable regulations, the FDA or other regulatory authorities could impose sanctions on us, including fines, injunctions, civil penalties, denial of marketing approval of our biologic drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of biologic drug candidates or our other products, operating restrictions and criminal prosecutions. Any of these actions could significantly and adversely affect supplies of our biologic drug candidates or other products and could have a material adverse effect on our business, financial condition and results of operations.

We have contracted with Lonza to manufacture quantities of our stem cell drug candidates for our clinical trials. If Lonza is unable to ramp up production sufficiently, we may also not be able to meet anticipated market demand in the future.

If our processing and storage facility or our clinical manufacturing facilities are damaged or destroyed, our business and prospects would be negatively affected.

If our processing and storage facility or the equipment in the facility were to be significantly damaged or destroyed, we could suffer a loss of some or all of the stored units of our biologic drug candidates and it would force us to halt our clinical trial processes.

We have a manufacturing facility located in Baltimore, Maryland at which we produce and store Osteocel prior to sale. If this facility or the equipment in it is significantly damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity. This facility is located on the Baltimore harbor, and in September 2003 it was flooded by Hurricane Isabel. This event resulted in a temporary suspension of our manufacturing operations. In the event of another temporary or protracted loss of this facility or equipment, we may be able to transfer manufacturing to a third

party, but the shift would likely be expensive, and the timing would depend on availability of third-party resources and the speed with which we could have a new facility comply with the necessary regulatory requirements. Such an event could halt our distribution of Osteocel due to a lack of available product.

We lease approximately 61,203 square feet of space in Columbia, Maryland, and plan to begin manufacturing Osteocel in Columbia during the second quarter of 2008. We intend to move all our manufacturing and storage from Baltimore to Columbia during the third quarter of 2008.

Currently, we maintain insurance coverage totaling $19.4 million against damage to our property and equipment, an additional $4.0 million to cover business interruption and extra expenses, and $5.6 million to cover R&D restoration expenses. If we have underestimated our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies.

Ethical and other concerns surrounding the use of stem cell therapy or human tissue may negatively affect public perception of us or our products or biologic drug candidates, or may negatively affect regulatory approval of our products or biologic drug candidates, thereby reducing demand for our products and adversely affecting the market price for our common stock.

The commercial success of Osteocel and our biologic drug candidates will depend in part on general public acceptance of the use of stem cell therapy and donated human tissue for the prevention or treatment of human diseases. The use of embryonic stem cells and fetal tissue for research and stem cell therapy has been the subject of substantial national and international debate regarding related ethical, legal and social issues. In the U.S., for example, federal government funding of embryonic stem cell research has been limited to specifically identified cell lines and is not otherwise available. We do not use embryonic stem cells or fetal tissue, but the public may not be able to, or may fail to, differentiate our use of adult stem cells from the use by others of embryonic stem cells or fetal tissue. This could result in a negative perception of our company or our products or biologic drug candidates.

We obtain our stem cells from volunteer adult bone marrow donors and we obtain cancellous human bone for the production of Osteocel from non-profit organizations that collect and process human organ and tissue donations. Bone marrow donors receive payment, but payment is not received by either human organ and tissue donors or their surviving family members. Ethical concerns have been raised by some about the use of donated human tissue in a for-profit setting, as we are doing.

Future adverse events in the field of stem cell therapy or changes in public policy could also result in greater governmental regulation of our products and biologic drug candidates and potential regulatory delays relating to the testing or approval of our biologic drug candidates.

We compete with other companies for funding and product sales. Many of our competitors have greater resources or capabilities than we have, or may already have or succeed in developing better products or in developing products more quickly than we do, and we may not compete successfully with them.

The pharmaceutical and biotechnology industries are highly competitive. We compete for funding and, if our products become available for commercial sale, we will compete in the market place. For funding, we compete primarily with other companies which, like us, are focused on developing novel products or therapies for the treatment of human disease based on stem cells or other novel scientific principles. These include Aastrom Biosciences, Advanced Cell Technology, Athersys, Cellerant Therapeutics, Cognate Therapeutics, Cytori Therapeutics, Gamida Cell,

Geron, Mesoblast, MultiCell Technologies, Neuronyx, Theradigm, ViaCell, and StemCells.

In the marketplace, we compete or may eventually compete with other companies and organizations that are marketing or developing therapies for our targeted disease indications, based on traditional pharmaceutical, medical device or other, non-cellular therapy and technologies. These

include: Johnson & Johnson, the manufacturer of CELLECT for the repair of bone, which competes with Osteocel; Medtronic and Stryker, the manufacturers of InFuse and OP-1, respectively, which compete with Osteocel; Novartis, the manufacturer of Neoral® for the prevention of organ rejection in transplant patients, which would compete with Prochymal for the treatment of GvHD; and Johnson & Johnson, the manufacturer of Remicade®, and Abbott, the manufacturer of Humira, which would compete with Prochymal for the treatment of Crohn s disease. In addition to those listed above, we have other potential competitors developing a variety of therapeutics.

We also face competition in the cell therapy field from academic institutions and governmental agencies. Many of our current and potential competitors have greater financial and human resources than we have, including more experience in research and development and more established sales, marketing and distribution capabilities.

We anticipate that competition in our industry will increase. In addition, the health care industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render our current product or any future product non-competitive or otherwise obsolete.

The use of our stem cell therapies in human subjects may expose us to product liability claims, and we may not be able to obtain adequate insurance.

We face an inherent risk of product liability claims. Neither Osteocel nor any of our biologic drug candidates has been widely used over an extended period of time, and therefore our safety data are limited. We derive the raw materials for manufacturing Osteocel and our biologic drug candidates from human donor sources, the manufacturing process is complex, and the handling requirements are specific, all of which increase the likelihood of quality failures and subsequent product liability claims. We will need to increase our insurance coverage if and when we begin commercializing our biologic drug candidates. We may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all. If we are unable to obtain insurance, or if claims against us substantially exceed our coverage, then our business could be adversely impacted. Whether or not we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in:

- significant awards against us;
- substantial litigation costs;
- recall of the product;
- injury to our reputation;
- withdrawal of clinical trial participants; and

- adverse regulatory action.

Any of these results could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Intellectual Property

If our patent position does not adequately protect Osteocel®, our biologic drug candidates or any future products, others could compete against us more directly, which would harm our business and have a material adverse effect on our financial condition and results of operations.

Our success depends, in large part, on our ability to obtain and maintain intellectual property protection for our biologic drug candidates. The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions and has been the subject of

much litigation. Neither the U.S. Patent and Trademark Office nor the courts has a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology patents.

The claims of our existing U.S. patents and those that may issue in the future, or those licensed to us, may not confer on us significant commercial protection against competing products. Third parties may challenge, narrow, invalidate or circumvent any patents we own or may obtain in the future. Our patents on MSC technology, in particular, are quite broad in that they cover mesenchymal stem cells and the therapeutic use thereof. Patents with broad claims tend to be more vulnerable to challenge by other parties than patents with more narrowly written claims. Also, our pending patent applications may not issue, and we may not receive any additional patents. Further, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies.

Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. We have nine granted patents and have filed six patent applications that correspond or are related to our commercially available product, Osteocel. The six patent applications have not yet issued and there can be no assurances that they will ever issue. Osteocel is different from our other biologic drug candidates in that it contains primary, or unexpanded, MSCs in a matrix of cancellous bone. Because FDA approval is generally not required for tissue based products like Osteocel, competitors might choose to enter this market and produce a substantially similar product whereby we may not be able to prevent the marketing and sale of any such similar products by others. Should others produce a substantially similar product, we will be subject to increased competition and our potential revenues from Osteocel sales may be limited.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. For instance, one of our base patents on MSC technology will expire in 2013. To the extent our biologic drug candidates based on that technology are not commercialized significantly ahead of this date, or to the extent we have no other patent protection on such products, those products would not be protected by patents beyond 2013. The background technologies used in the development of our biologic drug candidates are known in the scientific community, and it is possible to duplicate the methods we use to create our biologic drug candidates.

If we are unable to protect the confidentiality of our proprietary information and know-how, our competitive position would be impaired and our business, financial condition and results of operations could be adversely affected.

A significant amount of our technology, especially regarding manufacturing processes, is unpatented and is maintained by us as trade secrets. In an effort to protect these trade secrets, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual s relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. For example, a portion of the manufacture of Osteocel is protected by trade secrets. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and could have a material adverse effect on our business, financial condition and results of operations.

If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business, financial condition and results of operations.

Our research, development and commercialization activities, including any biologic drug candidates or products resulting from these activities, may infringe or be claimed to infringe patents owned by third parties and to which we do not hold licenses or other rights. There may be applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or biologic drug candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we may choose or be required to seek a license from the third party. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also impact our collaborators, which would also impact the success of the collaboration and therefore us.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the United States Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. For example, the patent that was granted to us in Europe for human mesenchymal stem cells has been opposed in the European Patent Office by two different companies. The outcome of the proceedings is uncertain at this time, but we are vigorously pursuing our rights. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace and, as a result, on our business, financial condition and results of operations.

We may become involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, which could be expensive and time consuming.

Competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. We are aware of several companies that are employing mesenchymal stem cell technology in their research and product development efforts. If such companies commercialize such products, there is no assurance that we would have a basis for initiating patent

infringement proceedings or that if initiated we would prevail in such proceedings.

Interference proceedings brought by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Risks Related to Regulatory Approval and Other Government Regulations

If we are not able to successfully develop and commercialize our biologic drug candidates and obtain the necessary regulatory approvals, we may not generate sufficient revenues to continue our business operations.

In order to generate sales revenue from our biologic drug candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate that our biologic drug candidates are safe and effective and obtain required regulatory approvals. Our early stage biologic drug candidates may fail to perform as we expect. Moreover, our biologic drug candidates in later stages of development may fail to show the desired safety and efficacy traits despite having progressed successfully through preclinical or initial clinical testing. We will need to devote significant additional research and development, financial resources and personnel to develop commercially viable products and obtain the necessary regulatory approvals.

If our biologic drug candidates do not prove to be safe and efficacious in clinical trials, we will not obtain the required regulatory approvals. If we fail to obtain such approvals, we may not generate sufficient revenues to continue our business operations.

Even if we obtain regulatory approval of a product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities, which may create additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer or facility, may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, regulatory agencies may establish additional regulations that could prevent or delay regulatory approval of our products.

We cannot market and sell our biologic drug candidates in the United States or in other countries if we fail to obtain the necessary regulatory approvals or licensure.

We cannot sell our biologic drug candidates until regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain. It is likely to take two to three years or more to obtain the required regulatory approvals for our lead stem cell biologic drug candidate, Prochymal, or we may never gain the necessary approvals. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our operations and cause our stock price to decline significantly.

Moreover, because our biologic drug candidates are all based on a single platform technology, MSCs, any adverse events in our clinical trials for one of our biologic drug candidates could negatively impact the clinical trials and approval process for our other biologic drug candidates.

To obtain marketing approvals in the United States for MSC products, for instance, we must, among other requirements, complete carefully controlled and well-designed clinical trials sufficient to demonstrate to the FDA that the biologic drug candidate is safe and effective for each disease for which we seek approval. Several factors could prevent completion or cause significant delay of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that MSCs are safe, effective and potent for use in humans. Negative or inconclusive results from or adverse medical events during a clinical trial could cause the clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful. The FDA can place a clinical trial on hold if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury. If safety concerns develop, we or the FDA could stop our trials before completion. Some participants in our MSC clinical trial have experienced serious adverse events, four of which have been determined to be possibly related to MSCs and one of which has been determined to be probably related. A serious adverse event is an event that results in significant medical consequences, such as hospitalization, disability or death, and must be reported to the FDA. We cannot assure you that safety concerns regarding MSCs will not develop.

The pathway to regulatory approval for MSCs may be more complex and lengthy than for approval of a new conventional drug. Similarly, to obtain approval to market our stem cell products outside of the United States, we will need to submit clinical data concerning our products and receive regulatory approval from governmental agencies, which in certain countries includes approval of the price we intend to charge for our product. We may encounter delays or rejections if changes occur in regulatory agency policies during the period in which we develop a biologic drug candidate or during the period required for review of any application for regulatory agency approval. If we are not able to obtain regulatory approvals for use of our biologic drug candidates under development, we will not be able to commercialize such products, and therefore may not be able to generate sufficient revenues to support our business.

If we are not able to conduct our clinical trials properly and on schedule, marketing approval by FDA and other regulatory authorities may be delayed or denied.

The completion of our clinical trials may be delayed or terminated for many reasons, including, but not limited to, if:

- the FDA does not grant permission to proceed and places the trial on clinical hold;
- subjects do not enroll in our trials at the rate we expect;
- subjects experience an unacceptable rate or severity of adverse side effects;
- third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice and regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or Institutional Review Boards (IRBs) of research institutions participating in our clinical trials, find regulatory violations that require us to undertake corrective action, suspend or

terminate one or more sites, or prohibit us from using some or all of the data in support of our marketing applications; or

- one or more IRBs suspends or terminates the trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial.

Our development costs will increase if we have material delays in our clinical trials, or if we are required to modify, suspend, terminate or repeat a clinical trial. If we are unable to conduct our clinical trials properly and on schedule, marketing approval may be delayed or denied by the FDA.

We may not be able to secure and maintain research institutions to conduct our clinical trials.

We rely on research institutions to conduct our clinical trials. Specifically, the limited number of bone marrow transplant centers further heightens our dependence on such research institutions for the Phase III Prochymal trials. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreement with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. We may not be able to secure and maintain suitable research institutions to conduct our clinical trials.

Final marketing approval of our biologic drug candidates by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

Any of the following factors may cause final marketing approval for our biologic drug candidates to be delayed, limited or denied:

- our biologic drug candidates require significant clinical testing to demonstrate safety and effectiveness before applications for marketing approval can be filed with the FDA;

- data obtained from preclinical and nonclinical animal testing and clinical trials can be interpreted in different ways, and the FDA may not agree with our interpretations;

- it may take many years to complete the testing of our biologic drug candidates, and failure can occur at any stage of the process;

- negative or inconclusive results or adverse side effects during a clinical trial could cause us to delay or terminate development efforts for a biologic drug candidate; and

- commercialization may be delayed if the FDA requires us to expand the size and scope of the clinical trials.

If marketing approval for our biologic drug candidates is delayed, limited or denied, our ability to market products, and our ability to generate product sales, would be adversely affected.

Should the FDA decide that Osteocel does not meet the appropriate regulatory requirements, we will be required to stop production, which will have a material adverse effect on our business, financial condition and results of operations.

The FDA has developed a tiered, risk-based regulatory framework, which includes criteria for facility management, quality assurance, donor selection, and processing of human cells, tissues, and cellular and tissue based products. We believe that commercial sale of Osteocel does not require pre-market approval by the FDA because we believe that it meets the regulatory definition of human cells, tissue, and cellular and tissue-based products, or HCT/Ps. However, should the FDA decide that Osteocel does not meet the regulatory definition of HCT/Ps, we will not be able to produce and sell Osteocel until we obtain FDA approval, which could take years to obtain and which could have a material adverse effect on our business, financial condition and results of operations.

Producing and marketing an approved drug or other medical product is subject to significant and costly post-approval regulation.

It is likely that Prochymal, if approved based on our currently contemplated Phase III trial, will receive conditional approval by the FDA, and we will be required to conduct Phase IV clinical trials to obtain full approval. Even if we obtain full approval of a product, that approval is subject to limitations on the indicated uses for which we can market it. After granting marketing approval, the FDA and

regulatory agencies in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities, creating additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, regulatory agencies may establish additional regulations that could prevent or delay marketing approval of our products.

Our business involves the use of hazardous materials that could expose us to environmental and other liability.

We have facilities in Maryland that are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro- organisms and various radioactive compounds used in connection with our research and development activities. In the United States, these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. We cannot assure you that accidental contamination or injury to our employees and third parties from hazardous materials will not occur. We do not have insurance to cover claims arising from our use and disposal of these hazardous substances other than limited clean-up expense coverage for environmental contamination due to an otherwise insured peril, such as fire.

We may not be able to obtain or maintain Orphan Drug designation for our biologic drug candidates.

Some jurisdictions, including the European Union and the United States, may designate drugs for relatively small patient populations as orphan drugs. Although the FDA and its European counterpart, EMEA have designated Prochymal for the treatment of steroid refractory GvHD as an orphan drug, none of our other biologic drug candidates have received such designation. Orphan Drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, but does make the product eligible for orphan drug exclusivity, reduced filing fees and specific tax credits. Generally, if a company receives the first marketing approval for a product with an Orphan Drug designation in the clinical indication for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that the health authorities will not approve another application to market the same drug for the same indication, except in limited circumstances, for a period of up to seven years in the United States and ten years in Europe. This exclusivity, however, could block the approval of our biologic drug candidates if a competitor obtains marketing approval before us. Even if we obtain orphan drug exclusivity for any of our biologic drug candidates, we may not be able to maintain it. For example, if a competitive product is shown to be clinically superior to our product, any orphan drug exclusivity we have will not block the approval of such competitive product.

The Fast Track designation for development of any of our products may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood the biologic drug candidate will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification. Although we have obtained a Fast Track designation from the FDA for Prochymal for the treatment of GvHD and treatment refractory Crohn s disease, receipt of Fast Track designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our Fast Track designation at any

time. If we lose our Fast Track designation, the approval process may be delayed. In addition, our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that Prochymal will receive regulatory approval for the treatments of steroid refractory GvHD or Crohn s disease.

Risks Related to Government Contracts

Federal government spending priority or our relationships with the federal government may change in a manner that harms our business or prospects.

Our ability to successfully pursue development and purchase agreements with United States and Allied governmental agencies for countermeasures to nuclear terrorism and other radiological emergencies, including the contract awarded to us by the DoD for the development and stockpiling of Prochymal for the treatment of acute radiation syndrome (ARS), depends upon continued federal government expenditures on defense, emergency preparadness and other programs. These expenditures will likely fluctuate over time. While spending authorizations for defense and emergency preparadness related programs by the government have increased in recent years, and in particular after the 2001 terrorist attacks, future levels of expenditures and authorizations for these programs may decrease, remain constant or shift to program areas inapplicable to us. Our business, prospects, financial condition and/or operating results could be materially harmed by budgetary constraints affecting federal government spending generally, or specific departments or agencies in particular, and by changes in fiscal policies or available funding, or by changes in federal government programs or requirements or delays in government appropriations process. In addition, our business, prospects, financial condition and/or operating results could be materially harmed if we are suspended or disbarred from contracting with the federal government or a significant governmental agency, or our reputation or relationship with governmental entities is impaired, or the government otherwise declines to do business with us, or significantly decreases the amount of business it is willing to do with us.

Federal government contracts contain provisions that may be unfavorable to us.

Federal government contracts contain provisions, and are subject to laws and regulations, that give the government rights and remedies not typically found in commercial contracts. These provisions may allow the government to terminate existing contracts for convenience, as well as for default, to reduce or modify contracts or subcontracts, to cancel multi-year contracts or related purchase orders if funds for contract performance for any subsequent year become unavailable, to decline to exercise an option to renew a multi-year contract or to decline to purchase product pursuant to an option afforded under a contract. If the government terminates a contract for convenience, we may recover only our incurred or committed costs, settlement expenses and profit on the work completed prior to the termination. If the government terminates a contract for default, we may not recover even those amounts, and instead may be liable for excess costs incurred by the government in procuring undelivered items and services from another source.

Unfavorable federal government audit results could subject us to penalties or sanctions and could impair our ability to win new contracts.

The Defense Contract Audit Agency (DCAA) and other government agencies routinely audit and investigate government contracts and systems. These agencies review a contractor s performance on its contract, cost structure and compliance with applicable laws, regulations and standards. The DCAA also reviews the adequacy of, and a contractor s compliance with, its internal control systems and policies, including the contractor s accounting, purchasing, property, estimating, compensation and managing information systems. Allegations of impropriety or deficient controls could harm our reputation and/or adversely influence the award of new contracts. Any costs founds to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be

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refunded. Therefore, a DCAA audit could result in a substantial adjustment to our revenue earned from federal government contracts.

The government may terminate our federal government contracts at any time.

Federal government contracts may span one or more base years and one or more option years, and may provide the government with one or more options in respect of continued performance by us thereunder. For example, our contract with the DoD for the development and stockpiling of Prochymal for the treatment of ARS provides the DoD with successive options for the purchase of Prochymal, assuming receipt of FDA approval for its use in the treatment of ARS. Federal government agencies have no obligation to exercise these options unless determined to be in the best interest of the government. Additionally, federal government contracts typically contain provisions permitting the government to terminate the contract for its convenience. A decision not to exercise an option or a decision to terminate a contract could have a material adverse effect on our business and prospects.

If we fail to comply with complex procurement laws and regulations, we could incur various penalties or sanctions.

To the extent which we enter into contracts or other arrangements with the United States or other Allied governments, we must comply with the laws and regulations relating to the formation, administration and performance of those contracts. These laws and regulations affect how we conduct business with our government contracts. In complying with these laws and regulations, we may incur additional costs, and non-compliance may also allow for the assignment of additional fines and penalties, including contractual damages. Among these laws and regulations are the Federal Acquisition Regulations, which comprehensively regulate the formation, administration and performance of United States federal government contracts, the Truth in Negotiations Act, which requires certification and disclosure of all costs and pricing data in connection with contract negotiations, and laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes, and restricting the export of certain products and technical data. We are subject to periodic review of our performance under and compliance with the terms of any federal government contracts to which we are a party. As a result of these reviews, we may learn that we are not in compliance with all of the terms of any such contracts and we could be subject to civil or criminal penalties or administrative sanctions for failure of compliance.

Risks Related to Our Common Stock

The trading price of the shares of our common stock is highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price they paid for it. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of our biologic drug candidates or those of our competitors;

- regulatory developments in the United States and foreign countries;

- variations in our financial results or those of companies that are perceived to be similar to us;

- changes in the structure of healthcare payment systems;

- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts reports or recommendations;

- sales of substantial amounts of our stock by existing stockholders;

- sales of our stock by insiders and 5% stockholders;

- general economic, industry and market conditions;

- additions or departures of key personnel;

- intellectual property, product liability or other litigation against us;

- expiration or termination of our relationships with our collaborators; and

- the other factors described in this Risk Factors section.

In addition, in the past, stockholders have initiated class action lawsuits against biotechnology and pharmaceutical companies following periods of volatility in the market prices of these companies stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and beneficial owners of 5% or more of our common stock and their affiliates, in aggregate, beneficially own approximately 60% of our outstanding common stock as of December 31, 2007. These persons, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with our interests or the interests of other stockholders.

Peter Friedli, our Chairman of the Board of Directors, and certain entities with which he is affiliated, beneficially own approximately 48% of our outstanding common stock as of December 31, 2007. Accordingly, Mr. Friedli currently has, and will continue to have, a significant influence over the outcome of all corporate actions requiring stockholder approval.

Certain provisions of Delaware law and of our charter and bylaws contain provisions that could delay and discourage takeover attempts and any attempts to replace our current management by stockholders.

Certain provisions of our certificate of incorporation and bylaws, and applicable provisions of Delaware corporate law, may make it more difficult for or prevent a third party from acquiring control of us or changing our Board of Directors and management. These provisions include:

- the ability of our Board of Directors to issue preferred stock with voting or other rights or preferences;
- the inability of stockholders to act by written consent;
- a classified Board of Directors with staggered three-year terms;
- requirements that special meetings of our stockholders may only be called by the chairman of our Board of Directors, upon request of stockholders holding at least 20% of our capital stock issued and outstanding, or upon a resolution adopted by, or an affirmative vote of, a majority of our Board of Directors; and
- requirements that our stockholders comply with advance notice procedures in order to nominate candidates for election to our Board of Directors or to place stockholders proposals on the agenda for consideration at meetings of stockholders.

We will also be afforded the protections of Section 203 of the Delaware General Corporation Law, which will prevent us from engaging in a business combination with a person who acquires at least 15% of our common stock for a period of three years from the date such person acquired such common stock, unless advance board or stockholder approval was obtained.

Any delay or prevention of a change of control transaction or changes in our Board of Directors or management could deter potential acquirors or prevent the completion of a transaction in which our stockholders could receive a substantial premium over the then current market price for their shares.

Item 1B. Unresolved Staff Comments.

Not Applicable.

Item 2. Properties.

Our corporate headquarters are located in Columbia, Maryland, where we lease approximately 61,000 square feet, currently at a rent of approximately $0.8 million per annum. This lease expires in July 2016, and includes options to extend the term of the lease for two additional five year periods. We also lease approximately 126,000 square feet in Baltimore, Maryland where we presently manufacture Osteocel. This lease expires in September 2008, by which time we intend to have consolidated our operations in our Columbia, Maryland facilities. During the second quarter of 2008, we expect to start production of Osteocel in our Columbia, Maryland facility and by the end of the third quarter of 2008, move all of our production activities to Columbia, Maryland. The lease cost for our Baltimore facilities is approximately $1.0 million per annum.

Item 3. Legal Proceedings.

Lawsuits and claims are filed against us from time to time in the ordinary course of our business, including without limitation, challenges to our intellectual property positions. We do not believe that any lawsuits or claims, or proceedings, currently pending against us, individually or in the aggregate, are material, or will have a material adverse effect on our financial condition or business.

Item 4. Submission of Matters to a Vote of Securities Holders.

No matters were submitted to a vote of our security holders during the fourth quarter of the year ended December 31, 2007.

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issurer Purchases of Equity Securities.

Market Information

Our common stock trades on the NADSAQ Global Market under the symbol OSIR. The following table lists the high and low sale prices per share for our common stock based on the closing sales prices as reported on the NASDAQ Global Market for the periods indicated.

	2007		2006	
	High	Low	High	Low
Quarter Ended				
March 31	$ 29.29	11.85	**	**
June 30	19.05	10.60	**	**
September 30	14.42	11.01	**	**
December 31	14.57	9.98	$ 27.93	$ 10.00

** Our stock began trading on the NASDAQ Global Market on August 4, 2006.

Stockholders

As of March 7, 2008, there were approximately 270 stockholders of record of our common stock and, according to our estimates, approximately 2,099 beneficial owners of our common stock.

Dividends

We have not paid dividends to our stockholders since our inception and we do not plan to pay cash dividends in the foreseeable future. We currently intend to retain earnings, if any, to finance our growth.

Unregistered Sales of Securities

In June 2007, we sold 1,757,469 shares of our common stock in a private placement at $11.38 per share, through the efforts of Friedli Corporate Finance, Inc., raising $20.0 million. The shares were sold under Regulation S of the Securities Act of 1933 to institutional and accredited

investors primarily based in Switzerland. There were no commissions paid on the proceeds raised. The proceeds from the private placement were used to fund further development of our stem cell products.

In December 2007, we sold 950,000 shares of our common stock in a private placement at $12.37 per share, through the efforts of Friedli Corporate Finance, Inc., raising $11.8 million. The shares were sold under Regulation S of the Securities Act of 1933 to institutional and accredited investors based in Switzerland. There were no commissions paid on the proceeds raised. The proceeds from the private placement are intended to be used to fund further development of our stem cell products and general corporate purposes. We deposited the proceeds in two highly rated financial institutions in the United States.

In December 2007, we induced the conversion of $18.8 million of our 10% convertible promissory notes, together with accrued interest, into 1,465,837 shares of common stock at the conversion price of $13.00 per share. In January 2008, we induced the conversion of the remaining $1.2 million of our 10% convertible promissory notes, together with accrued interest, into 85,714 shares of common stock at the conversion price of $14.00 per share. The notes were held by institutional and accredited investors primarily based in Switzerland.

The private placements and the debt conversions were led by Friedli Corporate Finance, Inc., of which Peter Friedli, our Chairman of the Board of Directors and largest shareholder, is President and sole owner. Included among the purchasers of the common stock was Mr. Friedli, who individually invested $14.0 million in the June 2007 private placement and $1.2 million in the December 2007 private placement, and $8.5 million in the December 2007 debt conversion. New Venturetec, Inc., a Swiss publicly traded company approximately 3% owned by Mr. Friedli who serves as its President, invested $3.0 million in the June 2007 private placement. Our Board of Directors, including all independent directors, but with Mr. Friedli abstaining, together with our Audit Committee, unanimously approved the private placements and note conversion transactions including to Mr. Friedli and New Venturetec, Inc., and the arrangements with Friedli Corporate Finance, Inc.

The securities sold in the two private placements and issued as a result of the debt conversion have not been registered under the United States Securities Act of 1933, as amended (the U.S. Securities Act) or any state securities laws and may not be offered or sold within the United States or to U.S. Persons unless registered under the U.S. Securities Act and applicable state securities laws or unless an exemption from such registration is available. Pursuant to the terms of the private placements and debt conversions, the holders were provided demand registration rights for the shares of common stock after such time as we became eligible to effect such registration pursuant to a registration statement on Form S-3 or another short form registration statement.

In January 2008, we filed a Registration Statement on Form S-3 to register 1,904,235 shares of our common stock issued in connection with these two private placements and the debt conversion. The shares of common stock held by Mr. Friedli and New Venturetec, Inc. were not included in this Registration Statement.

Issuer Purchase of Equity Securities and Use of Proceeds

There were no repurchases by us of our securities during fiscal 2007 or 2006.

Stock Performance Graph

The following graph shows the cumulative total return, assuming the investment of $100 on August 4, 2006 (the date on which our initial public offering was declared effective and our common stock began trading on the NASDAQ Global Market), on an investment in each of our common stock, the NASDAQ Composite Index (U.S. and Foreign) and the NASDAQ Biotechnology Index. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 201(d) of Regulation S-K, pursuant to paragraph (a) of this Item 5, is incorporated by reference to the information set forth under the caption Equity Compensation Plan Information in the Company s Proxy Statement for the 2008 Annual Meeting of Stockholders, which is anticipated to be filed pursuant to Regulation 14A no later than one hundred twenty (120) days following the end of the fiscal year reported on.

Item 6. Selected Financial Data.

We derived the selected financial data presented below for the periods or dates indicated from our financial statements. Our financial statements for these periods were audited by Stegman & Company, an independent registered public accounting firm. You should read the data below in conjunction with our financial statements, related notes and other financial information appearing in Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data.

	Year Ended December 31,				
	2007	2006	2005	2004	2003
	(in thousands, except per share data)				
Statement of Operations Data:					
Product sales	$ 15,240	$ 8,291	$ 957	$	$
Cost of goods sold	6,955	3,697	444		
Gross profit	8,285	4,594	513		
Revenue from collaborative research licenses and grants	2,048	1,181	3,013	3,911	3,981
Operating expenses:					
Research and development	50,851	37,590	16,927	11,888	18,639
General and administrative and other expenses	6,708	8,459	2,294	1,704	4,467
Total operating expenses	57,559	46,049	19,221	13,592	23,106
Loss from operations	(47,226)	(40,274)	(15,695)	(9,681)	(19,125)
Interest expense, net	(6,695)	(4,685)	(4,300)	(847)	(605)
Net loss	$ (53,921)	$ (44,959)	$ (19,995)	$ (10,528)	$ (19,730)
Basic and diluted net loss per share	$ (1.89)	$ (2.70)	$ (2.23)	$ (1.19)	$ (3.60)
Weighted average shares of common stock used in computing basic and diluted net loss per share	28,489	16,663	8,959	8,814	5,475

	At December 31,				
	2007	2006	2005	2004	2003
Balance Sheet Data:					
Cash and short-term investments	$ 18,164	$ 39,181	$ 43,471	$ 488	$ 1,339
Working capital	7,247	33,166	38,103	(5,459)	(5,314)
Total assets	37,041	49,168	51,014	5,972	9,748
Notes payable, less current portion	1,200	25,000	47,411	7,519	179
Mandatorily redeemable convertible preferred stock			64,267		
Convertible preferred stock			32,746	15,243	13,000
Accumulated deficit	(241,424)	(187,503)	(142,544)	(122,549)	(112,021)
Total stockholders equity (deficit)	14,336	11,287	(73,662)	(13,004)	(5,563)

Quarterly Financial Data (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2007				
Total revenues	$ 2,279	$ 3,547	$ 4,297	$ 7,165
Product sales	2,000	3,252	4,003	5,985
Cost of goods sold	901	1503	1,826	2,725
Research and development expenses	11,030	10,583	10,842	18,396
General and administrative expenses and fees	1,506	1,501	1,689	2,012
Net loss	(11,501)	(10,458)	(10,390)	(21,572)
**Net loss per common share, basic and diluted	(0.42)	(0.37)	(0.36)	(0.73)
2006				
Total revenues	$ 1,400	$ 1,987	$ 2,841	$ 3,244
Product sales	1,105	1,689	2,539	2,958
Cost of goods sold	489	762	1,113	1,333
Research and development expenses	4,368	10,922	9,242	13,058
General and administrative expenses and fees	1,138	1,209	5,300	812
Net loss	(5,121)	(11,605)	(15,565)	(12,668)
**Net loss per common share, basic and diluted	(0.56)	(1.27)	(0.75)	(0.46)
2005				
Total revenues	$ 385	$ 1,339	$ 1,285	$ 961
Product sales			284	673
Cost of goods sold			220	224
Research and development expenses	2,657	3,592	3,464	7,214
General and administrative expenses and fees	752	487	554	501
Net loss	(3,868)	(3,394)	(4,678)	(8,055)
**Net loss per common share, basic and diluted	(0.43)	(0.38)	(0.52)	(0.88)

** Earning per share are calculated on a quarterly basis and may not be additive to year-to-date amounts.

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following is a discussion and analysis of our financial condition, results of operations, liquidity and capital resources for each of the three years in the period ended December 31, 2007 and significant factors that could affect our prospective financial condition and results of operations. You should read this discussion together with our financial statements and notes included in Item 8. Financial Statements and Supplementary Data. Historical results and any discussion of prospective results may not indicate our future performance. This section contains certain forward-looking statements within the meaning of federal securities laws that involve risks and uncertainties, including statements regarding our plans, objective, goals, strategies and financial performance. Our actual results could differ materially from the results anticipated in these forward-looking statements.

2007 Highlights

We believe cellular therapies have certain advantages over traditional medical approaches. For example, cell therapies can be targeted, avoiding many of the safety complications arising from systemic treatments. Cell therapies can also be responsive to their environment, turning on or off certain effects as conditions in the surrounding tissue change. Cell therapies can also be multifaceted. For example, the cells in Prochymal, our leading biologic drug candidate, have demonstrated the ability to not only down regulate inflammation, but also repair the damage caused by the inflammation.

We believe the combination of these unique properties will allow us to solve many of the most challenging questions facing medicine today. We have established ourselves as the leader in the emerging field of cell therapy. We have the only stem cell product on the market, Osteocel, and have treated over 15,000 patients. We have six additional indications in the clinic behind Osteocel. Three of these clinical trials are in Phase III and each has been granted fast track status by the FDA.

During 2007, we:

- achieved $15.2 million in Osteocel sales, compared to $8.3 million during 2006;

- secured $61.7 million in new financing and financing commitments, comprised of a $30.0 million line of credit and $31.7 million of equity raised through two private placements to non-U.S. investors;

- eliminated $18.8 million of debt and accrued interest through the induced conversion of our 10% convertible promissory notes into common stock;

- partnered with Genzyme Corporation to develop medical countermeasures for nuclear and radiological threats;

- received notification of award of a contract award from the U.S. Department of Defense for the development of treatment of acute radiation syndrome with a fully funded value of $224.7 million, assuming FDA approval and exercise of all purchase options;

- received a $4.0 million funding commitment from the Juvenile Diabetes Research Foundation and obtained FDA clearance to conduct a Phase II trial evaluating Prochymal for the treatment of type 1 diabetes;

- reported positive Phase II data from Prochymal in the frontline treatment of acute Graft versus Host Disease (GvHD) and initiated a pivotal Phase III trial with FDA Fast Track Status;

- initiated a Phase III trial evaluating Prochymal in patients with treatment refractory Crohn s disease and received FDA Fast Track Status;

- reported positive results for Prochymal as a rescue agent in pediatric patients with end stage GvHD; and

- reported positive one-year data for Prochymal in patients suffering acute myocardial infarction.

Business Overview

We are a leading stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Our marketed product, Osteocel, and our biologic drug candidates utilize mesenchymal stem cells, or MSCs. In July 2005, we launched Osteocel for regenerating bone in orthopedic indications. We currently have eight clinical trials ongoing. We are currently enrolling patients in three Phase III clinical trials for Prochymal, our lead biologic drug candidate, for:

- the treatment of steroid refractory acute GvHD;
- first line treatment of acute GvHD; and
- biologics refractory Crohn s disease.

We have received Fast Track Status from the FDA for each of these pivotal Phase III trials. During 2007, we initiated a Phase II clinical trial to treat type 1 diabetes and are continuing to evaluate the results of our Phase I trial to treat acute myocardial infarction. In addition, we have completed a Phase I/II trial for Chondrogen, our biologic drug candidate for osteoarthritis, reporting statistically significant improvements in pain over placebo. We are currently designing the next phase of clinical testing for Chondrogen.

We have developed stem cell capabilities in research and development, manufacturing, marketing and distribution. We manufacture Osteocel and, together with AlloSource and Tissue Banks International, distribute Osteocel in orthopedic indications and jointly distribute Osteocel with Blackstone Medical, Inc., a division of Orthofix International, N.V., for spinal procedures.

We have incurred annual operating losses since inception and expect to incur substantial operating losses in the future in connection with the development of our core products. As of December 31, 2007, we had an accumulated deficit of $241.4 million.

Financial Operations Overview

Revenue

Osteocel is currently our only commercial product. Sales of Osteocel generated revenue of $15.2 million for the year ended December 31, 2007. This increase in Osteocel revenues was due primarily to increased sales volume.

In 2007 and prior years, we have entered into strategic agreements with other companies for the development and commercialization of select stem cell biologic drug candidates for specific indications and geographic markets. In 2007, we entered into a collaborative agreement with the Juvenile Diabetes Research Foundation (JDRF) to develop a treatment plan for early onset type 1 diabetes. Under this agreement, JDRF will provide us with up to $4.0 million in funding. Also in 2007, we entered into a collaborative agreement with Genzyme Corporation to develop medical countermeasures for nuclear and radiological threats. In 2003, we entered into an agreement with a foreign pharmaceutical company granting it exclusive rights to Prochymal for the treatment of GvHD in Japan. We recognized $0.5 million of revenue during 2007 and 2005 related to this agreement. We entered into an agreement in 2003 with a major pharmaceutical company relating to the development of our cardiac biologic drug candidate, and we received a $5.0 million fee for licensing the use of our technology. This agreement was terminated in 2007 and as a result we regained the worldwide rights to Prochymal for cardiac indications. We recognized $1.4 million in license fee revenue in 2007 and $1.0 million in 2006 and 2005 related to this agreement.

We have also recognized revenue from governmental grants for research and in 2005, we recorded $1.4 million in grant revenues from three separate grants. Revenue from research grants is recognized

as the related research expenditures are incurred. We are not currently working on any government research grants.

In early January 2008, we were awarded a contract from the United States Department of Defense (DoD) to develop and stockpile Prochymal for the repair of gastrointestinal injury resulting from radiation exposure. Under the terms of the contract, the DoD will provide funding to us in two stages, with an initial amount of $4.2 million expected to be realized during 2008. If we are successful in obtaining FDA approval for acute radiation syndrome, the contract provides for the purchase of up to 20,000 doses of Prochymal, at $10,000 per dose, in four 5,000 dose increments.

Other than Osteocel, we have no commercial products for sale. A substantial portion of our revenue in the future will be dependent on the approval and sale of our biologic drug candidates. Our revenue may vary substantially from quarter to quarter and from year to year. We believe that period-to-period comparisons of our results of operations are not meaningful and should not be relied upon as indicative of our future performance.

Cost of Goods Sold

Our cost of goods sold relate to direct costs of producing Osteocel. Cost of goods sold consist primarily of the costs of obtaining tissue and other chemicals and supplies, direct labor and allocated costs of our clean-room facilities and overhead.

Research and Development Costs

Our research and development costs consist of expenses incurred in identifying, developing and testing biologic drug candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for independent monitoring and analysis of our clinical trials, costs of contract research and manufacturing, costs of facilities, and the costs of manufacturing clinical batches of biologic drug candidates, quality control supplies and material to expand biologic drug candidates.

Consistent with our focus on the development of biologic drug candidates with potential uses in multiple indications, many of our costs are not attributable to a specifically identified product. We use our employee and infrastructure resources across several projects. Accordingly, we do not account for internal research and development costs on a project-by-project basis. As a result, we cannot state precisely the total costs incurred for each of our clinical and preclinical projects on a project-by-project basis. From inception through December 31, 2007, we incurred aggregate research and development costs of approximately $234 million.

We expect our research and development expenses to continue to increase substantially in the future, as we expand our clinical trial activity, as our biologic drug candidates advance through the development cycle and as we invest in additional product opportunities and research programs. Clinical trials and preclinical studies are time-consuming and expensive. Our expenditures on current and future preclinical and clinical development programs are subject to many uncertainties. We test our products in several preclinical studies, and we then conduct clinical trials for those biologic drug candidates that we determine to be the most promising. As we obtain results from clinical trials, we may elect to discontinue or delay trials for some biologic drug candidates in order to focus our resources on more promising biologic drug candidates. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, size of trial and intended use of a biologic drug candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a

variety of factors, including:

- the number of patients who participate in the trials;
- the number of sites included in the trials;

- the length of time required to enroll trial participants;

- the duration of patient treatment and follow-up;

- the costs of producing supplies of the biologic drug candidates needed for clinical trials and regulatory submissions;

- the efficacy and safety profile of the biologic drug candidate; and

- the costs and timing of, and the ability to secure, regulatory approvals.

As a result of the uncertainties discussed above, we are unable to determine with any significant degree of certainty the duration and completion costs of our research and development projects or when and to what extent we will generate revenues from the commercialization and sale of any of our biologic drug candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of the costs associated with our general management, including salaries, allocations of facilities and related costs, and professional fees such as legal and accounting expenses. In anticipation of and since the closing of our initial public offering in August 2006, we began to incur increases in our general and administrative expense for legal and accounting compliance costs, investor relations and other activities associated with operating as a publicly traded company. Continued increases will also likely result from the hiring of additional operational, financial, accounting, facilities engineering and information systems personnel.

Interest Income (Expense), Net

Interest income consists of interest earned on our cash and short-term investments. Interest expense consists of interest incurred on capital leases and other debt financings. We pay interest on our bank loan, capital leases and any convertible long-term debt.

Income Taxes

We have not recognized any deferred tax assets or liabilities in our financial statements since we cannot assure their future realization. Because realization of deferred tax assets is dependent upon future earnings, a full valuation allowance has been recorded on the net deferred tax assets, which relate primarily to net operating loss and research and development carry-forwards. In the event that we become profitable within the next several years, we have net deferred tax assets (before a 100% valuation allowance) of approximately $93.6 million that may be utilized prior to us having to recognize any income tax expense or make payments to the taxing authorities. Utilization of our net operating loss carry-forwards in any one year may be limited under IRC Section 382, and we could be subject to the alternative minimum tax.

Critical Accounting Policies

General

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, inventory valuation, deferred tax assets, share-based compensation, and contingencies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable. These results form the basis for making judgments

about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following critical accounting policies reflect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Our revenue recognition policies are governed by the Securities and Exchange Commission s, or SEC, Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*.

We have one commercial product on the market. We recognize revenue on sales when legal title to the product has passed to the customer, which is usually when the product is shipped from our Baltimore, Maryland facilities. We have agreements with our customers that specify the terms of sale, including price.

Revenues from collaborative agreements and grants are recognized as earned upon either the incurring of reimbursable expenses directly related to the particular research plan or the completion of certain development milestones as defined within the terms of the collaborative agreement. Payments received in advance of research performed are designated as deferred revenue. We recognize non-refundable upfront license fees and certain other related fees on a straight-line basis over the development period. Fees associated with substantive at risk, performance based milestones are recognized as revenue upon their completion, as defined in the respective agreements. Incidental assignment of technology rights is recognized as revenue at the time of receipt.

Milestone payments that are based on designated achievement points and that are considered at risk and substantive at the inception of the collaboration are recognized as earned when the corresponding payment is considered reasonably assured. We evaluate whether milestone payments are at risk and substantive based on the contingent nature of the milestone, specifically reviewing factors such as the technological and commercial risk that must be overcome and the level of the investment required. Milestone payments that are not considered at risk and substantive are recognized, when achieved, in proportion to the percentage of the collaboration completed through the date of achievement. The remainder of the milestone payment is recognized as services are performed over the remaining term of the collaboration.

Royalties for the use of our MSCs for clinical research purposes are recognized when earned, however, such amounts have not been material and are not expected to be material in the future. Additionally, we may receive royalty payments under our collaborative arrangements upon sales of product.

We evaluate all collaborative agreements on a quarterly basis to determine the appropriate revenue recognition for that period. The evaluation includes all of the potential revenue components from each specific collaborative agreement.

Accounts Receivable

Our accounts receivable are reported at their net realizable value. As of December 31, 2007 and 2006, there was no allowance for doubtful accounts as we believe the reported amounts are fully collectible. During the year ended December 31, 2006, we recognized $3 of bad debt expense. We did not recognize any bad debt expense for the years ended December 31, 2007 and 2005. Accounts receivable balances are not collateralized.

Share-Based Compensation

Effective January 1, 2006, we adopted Financial Accounting Standards Board (FASB) Statement No. 123(R) and began to recognize expense in our statement of operations associated with all share-based awards based on the grant-date fair value of the awards. Compensation expense related to share- based awards is recognized on a straight-line basis based on the value of share awards that are scheduled to vest during the requisite service period. We use the Black-Scholes option pricing model to estimate the fair value of share- based awards. The determination of the fair value of share-based awards using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. Those assumptions include estimating:

- the expected term of the award, or the length of time option holders will retain their vested awards;
- the expected volatility of the market price of our common stock over the expected term;
- the risk free interest rate expected during the option term; and
- the expected forfeiture rate.

We have reviewed each of these assumptions carefully and based on the analysis discussed in Note 6 Share-Based Compensation to our financial statements determined our best estimate for these variables. Of these assumptions, the expected term of the option, forfeiture rate and expected volatility of our common stock are the most difficult to estimate since they are based on the exercise behavior of option holders and the expected performance of our common stock. An increase in the volatility of our common stock will increase the amount of compensation expense on new awards. An increase in the expected term of the awards will also cause an increase in compensation expense. An increase in the forfeiture rate will cause a decrease in compensation expense as the employee is not likely to hold the option for the contractual term. Risk-free interest rates are less difficult to estimate, but an increase in the risk-free interest rate will increase compensation expense.

Under Statement No. 123(R), share-based compensation expense is based on awards ultimately expected to vest and must be reduced for estimated forfeitures. Forfeitures are estimated at the time an award is granted and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures were estimated to be between 0% and 20% based on historical experience. Changes in our estimated forfeiture rate could materially impact our estimate of the fair value of share-based compensation and consequently, the related amount of expense recognized in our statements of operations.

Significant New Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) 157, *Fair Value Measurements.* SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim

periods within those years. We do not expect the implementation of SFAS 157 to have a material impact on our financial statements.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 clarifies when tax benefits should be recorded in financial statements, requires certain disclosures of uncertain tax matters and indicates how any tax reserves should be classified in a balance sheet. On January 1, 2007, we adopted FIN 48. We have determined that adoption of FIN 48 did not have any impact on our financial condition or results of operations. It is our policy to recognize interest and penalties related to unrecognized tax liabilities within income tax expense in the statements of operations.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Liabilities.* SFAS 159 permits entities to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. This pronouncement is effective as of the beginning of an entity s first fiscal year beginning after November 15, 2007. We do not expect the implementation of SFAS 159 to have a material impact on our financial position or results of operations.

In June 2007, the FASB ratified a consensus opinion reached by the Emerging Issues Task Force (EITF) on EITF Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities.* The guidance in EITF Issue 07-3 requires us to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, we would be required to expense the related capitalized advance payments. The consensus in EITF Issue 07-3 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is to be applied prospectively to new contracts entered into on or after December 15, 2007. Early adoption is not permitted. Retrospective application of EITF Issue 07-3 is also not permitted. We intend to adopt EITF Issue 07-3 effective January 1, 2008. The impact of applying this consensus will depend on the terms of the our future research and development contractual arrangements entered into on or after December 15, 2007.

In December 2007, the FASB ratified a consensus reached by the EITF on Issue 07-1, *Accounting for Collaborative Arrangements.* The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and its terms, the nature of the entity s business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for us January 1, 2008 and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We do not expect the adoption of EITF 07-1 to have a material impact on our financial statements.

In December 2007, the FASB issued SFAS 141, Revised 2007 (SFAS 141R), *Business Combinations.* SFAS 141R s objective is to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after December 15, 2008. We do not expect the implementation of SFAS 141R to have a material impact on our financial statements.

In December 2007, the FASB issued SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements* . SFAS 160 s objective is to improve the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 shall be effective for fiscal years and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not expect the implementation of SFAS 160 to have a material impact on our financial statements.

Results of Operations

Year ended December 31, 2007 compared to December 31, 2006

Revenue

Total revenues increased 83% to $17.3 million for the twelve months ended December 31, 2007, compared to $9.5 million in the corresponding period in 2006. Our revenues in 2007, resulted primarily from $15.2 million generated from the sale of Osteocel and the recognition of $2.0 million in licensing fees and royalties. In the twelve months ended December 31, 2006, we recognized $8.2 million from the sale of Osteocel and $1.2 million in license fees and royalties. The 2007 license fees and royalties includes a $0.5 million milestone payment received from JCR Pharmaceuticals and the recognition of the unamortized license fees associated with our collaborative agreement with Boston Scientific Corporation, which was terminated in December 2007.

Cost of Goods Sold

Cost of goods sold were $7.0 million for the twelve months ended December 31, 2007 compared to $3.7 million in the prior year. The cost of goods sold associated with sales of Osteocel is comprised of payments to tissue banks, direct labor costs and the costs of processing, testing and preserving Osteocel, plus allocated costs of our facilities and overhead. The gross margin on Osteocel sales for the twelve months ended December 31, 2007 was 54%, compared with 55% for 2006.

Research and Development Expenses

Research and development expenses were $50.9 million for the twelve months ended December 31, 2007 compared to $37.6 million in the prior year. The increase in research and development expenses in 2007 reflects the increased number of clinical trials in process versus the prior year. In 2007, we incurred costs associated with the enrollment of three Phase III clinical trials for Prochymal, manufacturing the biologic drug candidates for use in our clinical trials, as well as costs associated with our Phase I and Phase II trials and other preclinical development activities.

General and Administrative Expenses

General and administrative expenses were $6.6 million for the twelve months ended December 31, 2007 compared to $4.3 million in the prior year. The increase in 2007 was attributable to additional personnel and related costs to support our growth and costs incurred in connection with being a public company.

Related Party Expenses

During 2007, we paid Peter Friedli, the Chairman of our Board of Directors and largest shareholder, 5,000 shares of our common stock, valued at $23.62 per share, for board related services. Fees paid to related parties were $0.5 million for the twelve months ended December 31, 2006 and were made in connection with pre-IPO financings. Also in 2006, we recorded $3.5 million in non-cash charges related to warrants issued to our chairman that were priced and vested upon completion of our initial public offering and $0.2 million in share-based compensation for stock awards for services of our board of directors.

Interest Income (Expense), Net

Interest income (expense), net was $6.7 million for the twelve months ended December 31, 2007 compared to $4.7 million in the prior year. The 2007 costs include a non-cash charge of $4.8 million resulting from the induced conversion of $18.8 million of our convertible promissory notes into common stock and $0.3 million of previously deferred debt financing fees. The 2006 costs include $2.7 million of previously deferred debt financing costs and premiums associated with debt that was

converted into common stock upon the completion of our initial public offering. Exclusive of these charges, net interest expense during 2007 was $1.9 million, compared with $2.0 million in 2006.

Year ended December 31, 2006 compared to December 31, 2005

Revenue

Total revenues increased 138% to $9.5 million for the twelve months ended December 31, 2006, compared to $4.0 million in the corresponding period in 2005. Our revenues in 2006 resulted primarily from $8.3 million generated from the sale of Osteocel and the recognition of $1.2 million in licensing fees and royalties. In the twelve months ended December 31, 2005, we recognized $1.0 million from the sale of Osteocel and $3.0 million in license fees and royalties and government grants.

Cost of Goods Sold

Cost of goods sold were $3.7 million for the twelve months ended December 31, 2006 compared to $0.4 million in the prior year. The cost of goods sold associated with sales of Osteocel was comprised of payments to tissue banks, direct labor costs and the costs of processing, testing and preserving Osteocel, plus allocated costs of our facilities and overhead. The gross margin on Osteocel sales for the twelve months ended December 31, 2006 was 55%, compared with 54% for 2005.

Research and Development Expenses

Research and development expenses were approximately $37.6 million for the twelve months ended December 31, 2006 compared to $16.9 million in the prior year. The increase in research and development expenses in 2006 reflects the increased number of clinical trials in process versus the prior year. In 2006, we incurred costs associated with the enrollment of a Phase II trial for Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD, a Phase II trial for Prochymal for treatment of steroid refractory GvHD, a Phase II trial for Prochymal for treatment of Crohn s disease, a Phase I/II clinical trial for Chondrogen, and a Phase I clinical trial for Prochymal for the treatment of heart disease.

General and Administrative Expenses

General and administrative expenses were $4.3 million for the twelve months ended December 31, 2006 compared to $2.2 million in the prior year. The increase in 2006 includes $0.9 million of non-cash charges associated with the completion of our initial public offering. Exclusive of these charges, general and administrative expenses in 2006 were $3.5 million and the increase over the prior year was attributable to additional personnel and related costs to support our growth and costs incurred in connection with being a public company.

Related Party Expenses

Fees paid to related parties were $0.5 million for the twelve months ended December 31, 2006 compared to $0.1 million in the prior year. In 2006, we recorded $3.5 million in non-cash charges related to warrants issued to our chairman that were priced and vested upon completion of our initial public offering and $0.2 million in share-based compensation for stock awards for services of our board of directors.

Interest Income (Expense), Net

Interest expense, net was $4.7 million for the twelve months ended December 31, 2006 compared to $4.3 million in the prior year. The 2006 costs include $2.7 million of previously deferred debt financing costs and premiums associated with debt that was converted into common stock upon the completion of our initial public offering. Exclusive of these charges, net interest expense during 2006 was $2.0 million, a decrease of $2.3 million compared to 2005. This decrease was the result of higher

interest income related to the investment of the proceeds of the initial public offering and the $21.8 million decrease in debt, which was converted into common stock upon the completion of the initial public offering in early August 2006.

Liquidity and Capital Resources

Liquidity.

At December 31, 2007, we had $0.7 million in cash and $17.5 million in short-term investments. In addition to the cash and short-term investments, at December 31, 2007, we had availability of $30.0 million under our line of credit with Friedli Corporate Finance, Inc.

At December 31, 2007, our short-term debt was $6.5 million.

Cash Flows.

	Years Ended December 31,		
	2007	2006	2005
	(amounts in thousands)		
Net cash used in operating activities	$ (46,518)	$ (35,310)	$ (14,620)
Net cash provided by (used in) investing activities	16,305	2,611	(43,112)
Net cash provided by financing activities	30,203	32,816	57,841

We have historically financed our research and development activities through cash flows provided by financing activity and have not generated net cash from operating activities since inception. Starting in 2005, we began to generate revenues and segment profits from the manufacture and sale of Osteocel, however during the same periods, we have increased our clinical trial activities as we strive to bring our biologic drug candidates to market. We believe these trends will continue in the foreseeable future.

Net cash used in operating activities was $46.5 million for the twelve months ended December 31, 2007 primarily reflecting our net loss of $53.9 million; partially offset by $6.9 million in non-cash interest, $1.3 million in non-cash stock-based compensation expense and $2.0 million in depreciation and amortization. Other long-term liabilities decreased by $1.1 million, reflecting the reclassification of the accrued interest on the Boston Scientific credit line which was converted into short-term debt upon the termination of our collaborative agreement. Net cash used for operating activities was $35.3 million for the twelve months ended December 31, 2006. Net cash used in operating activities for 2006 primarily reflected our net loss of $45.0 million, partially offset by $5.7 million in non-cash interest expense and $5.5 million of non-cash share-based payments.

Net cash provided by investing activities was $16.3 million for the twelve months ended December 31, 2007. Net cash provided by investing activities for the twelve months ended December 31, 2006 was $2.6 million. Net cash provided by investing activities in 2007 includes cash flows from the net sale of $21.0 million of short-term investments, less purchases of property and equipment of $4.7 million. In 2006, we had

net sales of short-term investments during the year of $4.3 million and purchase of property and equipment of $1.7 million.

Net cash provided by financing activities was $30.2 million for the twelve months ended December 31, 2007, principally from the two private placements of our common stock which raised $31.7 million. Net cash provided by financing activities was $32.8 million for the twelve months ended December 31, 2006 and consisted principally of $34.4 million in net proceeds from our initial public offering and the issuance of $20.0 million of convertible promissory notes in October 2006, which was offset by the redemption of the $20.6 million convertible note, also in October 2006.

Capital Resources.

Our future capital requirements will depend on many factors, including:

- the level of cash flows from Osteocel sales;

- the scope and results of our research and preclinical development programs;

- the scope and results of our clinical trials, particularly regarding the number of patients required for our three Phase III trials for Prochymal;

- the timing of and the costs involved in obtaining regulatory approvals for our biologic drug candidates, which could be more lengthy or complex than obtaining approval for a new conventional drug, given the FDA s limited experience with late-stage clinical trials and marketing approval for stem cell therapeutics;

- the costs of building and operating our manufacturing facilities, both in the near term to support Osteocel sales and our clinical activities and also in anticipation of expanding our commercialization activities;

- the costs of maintaining, expanding and protecting our intellectual property portfolio, including possible litigation costs and liabilities;

- the costs of repaying our debt; and

- the costs of enlarging our work force consistent with expanding our business and operations and status as a public company, and as necessary to enhance and train our sales network in anticipation of the approval of our biologic drug candidates for commercial sale.

As a result of these factors, we will need to seek additional funding prior to our becoming cash flow positive on an operational basis. We would likely seek such funding through public or private financings or some combination of them. We might also seek funding through collaborative arrangements if determined to be necessary or appropriate. Additional funding may not be available to us on acceptable terms, or at all. If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our technologies or biologic drug

candidates. If we raise capital through the sale of equity, or securities convertible into equity, dilution to our then existing stockholders would result. If we raise additional capital through the incurrence of debt, we would likely become subject to covenants restricting our business activities, and holders of debt instruments would have rights and privileges senior to those of our equity investors. In addition, servicing the interest and repayment obligations under these borrowings would divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we are unable to obtain adequate financing on a timely basis, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our business, financial condition and results of operations.

We expect that our available cash and interest income, including the availability under our line-of-credit, will be sufficient to finance currently planned activities through at least early 2009. These estimates are based on certain assumptions, which could be negatively impacted by the matters discussed under Risk Factors.

If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, which may have a material adverse affect on our business. See Risk Factors.

Off-Balance Sheet Arrangements.

We have no off-balance sheet financing arrangements and we have not entered into any transactions involving unconsolidated subsidiaries or special purpose entities.

Future Contractual Obligations

The following table sets forth our estimates as to the amounts and timing of contractual payments for our most significant contractual obligations at December 31, 2007. The information in the table reflects future unconditional payments and is based on the terms of the relevant agreements, appropriate classification of item under generally accepted accounting principles currently in effet and certain assumptions such as interest rates. Future events could cause actual payments to differ from these amounts.

	Payment Due by Fiscal Year				
Contractual Obligations	**Total**	**Less Than 1-Year**	**Years 1-3**	**Years 4-5**	**More Than 5-Years**
		(amounts in thousands)			
Long-term debt	$ 7,721	$ 6,521	1,200	$	$
Operating lease facilities	9,100	876	3,116	2,246	2,862
Capital leases facilities	880	880			
Capital leases equipment	19	8	11		
Interest payments	802	678	124		
Total contractual cash obligations	$ 18,552	$ 8,963	$ 4,451	$ 2,246	$ 2,862

Effect of Inflation.

Inflation and changing prices are not generally a material factor affecting our business. General operating expenses such as salaries, employee benefits and lease costs are, however, subject to normal inflationary pressures.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Due to the short duration of our investment portfolio and the high quality of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. Therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectability and establishment of appropriate allowances in connection with our internal controls and policies.

Foreign Current Exchange Rate Risk

We conduct clinical trial activities in areas that operate in a functional currency other than the United States dollar (USD). As a result, when the USD rises and falls against the functional currencies of these other nations, our costs will either increase or decrease by the relative change in the exchange rate. Foreign currency gains and losses were not significant during the three years ended December 31, 2007, and at the present time, we have elected not to hedge our exposure to foreign currency fluctuations.

Derivative Instruments

We do not enter into hedging or derivative instrument arrangements.

Item 8. Financial Statements and Supplementary Data.

Osiris Therapeutics, Inc.

Financial Statements

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MANAGEMENT S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for performing an assessment of the effectiveness of internal control over financial reporting as of December 31, 2007. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our system of internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with the authorization of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements. Under the supervision and with the participation of our management, including our Chief Executive Officer and Interim Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007 based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2007.

Stegman & Company, the independent registered public accounting firm that audited our financial statements, has issued an attestation report on their assessment of internal controls over financial reporting, which is included elsewhere in this Annual Report.

Date: March 13, 2008

/s/ C. RANDAL MILLS
C. Randal Mills, Ph.D.
President and Chief Executive Officer
(principal executive officer)

/s/ PHILIP R. JACOBY, JR.
Philip R. Jacoby, Jr.
Interim Chief Financial Officer
(principal financial officer)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

INTERNAL CONTROL OVER FINANCIAL REPORTING

To the Board of Directors and Stockholders

Osiris Therapeutics, Inc.

Columbia, Maryland

We have audited Osiris Therapeutics, Inc. s internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Osiris Therapeutics, Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Osiris Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets and the related statements of operations, stockholders equity (deficit), and cash flows of Osiris Therapeutics, Inc., and our report dated March 13, 2008 expressed an unqualified opinion.

/s/ STEGMAN & COMPANY

Baltimore, Maryland
March 13, 2008

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

FINANCIAL STATEMENTS

Board of Directors and Stockholders

Osiris Therapeutics, Inc.

Columbia, Maryland

We have audited the accompanying balance sheets of Osiris Therapeutics, Inc. as of December 31, 2007 and 2006, and the related statements of operations, stockholders equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2007. Osiris Therapeutics, Inc. s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Osiris Therapeutics, Inc. as of December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Osiris Therapeutics, Inc. s internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 13, 2008 expressed an unqualified opinion.

/s/ STEGMAN & COMPANY

Baltimore, Maryland
March 13, 2008

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OSIRIS THERAPEUTICS, INC.

BALANCE SHEETS

(amounts in thousands)

	December 31,	
	2007	**2006**
ASSETS		
Current assets:		
Cash	$ 704	$ 714
Short-term investments	17,460	38,467
Accounts receivable	4,873	1,596
Inventory	3,983	1,892
Other current assets	1,721	966
Total current assets	28,741	43,635
Property and equipment, net	6,616	3,942
Restricted cash	280	297
Deferred financing costs, net	19	567
Other assets	1,385	727
Total assets	$ 37,041	$ 49,168
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 14,087	$ 8,339
Note payable, current portion	6,521	49
Capital lease obligations, current portion	886	1,129
Deferred revenue, current portion		952
Total current liabilities	21,494	10,469
Notes payable and long-term line-of-credit, net of current portion	1,200	25,000
Capital lease obligations, net of current portion	11	895
Deferred revenue, net of current portion		397
Long-term interest payable and other liabilities		1,120
Total liabilities	22,705	37,881
Stockholders equity:		
Convertible preferred stock, issuable in series, $0.001 par value, 16,250 shares authorized, 12,250 shares designated and no shares outstanding		
Common stock, $0.001 par value, 90,000 shares authorized 31,648 and 27,321 shares outstanding in 2007 and 2006	32	27
Additional paid-in-capital	255,728	198,763
Accumulated deficit	(241,424)	(187,503)
Total stockholders equity	14,336	11,287

Total liabilities and stockholders equity	$ 37,041	$ 49,168

The accompanying notes are an integral part of these financial statements.

OSIRIS THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS

(amounts in thousands, except per share data)

	Years Ended December 31,		
	2007	**2006**	**2005**
Product sales	$ 15,240	$ 8,291	$ 957
Cost of goods sold	6,955	3,697	444
Gross profit	8,285	4,594	513
Revenue from collaborative research licenses, royalties and grants	2,048	1,181	3,013
Operating expenses:			
Research and development	50,851	37,590	16,927
General and administrative	6,590	4,340	2,229
Fees paid to related parties		451	65
Share-based payments to related party	118	3,668	
Total operating expenses	57,559	46,049	19,221
Loss from operations	(47,226)	(40,274)	(15,695)
Interest income (expense):			
Interest income	1,321	2,069	504
Interest expense	(8,016)	(6,754)	(4,804)
Total interest expense, net	(6,695)	(4,685)	(4,300)
Net loss	$ (53,921)	$ (44,959)	$ (19,995)
Basic and diluted net loss per share	$ (1.89)	$ (2.70)	$ (2.23)
Weighted average common shares outstanding, in thousands (basic and diluted)	28,489	16,663	8,959

The accompanying notes are an integral part of these financial statements.

OSIRIS THERAPEUTICS, INC.

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

(amounts in thousands, except for share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Deferred	Accumulated	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Capital	Compensation	Deficit	(Deficit)
Balance at January 1, 2005	3,093,544	$ 15,243	8,900,358	$ 9	$ 94,386	$ (93)	$ (122,549)	$ (13,004)
Exercise of options to purchase common stock ($0.40-$0.80 per share)			27,148		12			12
Share-based payment director services ($0.40 per share)			45,000		18			18
Conversion of restricted stock units to management ($0.40 per share)			125,000		50			50
Issuance of convertible preferred sstock Series E ($2.50 per share)	7,557,000	17,503						17,503
Redemption premium on mandatorily redeemable convertible preferred sstock, Series D, redeemable at $20.00 per share					(58,305)			(58,305)
Deferred compensation from stock option grants					247	(247)		
Forfeiture of stock options					(17)	17		
Amorization of deferred compensation from stock option grants					13	46		59
Net loss							(19,995)	(19,995)
Balance at December 31, 2005	10,650,544	32,746	9,097,506	9	36,404	(277)	(142,544)	(73,662)
Exercise of options to purchase common stock ($0.40-$0.80 per share)			178,378		73			73
Exercise of warrants to purchase common stock ($0.40 per share)			875,000	1	349			350
Share-based payment director services ($6.84 $11.00 per share)			22,807		198			198
Share-based payment consulting services ($6.84 per share)			6,250		43			43
Reclassification due to adoption of new accounting standard					(277)	277		
Initial public offering of common stock, net of offering costs			3,500,000	3	34,399			34,402
Conversion of convertible preferred stock into common stock	(10,650,544	(32,746)	2,833,914	3	32,743			
			8,033,388	8	64,259			64,267

Conversion of mandatorily redeemable preferred stock into common stock						
Conversion of convertible notes payable into common stock	2,774,076	3	25,320			25,323
Share-based payment employee compensation			1,725			1,725
Share-based payment related party			3,527			3,527
Net loss					(44,959)	(44,959)
Balance at December 31, 2006	27,321,319	27	198,763		(187,503)	11,287
Exercise of options to purchase common stock ($0.40-$6.84 per share)	141,312		60			60
Share-based payment director services ($23.62 per share)	12,500		295			295
Issuance of common stock in private placements to overseas investors ($11.38 $12.37 per share)	2,707,469	3	31,698			31,701
Induced conversion of convertible notes payable into common stock ($13.00 per share)	1,465,837	2	23,867			23,869
Share-based payment employee compensation			1,045			1,045
Net loss					(53,921)	(53,921)
Balance at December 31, 2007	$ 31,648,437	$ 32	$ 255,728	$	$ (241,424)	$ 14,336

The accompanying notes are an integral part of these financial statements.

OSIRIS THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

(amounts in thousands)

	Years Ended December 31,		
	2007	**2006**	**2005**
Cash flows from operating activities:			
Net loss	$ (53,921)	$ (44,959)	$ (19,995)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,033	1,546	1,515
Non cash share-based payments	1,340	5,494	109
Non cash interest expense	6,881	5,653	3,497
Changes in operating assets and liabilities:			
Accounts receivable	(3,277)	(622)	(913)
Inventory and other current assets	(2,846)	(2,491)	(276)
Other assets	(663)	(457)	(120)
Accounts payable and accrued expenses	6,404	3,374	1,875
Deferred revenue	(1,349)	(952)	(952)
Long-term interest and other liabilities	(1,120)	(1,896)	640
Net cash used in operating activities:	(46,518)	(35,310)	(14,620)
Cash flows from investing activities:			
Purchases of property and equipment	(4,702)	(1,696)	(338)
Proceeds from sale of short-term investments	50,900	40,112	2,200
Purchase of short-term investments	(29,893)	(35,805)	(44,974)
Net cash provide by (used in) investing activities	16,305	2,611	(43,112)
Cash flows from financing activities:			
Principal payments on capital lease obligations and notes payable	(1,115)	(21,692)	(1.000)
Restricted cash	17	(107)	23
Proceeds from convertible notes payable		20,000	39,957
Proceeds from the issuance of common and preferred stock, net of offering costs	31,701	34,824	21,360
Payment of debt financing costs	(400)	(209)	(2,499)
Net cash provided by financing activities	30,203	32,816	57,841
Net increase in cash	(10)	117	109
Cash at beginning of year	714	597	488
Cash at end of year	$ 704	$ 714	$ 597
Supplemental disclosure of cash flows information:			
Cash paid for interest	$ 1,450	$ 1,260	$ 448
Cash paid for taxes			

Supplemental schedule of non cash investing and financing activities:			
Conversion of notes payable to common stock	18,800	21,762	
Conversion of related parties notes payable to Series D Mandatorily Redeemable Convertible Preferred Stock			2,350
Conversion of accrued interest into common stock	5,069	3,558	
Conversion of related party convertible notes payable accrued interest and premium into Series D Mandatorily Redeemable Convertible Preferred Stock			355
Common stock issued to directors for services rendered	295	198	18
Share-based payment related party for financing services		3,527	
Redemption premium on Series D Mandatorily Redeemable Convertible Preferred Stock			58,305

The accompanying notes are an integral part of these financial statements.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

1. Description of Business and Significant Accounting Policies

Description of Business

Osiris Therapeutics, Inc. is a Delaware corporation headquartered in Columbia, Maryland. We began operations on December 23, 1992. The Company is a clinical stage biotechnology company founded to commercialize stem cell products from adult bone marrow. We launched our first commercial product in July 2005. Our operations consist primarily of research, development and clinical activities to bring our biologic drug candidates to the marketplace and efforts to secure adequate capital for anticipated growth and operations.

We are dependent upon the registration of our core products for sale before we can expand our commercial operations. We expect to submit product applications for approval with the United States Food and Drug Administration (FDA) in the future and plan to continue to seek additional equity and debt financing as the need arises. We believe our long-term cash position is inadequate to fund all of the costs associated with the full range of testing and clinical trials required by the FDA for our core products. We expect that our available cash and interest income, including the availability under our line-of-credit, will be sufficient to finance currently planned activities through at least early 2009. We have several research collaboration agreements and a government contract that provide us with funding.

No assurance can be given that (i) we will be able to expand our operations prior to FDA approval of our biologic drug candidates, or (ii) that the FDA approval will ever be granted for our biologic drug candidates.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Due to the inherent uncertainty involved in making those assumptions, actual results could differ from those estimates. We believe that the most significant estimates that affect our financial statements are those that relate to inventory valuation, deferred tax assets, and share-based compensation.

Short-term Investments

Short-term investments consist primarily of investment grade auction rate certificates with maturities of less than three months. Short-term investments are valued at cost, which approximates their fair value.

Accounts Receivable

Our accounts receivable are reported at their net realizable value. As of December 31, 2007 and 2006, there was no allowance for doubtful accounts as we believe the reported amounts are fully collectible. During the year ended December 31, 2006, we recognized $3 of bad debt expense. We did not recognize any bad debts expense in 2007 or 2005. Accounts receivable balances are not collateralized.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

1. Description of Business and Significant Accounting Policies (Continued)

Inventory

We commenced sales of our first commercial product, Osteocel, in July 2005 and began carrying inventory on our balance sheet thereafter. Inventory consists of tissue products in process and available for distribution. We determine our inventory values using the first-in, first-out method. Due to the nature of our Osteocel product, we incur all of the costs to manufacture the product prior to completing the extensive testing and evaluation necessary to determine if the product can be released. We estimate the reserve for work-in-process inventory based upon our historical experience. We have nominal amounts of finished goods inventory.

Inventory of supplies purchased to manufacture of biologic drug candidates and manufactured biologic drug candidate doses are presently used exclusively for research and development activities, including clinical trials. These items are expensed as incurred, consistent with our accounting for all other research and development costs.

Property and Equipment

We record property and equipment, including improvements that extend useful lives, at cost, while maintenance and repairs are charged to operations as incurred. We calculate depreciation using the straight-line method based on estimated useful lives ranging from three to seven years for furniture, equipment and internal use software. We amortize leasehold improvements and assets under capital leases over the shorter of the estimated useful life of the asset or the original term of the lease.

Valuation of Long-lived Assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or group of assets may not be fully recoverable. These events or changes in circumstances may include a significant deterioration of operating results, changes in business plans, or changes in anticipated future cash flows. If an impairment indicator is present, we evaluate recoverability by a comparison of the carrying amount of the assets to future undiscounted net cash flows we expect the assets to generate. We group assets at the lowest level for which there is identifiable cash flows that are largely independent of the cash flows generated by other asset groups. If the total of the expected undiscounted future cash flows is less than the carrying amount of the asset, an impairment loss is recognized for the difference between the fair value and carrying value of assets. Fair value is generally determined by estimates of discounted cash flows. The discount rate used in any estimate of discounted cash flows would be the rate required for a similar investment of like risk. There were no impairment losses recognized during the years 2007, 2006 or 2005.

Assets to be disposed of are reported at the lower of carrying values or fair values, less estimated costs of disposal.

Deferred Financing Costs

We amortize the costs we incur to obtain debt financing over the terms of the underlying obligations using the effective interest method. The amortization of debt financing costs is included in

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

1. Description of Business and Significant Accounting Policies (Continued)

interest expense. In 2007, we induced the conversion of $18.8 million of our convertible promissory notes into common stock and accelerated the amortization of $352 of previously deferred financing fees. In 2006, we refinanced a $20.6 million convertible promissory note to a foreign investor, and we converted $21.8 million of convertible debt into common stock concurrent with our initial public offering. In connection with these transactions, in 2006, we recognized $2.1 million in interest expense for the deferred costs associated with these instruments, which were paid off. In 2005, we recognized $476 in interest expense from the amortization of these costs.

Revenue Recognition

Our revenue recognition policies are in accordance with the Securities and Exchange Commission s (SEC) Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*.

In July 2005, we launched our first commercial product, Osteocel. We recognize revenue on Osteocel sales when legal title to the product has passed to the customer, which is generally when the product is shipped from our Baltimore, Maryland facilities. We have agreements with our customers that specify the terms of sale, including price. During 2007 and 2006, sales of our Osteocel product were primarily to two customers. We have entered into several strategic agreements with other pharmaceutical companies focusing on the development and commercialization of our stem cell drug products. In 2003, we entered into such an agreement with Boston Scientific Corporation pertaining to our cardiac drug development and we received a $5 million fee for licensing the use of our technology. We terminated the agreement with Boston Scientific Corporation in 2007 and recognized the remaining unamortized license fee of $1.3 million. We recognized $952 of license fee revenue in 2006 and 2005. Also in 2003, we entered into a similar agreement with JCR Pharmaceuticals Co., Ltd. (JCR) pertaining to our hematologic malignancies drugs for distribution in Japan. We recognized $500 of revenue in 2007 and $500 in 2005 from JCR upon the achievement of milestone events specified in the agreement.

Revenues from collaborative research licenses and grants are recognized as earned upon either the incurring of reimbursable expenses directly related to the particular research plan or the completion of certain development milestones as defined within the terms of the collaborative agreement. Payments received in advance of research performed are designated as deferred revenue. We recognize non-refundable upfront license fees and certain other related fees on a straight-line basis over the development period. Fees associated with substantive at risk, performance based milestones are recognized as revenue upon their completion, as defined in the respective agreements. Incidental assignment

of technology rights is recognized as revenue as earned and was received from an unrelated third party.

Historically, we have also recognized revenue from governmental grants for research products and in 2005 we recorded $1.4 million in grant revenue as we completed work on three separate grants. Revenue from research grants is recognized as the related research expenditures are incurred. We no longer solicit governmental grants, and did not recognize any revenue from grants during 2007 or 2006.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

1. Description of Business and Significant Accounting Policies (Continued)

Cost of Goods Sold

Costs of goods sold of Osteocel consist primarily of the costs to obtain the tissue and other chemicals and supplies, quality and sterility testing, plus labor and allocated overhead costs and the costs of operating the clean-room facilities.

Research and Development Costs

Research and development costs are expensed as incurred.

Income Taxes

Deferred tax liabilities and assets are recognized for the estimated future tax consequences of temporary differences, income tax credits and net operating loss carry-forwards. Temporary differences are primarily the result of the differences between the tax bases of assets and liabilities and their financial reporting values. Deferred tax liabilities and assets are measured by applying the enacted statutory tax rates applicable to the future years in which deferred tax liabilities or assets are expected to be settled or realized. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense, if any, consists of the taxes payable for the current period and the change during the period in deferred tax assets and liabilities. For all periods presented, valuation allowances have been provided for the full amount of net deferred tax assets and no income tax expense or benefit has been recognized.

Comprehensive Income

In 2007, 2006 and 2005, except for our net loss, we did not have any components of comprehensive income as defined in the accounting literature.

Loss per Common Share

Basic loss per common share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share adjusts basic loss per share for the potentially dilutive effects of shares issuable under our stock option plans, and the conversion of our preferred stock and convertible debt, using the treasury stock method. Common equivalent shares from the conversion of preferred stock and convertible debt and the exercise of stock options and warrants are excluded from the computation of diluted loss per share as their effect is anti-dilutive. Since our initial public offering in August 2006, the market value of our common stock is determined based upon the closing price on the NASDAQ Global Market. Prior to August 2006 when our common stock started publicly trading, our Board of Directors determined the fair value of our common stock.

Share-Based Compensation

In December 2004, the Financial Accounting Standards Board, (FASB) issued Statement No. 123(R), *Share-Based Payment*, which is a revision of Statement No. 123, *Accounting for Stock*

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

1. Description of Business and Significant Accounting Policies (Continued)

Issued to Employees. Effective January 1, 2006, we adopted Statement No. 123(R) using the modified prospective method under which prior period amounts are not restated for comparative purposes. Under the modified prospective method, we are required to recognize compensation cost:

- for all share-based payments granted after January 1, 2006 based upon the requirements of Statement No. 123(R); and

- for all unvested awards granted prior to January 1, 2006 using the compensation cost calculated for pro forma disclosure purposes under Statement No. 123.

Under Statement No. 123(R), we are required to recognize all share-based payments to employees and non-employee directors in our financial statements based on their grant date fair values, using prescribed option-pricing models. We use the Black-Scholes option pricing model to value share-based payments. Compensation expense related to share-based awards is recognized on a straight-line basis based on the value of share awards that are scheduled to vest during the requisite service period. Under Statement No. 123(R), share-based compensation expense is based on awards ultimately expected to vest and must be reduced for estimated forfeitures.

Upon adoption of Statement No. 123(R), we reclassified our unamortized unearned compensation related to option awards to additional paid-in capital in our balance sheet.

Concentration of Risk

We maintain cash and short-term investment balances in accounts that exceed federally insured limits, although we have not experienced any losses on such accounts. We invest our excess cash in investment grade securities, generally with maturities of three months or less. We provide credit, in the normal course of business, to the distributors of our product. Our receivables at December 31, 2007 consist primarily of amounts due from four commercial customers, and we expect these receivables to be collected.

Significant New Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) 157, *Fair Value Measurements.* SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those years. We do not expect the implementation of SFAS 157 to have a material impact on our financial statements.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 clarifies when tax benefits should be recorded in financial statements, requires certain disclosures of uncertain tax matters and indicates how any tax reserves should be classified in a balance sheet. On January 1, 2007, the Company adopted FIN 48. We have determined that adoption of FIN 48 did not have any impact on our financial condition or results of operations. It is our policy to recognize interest and penalties related to unrecognized tax liabilities within income tax expense in the statements of operations.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

1. Description of Business and Significant Accounting Policies (Continued)

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Liabilities.* SFAS 159 permits entities to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. This pronouncement is effective as of the beginning of an entity s first fiscal year beginning after November 15, 2007. We do not expect the implementation of SFAS 159 to have a material impact on our financial position or results of operations.

In June 2007, the FASB ratified a consensus opinion reached by the Emerging Issues Task Force (EITF) on EITF Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities.* The guidance in EITF Issue 07-3 requires us to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, we would be required to expense the related capitalized advance payments. The consensus in EITF Issue 07-3 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is to be applied prospectively to new contracts entered into on or after December 15, 2007. Early adoption is not permitted. Retrospective application of EITF Issue 07-3 is also not permitted. We intend to adopt EITF Issue 07-3 effective January 1, 2008. The impact of applying this consensus will depend on the terms of the our future research and development contractual arrangements entered into on or after December 15, 2007.

In December 2007, the FASB ratified a consensus reached by the EITF on Issue 07-1, *Accounting for Collaborative Arrangements.* The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and its terms, the nature of the entity s business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for us January 1, 2008 and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We do not expect the adoption of EITF 07-1 to have a material impact on our financial statements.

In December 2007, the FASB issued SFAS 141, Revised 2007 (SFAS 141R), *Business Combinations.* SFAS 141R s objective is to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after December 15, 2008. We do not expect the implementation of SFAS 141R to have a material impact on our financial statements.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

1. Description of Business and Significant Accounting Policies (Continued)

In December 2007, the FASB issued SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements.* SFAS 160 s objective is to improve the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 shall be effective for fiscal years and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not expect the implementation of SFAS 160 to have a material impact on our financial statements.

2. Initial Public Offering and Reverse Stock Split

On August 9, 2006, we consummated our initial public offering, consisting of 3,500,000 shares of common stock at a public offering price of $11.00, resulting in net proceeds to us of approximately $34.4 million (after deducting payment of underwriters discounts and commissions, as well as offering expenses). Our common stock began trading on the NASDAQ Global Market on August 4, 2006.

In connection with the initial public offering, we effected a 1-for-4 reverse stock split of our issued and outstanding common stock. Information relating to our common stock and common stock-equivalents set forth in this report has been restated to reflect this split for all periods presented. Upon consummation of the initial public offering, all outstanding shares of the Class I, Series 2003, Series B, Series C, Series E and the Mandatorily Redeemable Series D convertible preferred stock were converted into an aggregate of 10,867,302 shares of our common stock. In addition, approximately $21.8 million of our convertible notes payable, together with accrued interest, were converted into an aggregate of 2,774,076 shares of our common stock.

Immediately following the initial public offering, we had 27,198,307 shares of common stock outstanding.

We incurred $7.0 million in non-cash charges relating to the completion of the initial public offering. Included in General and Administrative expenses in 2006 are a non-cash charge of $0.8 million for stock-based compensation related to the accelerated vesting of certain employee stock options pursuant to employment agreements. We also recognized a $3.5 million share-based payment to related party related to warrants

that were priced upon the completion of the initial public offering and $0.2 million in share-based compensation for stock awarded to our directors for service on our board. Interest expense includes $2.7 million in previously deferred financing costs and premiums that were expensed as a result of debt that was converted into common stock at the completion of the initial public offering.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

3. Property and Equipment

Property and equipment consist of the following at December 31,

	2007	2006
Laboratory and manufacturing equipment	$ 5,612	$ 4,720
Computer hardware, furniture and fixtures	1,402	1,213
Leased assets	11,725	11,725
Leasehold improvements	8,669	4,517
Construction in process	14	545
	27,422	22,720
Accumulated depreciation and amortization	(20,806)	(18,778)
Property and equipment, net	$ 6,616	$ 3,942

4. Notes Payable and Capital Lease Obligations

	December 31,	
	2007	2006
Bank Loan, payable in quarterly installments and bearing interest at LIBOR plus applicable margins, 7.33% 7.83% in 2006	$	$ 49
Boston Scientific Corporation Term Note, 8%, due quarterly through January 2009	6,521	5,000
Term Notes, 10%, convertible into common stock at $18 per share and under specified conditions	1,200	20,000
	7,721	25,049
Less current portion	(6,521)	(49)
Notes payable long-term	$ 1,200	$ 25,000
Total capital lease obligations	$ 897	$ 2,024

Less current portion		(886)		(1,129)
Capital lease obligations, long-term	$	11	$	895

During June 1995, we borrowed $750 from a commercial bank in connection with the acquisition and renovation of our Baltimore, Maryland facilities. This loan was partially guaranteed by an agency of the State of Maryland and matured in September 2007. Prior to maturity, this loan accrued interest at LIBOR plus 2.0% to 2.5%. This loan was repaid upon maturity.

In 2004, we borrowed $5.0 million on the $50.0 million line-of-credit entered into with Boston Scientific Corporation which was part of a collaborative arrangement for the development of our biologic drug candidate for cardiac indications. Under the terms of the original line-of-credit, this loan was to be repaid from the proceeds of future sales. In December 2007, the collaborative agreement was terminated. The line-of-credit was cancelled and the outstanding principal, together with accrued interest, was converted into a one-year term note, bearing interest at 8% and payable in quarterly installments starting in January 2008.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

4. Notes Payable and Capital Lease Obligations (Continued)

In October 2006, we issued $20.0 million in convertible promissory notes in a private placement to several Swiss investors. The notes accrued interest at a rate of 10%, with semi-annual payments of accrued interest becoming due and payable on April 30 and October 30 of each calendar year, until maturity on April 30, 2009. The notes were convertible at the option of the respective holders at any time after February 9, 2007, into shares of common stock at the conversion price of $18.00 per share. The notes initially provided for automatic conversion into common stock at the same conversion price, if at any time after February 9, 2007, the closing price of the our common stock on the NASDAQ Global Market closed for ten consecutive trading days at $25.00 per share or greater. The notes also provided for redemption at any time at our option, with 30-day written notice.

In December 2007, we reduced the conversion price of the 10% notes to $13.00 per share and induced the conversion of $18.8 million of the notes, together with accrued interest into 1,465,837 shares of common stock. In connection with this induced conversion, we recorded a non-cash charge of $4.8 million as interest expense. In January 2008, we induced the conversion the remaining $1.2 million of these notes, together with accrued interest into 85,714 shares of common stock at the conversion price of $14.00 per share, which resulted in a non-cash charge of $248 as interest expense.

Future Maturities of Notes Payable and Capital Lease Obligations

For years subsequent to 2007, scheduled annual maturities of notes payable and capital lease obligations outstanding as of December 31, 2007, are as follows:

	Notes Payable	Capital Lease Obligations	Total
2008	$ 6,521	$ 886	$ 7,407
2009	1,200	7	1,207
2010		4	4
	$ 7,721	$ 897	$ 8,618

5. Preferred Stock Conversion

All our convertible preferred stock was converted into common stock upon the completion of our initial public offering in August 2006.

	No. Shares of Common Stock Issued Upon Conversion at IPO (Aggregate Liquidation Preference / Conversion Price) Per Share
Convertible preferred stock, Class I, Series 2003, $0.001 par value, 2,000,000 shares designated, issued and outstanding in 2005	500,000
Convertible preferred stock, Series B, $0.001 par value, 750,000 shares designated, 545,454 shares issued and outstanding in 2005	136,364
Convertible preferred stock, Series C, $0.001 par value, 3,500,000 shares designated, 548,090 shares issued and outstanding in 2005	308,300
Convertible preferred stock, Series E, $0.001 par value, 8,000,000 shares designated, 7,557,000 shares issued and outstanding in 2005	1,889,250
	2,833,914

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

5. Preferred Stock Conversion (Continued)

We issued 2,000,000 shares of our Class I, Series 2003 convertible preferred stock to a collaborative partner as part of an agreement related to product development, clinical trials and FDA approval. These shares were converted into 500,000 shares of our common stock at the conversion price of $20.00 per share.

We issued 545,454 shares of our Series B convertible preferred stock in 2003, as part of a collaborative agreement. These shares were converted into 136,364 shares of our common stock at the conversion price of $22.00 per share.

We issued 548,090 shares of our Series C convertible preferred stock in 2004 at the price of $4.50 per share. These shares were converted into 308,300 shares of our common stock at the conversion price of $8.00 per share.

We issued 7,557,000 shares of our Series E convertible preferred stock in 2005 at a price of $2.50 per share. These shares were converted into 1,889,250 shares of our common stock at the conversion price of $10.00 per share.

Also in 2005, we issued 3,213,335 shares of Series D Mandatorily Redeemable Convertible Preferred Stock at a price of $2.00 per share. These shares were converted into 8,033,388 shares of our common stock at the conversion price of $0.80 per share.

These Series D shares included a mandatory redemption feature whereby if we did not complete an initial public offering prior to June 1, 2007 and the shares were not previously converted into common stock, we would be required to redeem the shares at a price of $20.00 per share. The Series D Mandatorily Redeemable Convertible Preferred Stock was recorded as a liability in the balance sheet at December 31, 2005, in accordance with SFAS No. 150 *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. In addition to the initial net proceeds of $6.0 million from the Series D offering, a redemption premium of $58.3 million was recorded as a liability.

6. Share-Based Compensation

In April 2006, we adopted our 2006 Omnibus Plan. In addition, we had previously established our Amended and Restated 1994 Stock Incentive Plan. Both Plans authorize the issuance of various forms of stock-based awards, including incentive and non-qualified stock options, stock purchase rights, stock appreciation rights and restricted and unrestricted stock awards. A total of 850,000 shares of our common stock have been reserved for issuance under the 2006 Omnibus Plan, and 736,378 shares were reserved under our Amended and Restated 1994 Stock Incentive Plan. We ceased all grants under the Amended and Restated 1994 Stock Incentive Plan concurrent with our initial public offering in August 2006. As a result, no shares are currently available for future awards under the Amended and Restated 1994 Stock Incentive Plan. At December 31, 2007, there were 426,260 shares available for future awards under the 2006 Omnibus Plan.

We generally issue stock option awards that vest over four years and have a ten-year life. We estimate the fair value of stock options using the Black-Scholes option-pricing model. Our common stock started trading on the public market in August 2006, and the historical data to determine volatility does not presently exist. We determine volatility by using the historical stock volatility of other

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

6. Share-Based Compensation (Continued)

companies with similar characteristics. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

The fair value of stock options granted during each of the periods was estimated using the following assumptions:

	Years ended December 31,		
	2007	**2006**	**2005**
Assumptions			
Weighted average risk-free interest rate	4.61%	4.75%	4.21%
Dividend yield	0.0%	0.0%	0.0%
Expected life of option grants	4.5-years	5-years	5-years
Weighted average expected stock price volatility	67.07%	74.11%	85.64%

A summary of stock option activity for the years ended December 31, 2007, 2006 and 2005 is as follows:

	Number of Shares	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Life**	**Aggregate Intrinsic Value (in thousands)**
Outstanding at January 1, 2005	543,652	$ 0.70	7.9-years	
Granted	106,000	$ 0.40		
Exercised	(27,148)	$ (0.41)		$ 7
Forfeited or canceled	(56,024)	$ (3.45)		
Outstanding at December 31, 2005	566,480	$ 0.40	8.4-years	
Granted	314,500	$ 4.06		
Exercised	(178,378)	$ (0.41)		$ 1,827
Forfeited or canceled	(6,687)	$ (1.36)		

Balance, December 31, 2006	695,915	$	2.05	8.3-years		
Granted	373,500	$	18.30			
Exercised	(141,312)	$	(0.42)		$	2,174
Forfeited or canceled	(47,693)	$	(12.49)			
Balance, December 31, 2007	880,410	$	8.64	8.3-years	$	5,091
Exercisable at December 31, 2007	353,961	$	1.18	7.2-years	$	3,837

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

6. Share-Based Compensation (Continued)

A summary of stock options outstanding at December 31, 2007, by price range is as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life (in years)	Weighted-Average Exercise Price	Number Outstanding	Weighted-Average Exercise Price
$0.40 to $0.79	367,315	7.2	$ 0.40	311,809	$ 0.40
0.80 to 2.00	1,282	5.7	0.80	1,282	0.80
2.01 to 10.00	152,563	8.5	6.84	37,812	6.84
10.01 to 15.00	190,250	9.5	12.78	3,058	11.17
15.01 to 20.00	1,500	9.1	17.27		
$20.01 to $28.56	167,500	9.1	23.64		
	880,410	8.3	$ 8.64	353,961	$ 1.18

The weighted fair value of options granted during the years ended December 31, 2007, 2006 and 2005 were $10.61, $7.11 and $2.84, respectively.

Both contemporaneous and retrospective valuations were performed by our Board of Directors for options granted from January 2005 through the date of our initial public offering. As a result of these valuations, we, for financial reporting purposes, retrospectively adjusted the fair market value of the equity instruments granted during certain periods.

During 2003, we cancelled and reissued 126,366 stock options that had previously been granted at amounts equal to the estimated fair value of the underlying stock. The exercise price of the reissued stock options was reduced to $0.40 per share at a time when the estimated fair value of the common stock was $6.00 per share. We are accounting for these options as if they were simply repriced. As such, we accounted for these repriced options using variable accounting under FASB Interpretation No. 44. *Accounting for Certain Transactions Involving Stock Compensation (an Interpretation of APB No. 25)* Consequently, during each reporting period we record compensation expense relating to the vested portion of the repriced options to the extent that the fair market value of our common stock exceeds the exercise price of such options.

Compensation expense of $0, $530 and $35 was recognized during the years ended December 31, 2007, 2006 and 2005, respectively.

In connection with the stock options exercised during the year ended December 31, 2007, we received cash proceeds of $60. At December 31, 2007, there was $3.2 million of total unrecognized compensation costs related to non-vested stock options, which is expected to be recognized over a weighted average period of three years.

The table below reflects the total share-based compensation expense recognized in our income statements for the years ended December 31, 2007, 2006 and 2005. FASB Statement No. 123(R) requires forfeitures to be estimated at the time an award is granted and revised, if necessary, in subsequent periods if factual forfeitures differ from those estimates. Pre-vesting forfeitures were estimated to be between 0% and 20% based on historical experience. For the years ended December 31, 2007 and 2006, share-based compensation expense is based on awards ultimately

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

6. Share-Based Compensation (Continued)

expected to vest and has been reduced for estimated forfeitures. In our pro forma disclosures of share-based compensation under FASB Statement No. 123, we accounted for forfeitures as they occurred.

	Year ended December 31,		
	2007	2006	2005
Cost of goods sold	$ 30	$	$
Research and development	608	755	
General and administrative	702	4,738	109
Share-based compensation	$ 1,340	$ 5,493	$ 109

As permitted by Statement No. 123, prior to January 1, 2006, we accounted for share-based payments to employees using the intrinsic value method prescribed by Accounting Principles Board (APB) Opinion No. 25. Under APB Opinion No. 25, we recorded compensation expense over the vesting period to the extent that the fair value of the underlying shares of common stock on the grant date exceeded the exercise or acquisition price of the share-based award. Primarily because options granted under our share-based incentive compensation plans had an exercise price equal to the market value of the underlying common stock on the grant date, we generally did not recognize compensation cost related to employee stock options. For the year ended December 31, 2005, the following table illustrates the effect on net income and earnings per share if we had determined compensation cost by applying the fair value recognition provisions of Statement No. 123 to share-based employee awards.

	2005
Net loss, as reported	$ (19,995)
Add stock-based employee compensation included in reported net loss	109
Deduct total stock-based employee compensation determined under fair-value-based method for all awards	(8)
Pro forma net loss	$ (19,894)
Basic and diluted loss per share, as reported	$ (2.23)

Basic and diluted loss per share, pro forma	$	(2.23)

7. Related Party Transactions

General. Peter Friedli, the Chairman of our Board of Directors, or entities with which he is affiliated, have been responsible for procuring since 1993, an aggregate of approximately $250 million in debt and equity financing for us and our predecessor company. Mr. Friedli is the beneficial owner of more than 48% of our common stock as of December 31, 2007. Of the shares beneficially owned by Mr. Friedli, 25,000 shares were received by him as Board compensation since 1996, 12,500 shares were granted in recognition of his fundraising efforts, as discussed below, and the remaining shares were acquired through investment or purchase from third parties.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

7. Related Party Transactions (Continued)

Consulting Agreement. Beginning in 1995, we and our predecessor company were party to a Consulting Agreement, originally with Friedli Corporate Finance AG, and subsequently Friedli Corporate Finance, Inc., or FCF, for the provision of business and advisory services to us. Mr. Friedli is the sole owner of FCF. Under this agreement, FCF provided general business, financial and investment advice to us, and served as a liaison between us and FCF clients who have invested in us, many of which are located in Switzerland. The Consulting Agreement between us and FCF was terminated upon the closing of our initial public offering in August 2006. The base compensation paid by us under this agreement was $47 in 2006 and $65 in 2005. In addition, pursuant to this Consulting Agreement, we paid $50 as expense reimbursements in 2005 and $350 in 2006, to or as directed by FCF. No fees were paid to Mr. Friedli or FCF during 2007.

Private Placements. Separate from the Consulting Agreement, FCF served as our agent in Europe in connection with:

- the issuance and sale in 2005 of 3,187,056 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock at a purchase price of $2.00 per share, representing aggregate gross proceeds of $6.4 million;

- the issuance and sale in 2005 of $19.4 million of our Convertible Preferred Notes;

- the issuance and sale in 2005 of 7,557,000 shares of our Series E Convertible Preferred Stock at a purchase price of $2.50 per share, representing aggregate gross proceeds of $18.9 million;

- the issuance and sale in 2006 of $20 million of our Convertible Notes, which were converted into an aggregate of 1,553,361 shares of our Common Stock in December 2007 and January 2008, at prices above the NASDAQ closing price on the dates of conversion;

- the issuance and sale in June 2007 of 1,757,469 shares of our common stock in a private placement to non-US investors at a purchase price of $11.38 per share, which represented the NASDAQ closing price on the date of the transaction, representing gross proceeds of $20.0 million; and

- the issuance and sale in December 2007 of 950,000 shares of our common stock in a private placement to non-US investors at a purchase price of $12.37 per share, which represented the NADSAQ closing price on the date of the transaction, representing gross proceeds of $11.8 million.

Mr. Friedli also arranged the placement through a European investment bank of a $20.6 million convertible promissory note in late fall 2005. In connection with all of these transactions, an aggregate of $103.7 million in gross proceeds was raised for us.

In October 2007, we also obtained a $30.0 million financing commitment from FCF. This financing commitment is for a twelve month term and provides for financing through the issuance by us of common stock at a price determined as the basis of market value, or the issuance by us of three-year promissory notes bearing interest at LIBOR plus 4%. Although we control the timing of any draws made during the term of the commitment, FCF determines the identity of the purchasers and whether we issue common stock or promissory notes, subject, however to limitations on, among other things, the

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

7. Related Party Transactions (Continued)

aggregate number of shares of common stock that may be issued. We did not incur any fees in connection with the establishment of this financing commitment.

We did not pay any fees for any of the financings arranged in 2007 through Mr. Friedli or entities with which he is affiliated.

Prior to 2007, we paid referral fees and costs of $3.4 million to accounts designated by Mr. Friedli, including accounts of unrelated third parties. Also prior to 2007, we paid expense reimbursement of $350 to Mr. Friedli and issued 12,500 shares of our common stock to him in recognition of his fundraising efforts on our behalf in 2004 and 2005. In addition, specific to the placement of the $20.6 million convertible promissory note in late fall 2005, we paid placement agency fees to the European investment bank.

In addition, we paid $600 to Friedli Corporate Finance, Inc. in connection with the issuance of the $20.0 million in Convertible Notes in 2006. Included among the purchasers was Mr. Friedli, individually, who purchased $4,500,000, and New Venturetec, Inc., a Swiss publicly traded company approximately 3% owned by Mr. Friedli who serves as its President, which purchased an additional $4,000,000 of the Convertible Notes. The $4,000,000 in Convertible Notes originally purchased by New Venturetec, Inc. were subsequently acquired by Mr. Friedli from New Venturetec in a separate transaction. Our Board of Directors, including all of our independent directors, but with Mr. Friedli abstaining, together with the audit committee, unanimously approved the offering and sale of the Convertible Notes, including the sales to Mr. Friedli and New Venturetec, Inc. and the arrangements with Friedli Corporate Finance, Inc.

New Venturetec/Pine Loans. In 2004, we obtained $2.35 million in debt financing through two entities with which Mr. Friedli is affiliated. The first of these entities was, Venturetec, Inc., a wholly owned subsidiary of New Venturetec, Inc. The other entity is Pine, Inc., a company which at the time of the financing was majority owned and managed by Mr. Friedli. These convertible demand notes accrued interest at 10% and included a 10% premium due upon redemption.

In this financing, Venturetec, Inc. lent us $1.35 million, and Pine lent us $1.0 million. In consideration of these loans, we issued to the lenders promissory notes in the principal amount of the sums lent to us. We also issued warrants to Venturetec, Inc. for 237,500 shares of our common stock at $0.40 per share. These warrants were exercised concurrent with our initial public offering.

To facilitate these borrowings and other financings, and for commitments of consideration in respect of yet additional financing if needed, we issued warrants for an aggregate of 1,250,000 shares at an exercise price of $0.40 per share. Mr. Friedli subsequently arranged for the acquisition of those warrants and they have since been cancelled. In recognition of his efforts in procuring the cancellation of all of these warrants, we issued a new warrant to Mr. Friedli, exercisable for up to 1,000,000 shares of our common stock at $11.00 per share, the price for which shares were sold in the initial public offering. This warrant expires in May 2011.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

7. Related Party Transactions (Continued)

Other Financings. We have engaged in the following additional financings that involved Mr. Friedli, or entities with which he is affiliated:

- In 2005, Venturetec, Inc. purchased an additional 47,244 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock at $2.00 per share, representing aggregate gross proceeds of $94. Also in 2005, it purchased 400,000 shares of our Series E Preferred Stock at $2.50 per share, representing aggregate gross proceeds of $1.6 million.

- US Venture 05, Inc., a venture fund for which Mr. Friedli is president and investment manager, purchased in 2005 4,000,000 shares of our Series E Preferred Stock at $2.50 per share, representing aggregate gross proceeds of $10.0 million. Mr. Friedli has no ownership interest in this investor.

- World Communication Development AG, a Swiss corporation of which Mr. Friedli is a member of the board of directors, purchased in 2005, 66,666 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock at $2.00 per share, representing aggregate gross proceeds of $133. Mr. Friedli has no ownership interest in this investor.

- Joyce Ltd., an entity which at the time was majority owned by Mr. Friedli, purchased 340,495 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock in 2005 at $2.00 per share, representing aggregate gross proceeds of $681.

- Mr. Friedli purchased 488,118 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock in 2005 at $2.00 per share, representing aggregate gross proceeds of $976. Mr. Friedli also purchased and acquired $8.5 million of the $20 million of Notes issued in October 2006. The $8.5 million in Convertible Notes were converted into 662,746 shares of Common Stock in December 2007 at $13.00 per share. In addition, Mr. Friedli purchased 1,230,229 shares of our Common Stock in the June 2007 private placement, representing aggregate proceeds of $14 million, and 100,000 shares of our Common Stock in the December 2007 private placement, representing aggregate proceeds of $1.2 million. Both these private placements were priced at market.

Lockup Agreement. On October 30, 2006, we entered into a Lockup Agreement with Mr. Friedli, Venturetec, Inc. and U.S. Venture 05, Inc. Pursuant to the Lockup Agreement, Mr. Friedli and such entities initially agreed with us, subject to limited exceptions, not to transfer our securities held by them without our approval, until January 30, 2008. The Lockup Agreement was amended in September 2007, by an Amendment to Lockup Agreement, pursuant to which Mr. Friedli and Venturetec. Inc have agreed to extend the term of the Lockup Agreement as applicable to them, until January 30, 2009.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

8. Warrants

At December 31, 2007, we had warrants to purchase our common stock outstanding as shown in the following table.

	Common Stock	
	# of Shares	Weighted Average Price
Warrants outstanding, January 1, 2006	2,125,000	$ 0.40
Warrants granted	1,000000	11.00
Warrants exercised	(875,000)	0.40
Warrants cancelled	(1,250,000)	0.40
Warrants outstanding, December 31, 2006	1,000,000	$ 11.00
Warrants granted		
Warrants cancelled		
Warrants exercised		
Warrants outstanding, December 31, 2007	1,000,000	$ 11.00

Following is the summary of the status of outstanding warrants to purchase our common stock at December 31, 2007.

Warrant Price	Common Shares	Weighted Average Remaining Contractual Life	Intrinsic Value
$ 11.00	1,000,000	3.5 years	$ 1,000

In August 2006, when the price of the 2006 warrant was determined, we computed its value using the Black-Scholes option pricing method, using a risk free interest rate of 4.80%, the expected life of 2.5-years and a stock volatility factor of 44.66%. Since the Company just recently completed its initial public offering and previously its stock did not trade, we determined the volatility by selecting a comparable public company in the biotech industry and tracking its stock prices over the past 2.5-years. The value of this warrant was determined to be $3.5 million which as been recorded in the accompanying statement of operations as General and Administrative expenses during the year ended December 31, 2006.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

9. Income Taxes

The components of the Company s net deferred tax assets at December 31 are as follows:

	2007	2006
Deferred Tax Assets:		
Net operating loss carry-forwards	$ 85,016	$ 63,157
Research and experimentation credit carry-forwards	7,167	5,142
Property and equipment	1,432	1,546
Other		51
	93,615	69,896
Valuation allowance	(93,615)	(69,896)
Net deferred tax assets	$	$

Our deferred tax assets have been fully reserved in both 2007 and 2006 since their ultimate future realization cannot be assured. The valuation allowance increased by $23.7 million for the year ended December 31, 2007. We presently have available for federal income tax purposes, approximately $215 million of net operating loss carry-forwards and $7.1 million of research and experimentation credit carry-forwards, which expire beginning in 2009 through 2027. However, as a result of changes in our ownership since inception, the amount of these carry-forwards available to offset future taxable income and income taxes could be subject to annual limitations under IRC Section 382.

10. Research Collaboration Agreements and Government Contract

United States Department of Defense Contract. In January 2008, we were awarded a contract from the United States Department of Defense (DoD) to develop and stockpile Prochymal for the repair of gastrointestinal injury resulting from radiation exposure. Under the terms of the contract, the DoD will provide funding to us for the development of Prochymal for acute radiation syndrome (ARS) in two stages, with an initial amount of $4.2 million in 2008. If we are successful in obtaining FDA approval for ARS, the contract provides for the purchase of up to 20,000 doses, at

$10,000 per dose, of Prochymal in four 5,000 dose increments.

Genzyme Corporation Agreement. In 2007, we entered into a collaborative agreement with Genzyme Corporation (Genzyme) for the preparation and execution of development and purchase agreements made with U.S. and Allied governmental agencies. We will contribute Prochymal and corresponding safety and efficacy data to the effort and Genzyme will lend its vast product development and large-scale commercialization expertise. The agreement provides for Genzyme to receive a royalty of 15% on sales of Prochymal, limited to those sales made under contract to U.S. or Allied governmental agencies for emergency preparedness. We did not recognize any revenue or expense related to this collaborative agreement during 2007.

Juvenile Diabetes Research Foundation Agreement. In 2007, we entered into a collaborative agreement with the Juvenile Diabetes Research Foundation (JDRF) which provides for $4.0 million in funding to support the development of Prochymal as a treatment for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus. We initiated a Phase II clinical

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

10. Research Collaboration Agreements and Government Contract (Continued)

trial evaluating Prochymal as a treatment for type 1 diabetes in the fourth quarter of 2007. We expect to receive $2.0 million from JDRF during 2008 based upon the achievement of clinical milestones and the remaining $2.0 million in 2009, however, there can be no assurance of achieving these future milestones.

JCR Pharmaceuticals Agreement. In 2003, we entered into a strategic alliance with JCR Pharmaceuticals Co., Ltd. (JCR). Under the JCR agreement, we have granted JCR the exclusive right in Japan to use our technology in conjunction with the treatment of hematologic malignancies using hematopoietic stem cell transplants. The JCR agreement entitles us to a licensing fee and to royalties on any resulting revenue. Upon commencement of the agreement, JCR purchased 545,454 shares of our Series B Convertible Preferred Stock for $3.0 million. These shares were converted into 136,363 shares of our common stock concurrent with our initial public offering in August 2006. They also paid us a $3.0 million licensing fee, which was recognized as revenue in 2004 and 2003. In 2007 and 2005, upon the completion of certain milestones, we received $500 in each of those years as additional licensing fees, which was recognized as revenue.

Boston Scientific Agreement. Also in 2003, we entered into a long-term collaboration agreement with Boston Scientific Corporation (BSC) focusing upon the development and commercialization of the use of mesenchymal stem cells technology to treat cardiovascular disease. The BSC agreement paid us a licensing fee and provided for royalties on resulting revenue, and included both a BSC equity investment and significant BSC debt financing for the cardiovascular project.

We received a $5.0 million licensing fee for the use of our technology by BSC. This revenue was being recognized as revenue over a 63-month period, $952 of which was recognized in 2006 and 2005. In 2007, we recognized the remaining unamortized licensing fee of $1.3 million.

As provided for in the agreement, BSC purchased 2 million shares of our Class 1, Series 2003 Convertible Preferred Stock for $10 million. These shares were converted into 500,000 shares of common stock concurrent with our initial public offering in August 2006.

The agreement provided for a $50.0 million line of credit with BSC. In March 2004, the Company drew $5 million under this line of credit, which was recorded as long-term debt and accrued interest at 8%.

In December 2007, we terminated the Agreement with BSC and regained the worldwide rights to cardiac indications. Upon termination, the line of credit was cancelled and the outstanding borrowings together with accrued interest was converted into a one-year 8% promissory note which is payable in quarterly installments beginning in January 2008.

11. Defined Contribution Plan

We have a 401(k) plan that is available to all employees. Employee contributions are voluntary and are determined on an individual basis up to the amount allowable under federal regulations. Employer contributions to the plan are at the discretion of the Board of Directors and vest over a seven year period beginning after the third year of eligibility. No employer contributions have been made to date.

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

12. Commitments and Contingencies

During 2006, we entered into a sublease agreement for approximately 61,000 square feet of laboratory, production, warehouse and office space in Columbia, Maryland. We have also entered into a direct lease with the owner of this facility that is effective upon the expiration of the sublease and expires in July 2016. This lease has two five-year renewal options. We have an outstanding letter of credit of $130 that is used in lieu of a security deposit for this lease. The letter of credit is fully collateralized by restricted cash.

We also lease approximately 126,000 square feet of laboratory, production, warehouse and office space in Baltimore, Maryland under an amended lease agreement that expires in September 2008. We intend to vacate the Baltimore facility upon the expiration of this amended lease and consolidate our operations in our Columbia, Maryland facility. This lease was originally arranged by the Maryland Economic Development Corporation and the City of Baltimore who arranged the financing of the building improvements. We have an outstanding letter of credit of $150 that is used as security for this lease. The letter of credit is fully collateralized by restricted cash. We sublease a portion of the office and warehouse space to a third party on a month-to-month basis and record the $10 monthly rent as a reduction of our facilities expense.

We also have entered into various financing arrangements to lease laboratory and other equipment. The terms of these facilities and equipment leases are considered capitalized leases, and the following amounts are included in our balance sheets at December 31, 2007 and 2006:

	2007	2006
Facilities leases	$ 8,568	$ 8,568
Equipment leases	3,157	3,157
	11,725	11,725
Less accumulated amortization	(11,098)	(10,351)
Leased property and equipment, net	$ 627	$ 1,374

Future minimum lease payments under these capitalized facilities and equipment arrangements are as follows:

	Facilities	Equipment	Total
2007	$ 906	$ 8	$ 914
2008		8	8
2009		3	3
	906	19	925
Less interest	(26)	(2)	(28)
Present value of minimum lease payments	880	17	897
Less long-term portion		(11)	(11)
Capital lease obligations, current	$ 880	$ 6	$ 886

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

12. Commitments and Contingencies (Continued)

The future minimum lease payments due under the operating lease for our Columbia, Maryland facility are as follows:

	Columbia Facility
2008	$ 876
2009	978
2010	1,056
2011	1,082
2012	1,109
2013 - 2016	3,999
	$ 9,100

Agreement. In 1994, we entered into a Technology Transfer and License Agreement with Case Western Reserve University (CWRU) under which we purchased rights to certain mesenchymal stem cell and related technology and patents. We are required to pay royalties on revenues related to CWRU developed technology, with minimum royalties of $50 per year. We paid CWRU $50 in 2007, 2006 and 2005.

13. Segment Reporting

In 2007, we began to manage our business in two reportable operating segments: the Biologic Drug Candidates segment and the Biologic Tissue Product segment. Our Biologic Drug Candidates segment focuses on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Its operations have focused on clinical trials and discovery efforts to identify additional medical indications. Our Biologic Drug Candidates segment does not presently have any products approved for sale and its revenues consist of license fees and royalties from collaborative research agreements.

Our Biologic Tissue Product segment includes the manufacture and sale of Osteocel, which we launched in July 2005 and is currently being used by orthopedic surgeons for focal bone repair.

We evaluate the performance of our Biologic Tissue Product segment based upon gross margin and operating income before net interest expense, depreciation, and corporate general and administrative expenses, which we refer to as segment profit or loss. We have presented estimated 2006 segment results through the gross profit result to compare to our 2007 presentation in the table below. However, because our Biologic Tissue Product segment was not managed as a separate segment prior to 2007, we are unable to determine the other operating expenses that may have been attributable to this segment in 2006 and 2005.

In general, our total assets, including long-lived assets such as property and equipment, and our capital expenditures are not specifically allocated to any particular operating segment. Accordingly, capital expenditures and total asset information by reportable segment is not presented. The reportable

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

13. Segment Reporting (Continued)

segments use the same accounting policies as those used by the Company. There are no significant inter-segment sales or transfers.

Substantially all of our revenues and assets are attributed to and are received from entities located in the United States. During the years ended December 31, 2007, 2006 and 2005, we sold product produced in our Biologic Tissue Product segment primarily to two customers, both of which represent greater than ten percent of our revenues.

The table below sets forth the revenues, gross margin and segment profit (loss) for the year ended December 31, 2007, and the revenues and gross margin for the years ended December 31, 2006 and 2005.

	Biologic Drug Candidates	Biologic Tissue Product	Corporate	Total
Year Ending December 31, 2007				
Revenues	$ 2,048	$ 15,240	$	$ 17,288
Gross margin		8,285		8,285
Segment profit (loss) unaudited	(45,092)	4,574	(6,708)	(47,226)
Year Ended December 31, 2006				
Revenues	$ 1,181	$ 8,291	$	$ 9,472
Gross margin		4,594		4,594
Year Ended December 31, 2005				
Revenues	$ 3,013	$ 957	$	$ 3,970
Gross margin		513		513

We reported a loss in our Biologic Tissue Product segment for the quarter ending March 31, 2007 which was primarily attributable to costs associated with the expansion of our Osteocel manufacturing facility, as we experienced failed production qualification runs while expanding our capacity. The production issues were subsequently resolved in late March 2007, and the expanded facility has produced product in line with

our expectations during the remainder of 2007. During the second quarter of 2008, we expect to start production of Osteocel in our Columbia, Maryland facility and by the end of the third quarter of 2008, move all of our production activities to Columbia, Maryland

OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(amounts in thousands, except for share and per share data)

14. Quarterly Financial Data (Unaudited)

Following is a summary of our Unaudited quarterly results for the years ended December 31, 2007, 2006 and 2005:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2007				
Total revenues	$ 2,279	$ 3,547	$ 4,297	$ 7,165
Product sales	2,000	3,252	4,003	5,985
Cost of goods sold	901	1503	1,826	2,725
Research and development expenses	11,030	10,583	10,842	18,396
General and administrative expenses and fees	1,506	1,501	1,689	2,012
Net loss	(11,501)	(10,458)	(10390)	(21,572)
**Net loss per common share, basic and diluted	(0.42)	(0.37)	(0.36)	(0.73)
2006				
Total revenues	$ 1,400	$ 1,987	$ 2,841	$ 3,244
Product sales	1,105	1,689	2,539	2,958
Cost of goods sold	489	762	1,113	1,333
Research and development expenses	4,368	10,922	9,242	13,058
General and administrative expenses and fees	1,138	1,209	5,300	812
Net loss	(5,121)	(11,605)	(15,565)	(12,668)
**Net loss per common share, basic and diluted	(0.56)	(1.27)	(0.75)	(0.46)
2005				
Total revenues	$ 385	$ 1339	$ 1285	$ 961
Product sales			284	673
Cost of goods sold			220	224
Research and development expenses	2,657	3,592	3,464	7,214
General and administrative expenses and fees	752	487	554	501
Net loss	(3,868)	(3,394)	(4,678)	(8,055)
**Net loss per common share, basic and diluted	(0.43)	(0.38)	(0.52)	(0.88)

** Loss per share is calculated on a quarterly basis and may not be additive to year-to-date amounts.

Part III

Certain information required in Part III is omitted from this report, but is incorporated by reference from our definitive proxy statement for the 2008 Annual Meeting of Stockholders to be filed within 120 days after the end of our fiscal year ended December 31, 2007, pursuant to Regulation 14A with the Securities and Exchange Commission.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures. An evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Annual Report on Form 10-K was made under the supervision and with the participation of our management, including our Chief Executive Officer and Interim Chief Financial Officer. Based upon this evaluation, our Chief Executive Officer and Interim Chief Financial Officer have concluded that our disclosure controls and procedures (a) are effective to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is timely recorded, processed, summarized and reported and (b) include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management s Report on Internal Control over Financial Reporting. Management s report on internal control over financial reporting is included in Item 8. Financial Statements and Supplementary Data.

Changes in Internal Control over Financial Reporting. There have not been any changes in our internal control over financial reporting that occurred during the year ended December 31, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 10. Directors, Executive Officers and Corporate Governance.

The information contained in our proxy statement under the captions Information About the Board of Directors and Committees, Corporate Governance, Executive Officers and Compensation and Section 16(a) Beneficial Ownership Reporting Compliance is incorporated herein by reference.

We have adopted the Osiris Therapeutics, Inc. Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers and the Osiris Therapeutics, Inc. Code of Conduct which applies to all our employees and members of the Board of Directors. These policies are publicly available on our website at http://www//investor.osiris.com/documents.cfm.

Item 11. Executive Compensation.

The information contained in our proxy statement under the caption Executive Officers and Compensation is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information contained in our proxy statement under the captions Security Ownership of Certain Beneficial Owners and Management and this Annual Report on Form 10-K under the caption Part II Item 5. Market for the Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Securities Authorized for Issuance under Equity Compensation Plans is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information contained in our proxy statement under the caption Executive Officers and Compensation Certain Relationships and Related Party Transactions, Information About the Board of Directors and Committees and Corporate Governance is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information contained in our proxy statement under the caption Auditor Services is incorporated herein by reference.

Part IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

1. The following financial statements are included in Item 8 of this Annual Report:

Management s Report on Internal Control Over Financial Reporting

Report of Independent Registered Public Accounting Firm Internal Control Over Financial Reporting

Report of Independent Registered Public Accounting Firm Financial Statements

Balance Sheets as of December 31, 2007 and 2006

Statements of Operations for the years ended December 31, 2007, 2006 and 2005

Statements of Stockholders Equity (Deficit) for the years ended December 31, 2007, 2006 and 2005

Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005

Notes to Financial Statements

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable.

2. Exhibits

Exhibit Number		Description of Exhibit
3.1		Amended and Restated Certificate of Incorporation of the Registrant.
3.2		Amended and Restated Bylaws of the Registrant.
4.1		Form of Common Stock Certificate.
10.1		Amended and Restated 1994 Stock Incentive Plan, as amended.
10.2		2006 Omnibus Plan.
10.3		Director Compensation Policy.
10.4		Employment Agreement by and between the Registrant and C. Randal Mills, Ph.D., dated as of May 15, 2004.
10.5		Employment Agreement by and between the Registrant and Cary J. Claiborne, dated as of December 3, 2004.
10.6		Employment Agreement by and between the Registrant and Harry Carmitchel, dated as of September 1, 2004.
10.7		Employment Agreement by and between the Registrant and Earl R. Fender, dated as of June 12, 2006.
10.8		Loan Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003, as amended.
10.9		Amendment No. 1 to the Loan Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 12, 2004.
10.10		Security Agreement from the Registrant to Boston Scientific Corporation, dated as of March 12, 2004.
10.11	*	Contract Manufacturing Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.12	*	Development Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.13		Investment Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.14		Investor Rights Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.15	*	License Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.16		Investor Rights Agreement by and between the Registrant and JCR Pharmaceuticals, Inc. dated August 26, 2003.
10.17	*	License Agreement by and between the Registrant and JCR Pharmaceuticals, Inc. dated August 26, 2003.
10.18	*	Distribution and Supply Agreement by and between the Registrant and Blackstone Medical, Inc., dated as of November 10, 2005.
10.19		Technology Transfer and License Agreement by and between the Registrant and Case Western University, dated as of January 1, 1993, as amended.
10.20	*	Marketing Collaboration and License Agreement by and between the Registrant and BioWhittaker, Inc., dated as of August 11, 1999.
10.21		Registration Rights Agreement by and between the Registrant and Cambrex Corporation, dated November 28, 2005.
10.22		Form of Convertible Promissory Note, dated October 30, 2006.
10.23		Lease Agreement by and between the Registrant and SAGA Limited Partnership, dated as of January 18, 1995, as amended.

10.24 Second Amended and Restated Sublease Agreement by and between the Registrant and Maryland Economic Development Corporation, dated as of June 30, 1998, as amended.
10.25 Lease Agreement by and between Gateway S-8, LLLP and Nova Telecommunications, Inc., dated August 11, 1998, as amended.
10.27 Agreement of Lease by and between the Registrant and Columbia Gateway S-28, L.L.C., dated June 6, 2006.
10.28 Consulting Agreement by and between the Registrant and Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, dated November 1995, as amended.
10.29 Termination Letter from Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, to the Registrant, dated May 10, 2006.
10.30 Indemnification Letter from Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, and Peter Friedli to the Registrant, dated May 19, 2006.
10.31 Warrant to Purchase up to 1,000,000 shares of Common Stock granted by Registrant to Peter Friedli, dated May 24, 2006.
10.32 Lock-up Agreement, dated October 30, 2006, by and among the Registrant, Peter Friedli, Friedli Corporate Finance, Inc. and US Venture 05, Inc.
10.33 Letter Agreement, dated October 30, 2006, by and between the Registrant and Friedli Corporate Finance, Inc.
10.34 Employment Agreement, dated July 31, 2006, by and between the Registrant and Lode Debrabandere.
10.35 Letter Agreement, dated June 6, 2007, by and between Friedli Corporate Finance, Inc. and Osiris Therapeutics, Inc. (Incorporated herein by reference to Current Report on Form 8-K filed by the Registrant with the SEC on June 7, 2007).
10.36 Form of Subscription Agreement, dated June 6, 2007, by and between the Registrant and Private Placement Investor (Incorporated herein by reference to Current Report on Form 8-K filed by the Registrant with the SEC on June 7, 2007).
10.37 Amendment to Lock-up Agreement, acknowledged September 20, 2007, by and between the Registrant and Peter Friedli and Venturetec, Inc., (Incorporated herein by reference to Current Report on Form 8-K filed by the Registrant with the SEC on September 20, 2007).
10.38 Letter Agreement, dated October 3, 2007, between Friedli Corporate Finance, Inc. and the Registrant (together with forms of subscription agreements and promissory note), (Incorporated herein by reference to Current Report on Form 8-K filed by the Registrant with the SEC on October 10, 2007).
10.39 Employment Separation Agreement and Release, dated November 23, 2007, by and between the Registrant and Cary J. Claiborne (Incorporated herein by reference to Current Report on Form 8-K filed by the Registrant with the SEC on November 23, 2007).
10.40 Form of Agreement, dated December 19, 2007, by and between the Registrant and the holders of Convertible Promissory Notes (Incorporated herein by reference to Registration Statement on Form S-3 filed by the Registrant with the SEC on January 18, 2008).

10.41	Form of Subscription Agreement, dated December 19, 2007, by and between the Registrant and Private Placement Investor (Incorporated herein by reference to Current Report on Form 8-K filed by the Registrant with the SEC on June 7, 2007).
10.42	Termination Agreement, dated December 31, 2007, by and between the Registrant and Boston Scientific Corporation (filed herewith).
10.43	Promissory Note, dated December 31, 2007, made by the Registrant in favor of Boston Scientific Corporation (filed herewith).
10.44	Award/Contract, dated January 3, 2008, issued by the U.S. Army Space & Missile Defense Command to the Registrant (Incorporated herein by reference to Current Report on Form 8-K filed by the Registrant with the SEC on January 4, 2008).
11.1.1	Statement re: Computation of Per Share Loss (included in Note 1 to Financial Statements included in Part II Item 8 herein).
23.1.1	Consent of Independent Registered Public Accounting Firm (filed herewith).
31.1.1	Rule 15d-14(a) Certification of C. Randal Mills, President and Chief Executive Officer (filed herewith).
31.2.1	Rule 15d-14(a) Certification of Philip R. Jacoby, Jr., Interim Chief Financial Officer (filed herewith).
32.1.1	Section 1350 Certification of C. Randal Mills, Chief Executive Officer, and Philip R. Jacoby, Jr., Interim Chief Financial Officer (filed herewith).

Incorporated herein by reference to corresponding Exhibit to the Registrant s Registration Statement on Form S-1, which was declared effective by the SEC on August 3, 2006.

Incorporated herein by reference to corresponding Exhibit to the Registrant s Current Report on Form 8-K, as filed with the SEC on November 2, 2006.

* Confidential treatment has been granted for certain portions thereof pursuant to an order of the United States Securities and Exchange Commission issued in connection with our Registration Statement on Form S-1, declared effective on August 3, 2006.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OSIRIS THERAPEUTICS, INC.

March 17, 2008 By: /s/ C. RANDAL MILLS
C. Randal Mills, Ph.D.
President & Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ C. RANDAL MILLS C. Randal Mills, Ph.D.	President and Chief Executive Officer (principal executive officer)	March 17, 2008
/s/ PHILIP R. JACOBY, JR. Philip R. Jacoby, Jr.	Interim Chief Financial Officer & Corporate Secretary (principal financial officer and principal accounting officer)	March 17, 2008
/s/ GREGORY H. BARNHILL Gregory H. Barnhill	Director	March 17, 2008
/s/ PETER FRIEDLI Peter Friedli	Director	March 17, 2008
/s/ FELIX GUTZWILLER Felix Gutzwiller	Director	March 17, 2008
/s/ JAY M. MOYES Jay M. Moyes	Director	March 17, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2008

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 001-32966

OSIRIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**71-0881115**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

7015 Albert Einstein Drive, Columbia, Maryland 21046

(Address of principal executive offices) (Zip Code)

443-545-1800

(Registrant s telephone number, including area code)

None

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Class	**Outstanding at May 9, 2008**
Common Stock, par value $0.001 per share	31,765,941

OSIRIS THERAPEUTICS, INC.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements - Unaudited.

OSIRIS THERAPEUTICS, INC.

Condensed Balance Sheets

Unaudited

Amounts in thousands

	March 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash	$ 4,791	$ 704
Short-term investments	7,280	17,460
Accounts receivable	360	549
Prepaid expenses and other current assets	1,334	1,583
Current assets of discontinued operations	8,649	8,445
Total current assets	22,342	28,741
Property and equipment, net	1,629	2,020
Restricted cash	280	280
Other assets	1,106	1,404
Long-term assets of discontinued operations	5,539	4,596
Total assets	$ 30,896	$ 37,041
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 13,430	$ 11,535
Notes payable, current portion	12,891	6,521
Capital lease obligations, current portion	587	886
Current liabilities of discontinued operations	3,068	2,552
Total current liabilities	29,984	22,705
Note payable, net of current portion		1,200
Capital lease obligations, net of current portion	8	11
Total liabilities	35,148	37, 881
Stockholders equity:		
Common stock, $0.001 par value, 90,000 shares authorized 31,766 and 31,648 shares outstanding in 2008 and 2007	32	32
Additional paid-in-capital	257,904	255,728
Accumulated deficit	(257,024)	(241,424)
Total stockholders equity	912	14,336
Total liabilities and stockholders equity	$ 30,896	$ 37,041

The accompanying notes are an integral part of these condensed financial statements.

OSIRIS THERAPEUTICS, INC.

Condensed Statements of Operations

Unaudited
Amounts in thousands, except per share data

	Three Months Ended March 31, 2008	2007
Revenue from government contracts, collaborative research licenses and royalties	$ 362	$ 279
Operating expenses:		
Research and development	16,694	8,494
General and administrative	2,608	1,506
Total operating expenses	19,302	10,000
Loss from operations	(18,940)	(9,721)
Interest expense, net	(209)	(343)
Loss from continuing operations	(19,149)	(10,064)
Income (loss) from operations of discontinued operations	3,549	(1,437)
Net loss	$ (15,600)	$ (11,501)
Basic and diluted net loss per share		
(Loss) from continuing operations	$ (0.60)	$ (0.37)
Income (loss) from discontinued operations	0.11	(0.05)
Net loss	$ (0.49)	$ (0.42)
Weighted Average Common Shares (basic and diluted)	31,741	27,372

The accompanying notes are an integral part of these condensed financial statements.

OSIRIS THERAPEUTICS, INC.

Condensed Statement of Stockholders Equity

For the three months ended March 31, 2008
Unaudited
Amounts in thousands, except for share and per share data

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2008	31,648,437	$ 32	$ 255,728	$ (241,424)	$ 14,336
Induced conversion of convertible notes into common stock ($14.00 per share)	89,380		1,498		1,498
Exercise of options to purchase common stock ($0.40 per share)	6,624		3		3
Issuance of common stock for services rendered by directors ($12.01 per share)	21,500		258		258
Share-based payment employee compensation			417		417
Net loss				(15,600)	(15,600)
Balance at March 31, 2008	31,765,941	$ 32	$ 257,904	$ (257,024)	$ 912

The accompanying notes are an integral part of these condensed financial statements.

OSIRIS THERAPEUTICS, INC.

Condensed Statements of Cash Flows

Unaudited
Amounts in thousands

	Three Months Ended March 31, 2008	2007
Cash flows from operating activities:		
Continuing Operations:		
Loss from continuing operations	$ (19,149)	$ (10,064)
Adjustments to reconcile loss from continuing operations to net cash used in continuing operations:		
Depreciation and amortization	481	411
Non cash share-based payments	650	520
Non cash interest expense	146	60
Changes in operating assets and liabilities:		
Accounts receivable	189	82
Prepaid expenses and other current assets	250	81
Other assets	279	164
Accounts payable and accrued expenses	1,895	(864)
Deferred revenue		(238)
Long-term interest payable and other liabilities		100
Net cash used in continuing operations	(15,259)	(9,748)
Discontinued Operations:		
Income (loss) from discontinued operations	3,549	(1,437)
Adjustments to reconcile income (loss) to net cash provided by discontinued operations:		
Depreciation and amortization	42	17
Non cash share-based payments	25	9
Changes in operating assets and liabilities:		
Accounts receivable	369	1.326
Inventory and other current assets	(574)	1,154
Accounts payable and accrued expenses	516	118
Net cash provided by discontinued operations	3,927	1,187
Net cash used by operating activities	(11,332)	(8,561)
Cash flows from investing activities:		
Purchases of property and equipment	(1,077)	(870)
Proceeds from sale of short-term investments	10,353	10,839
Net cash provided by investing activities	9,276	9,969
Cash flows from financing activities:		
Principal payments on capital lease obligations and notes payable	(1,932)	(290)
Restricted cash		6
Proceeds from convertible notes payable	8,000	
Proceeds from the exercise of stock options	3	54
Net cash provided by (used in) financing activities	6,071	(230)
Net increase in cash	5,015	1,178
Cash at beginning of period	704	714
Cash at end of period:	$ 4,719	$ 1,892

The accompanying notes are an integral part of these condensed financial statements.

OSIRIS THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

Amounts in thousands, except for share and per share data

1. Basis of Presentation

The accompanying unaudited condensed financial statements of Osiris Therapeutics, Inc. (the Company) have been prepared in accordance with generally accepted accounting principles in the United States and the rules and regulations of the Securities and Exchange Commission (the SEC), for interim financial information. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles for complete financial statements and should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2007. The interim financial statements are unaudited, but in the opinion of management all adjustments, consisting only of normal recurring accruals, considered necessary for a fair statement of the results of these interim periods have been included. The results of the Company s operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year.

2. Significant Accounting Policies and Recent Accounting Pronouncements

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Due to the inherent uncertainty involved in making those assumptions, actual results could differ from those estimates. We believe that the most significant estimates that affect our financial statements are those that relate to inventory valuation, deferred tax assets, and share-based compensation.

Revenue Recognition

Our revenue recognition policies are in accordance with the SEC s Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*.

In January 2008, we were awarded a contract from the United States Department of Defense (DoD) to develop and stockpile Prochymal for the repair of gastrointestinal injury resulting from radiation exposure, and began recognizing contract revenue during the first quarter of 2008. Contract revenue is recognized as the related costs are incurred, in accordance with the terms of the government contract.

Loss per Common Share

Basic loss per common share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share adjusts basic loss per share for the potentially dilutive effects of common share equivalents, using the treasury stock method. All common equivalent shares from the conversion of convertible debt and outstanding stock options and warrants are excluded from the computation of diluted loss per share as their effect is antidilutive.

Stock-Based Compensation Plans

In 1994, we adopted the Amended and Restated 1994 Stock Incentive Plan (the 1994 Plan) under which 875,000 shares of common stock have been reserved for issuance upon the exercise of options or other equity grants that we issue from time to time. In 2006, we adopted the 2006 Omnibus Plan, under which we reserved 850,000 shares of common stock for issuance upon the exercise of stock options or other equity grants. We stopped granting options under the 1994 Plan upon the completion of our initial public offering in August 2006.

A summary of the combined activity under both of our stock-based compensation plans as of March 31, 2008 and changes during the three months then ended is presented below.

	Number of Shares	Weighted Average Exercise Price Per Share at Grant Date	Weighted Average Remaining Term (in Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	880,410	$ 8.64	7.2	$ 5,091
Granted	277,500	11.95		
Exercised	(6,624)	0.40		73
Forfeited or expired	(2,000)	9.40		
Outstanding at March 31, 2008	1,149,286	9.40	8.5	5,497
Exercisable at March 31, 2008	399,024	3.73	7.2	3,996

The weighted average grant date fair value of options granted during the three months ended March 31, 2008 was $7.94 per share. We received a total of $3 in cash from the exercise of options during the three months ended March 31, 2008.

Also during the three months ended March 31, 2008, we granted 21,500 unrestricted shares of common stock to members of our Board of Directors under our 2006 Omnibus Plan and recognized $258 in share-based expense. As of March 31, 2008, 129,260 shares of common stock remain available for future grants under our 2006 Omnibus Plan.

Share-based compensation, (including director compensation) included in the statements of operations for the three months ended March 31, 2008 and 2007 was:

	Three Months Ended March 31, 2008	2007
Biologic drug candidates	$ 229	$ 144
Discontinued operations	25	9
General and administrative	421	376
Total	$ 675	$ 529

As of March 31, 2008, there was approximately $5.8 million of total unrecognized share-based compensation cost related to options granted under our plans that will be recognized over a weighted-average period of approximately 3.5 years.

Supplemental Cash Flow Information

	Three Months Ended March 31, 2008	2007
Supplemental disclosure of cash flows information:		
Cash paid for interest	$ 208	$ 101
Cash paid for taxes		
Supplemental schedule of non-cash investing and financing activities:		
Common stock issued to directors for services rendered	258	295

Significant New Accounting Pronouncements

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133.* SFAS No. 161 will require entities to provide qualitative disclosures about the objectives and strategies for using derivatives, quantitative disclosures about the fair value of gains and losses on derivative contracts, and disclosures about credit-risk related to contingent features in their hedged positions. The statement also asks entities to disclose more information about (i) the location and amounts of derivative instruments in financial statements; (ii) how derivatives and related hedges are accounted for under SFAS No. 133; and (iii) how the hedges affect the entity s financial position, financial performance and cash flows. The statement is effective for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged, but not required. As of March 31, 2008 we have not adopted SFAS No. 161. We do not expect the adoption of SFAS No. 161 to have a material impact on our financial statements.

3. Discontinued Operations

In April 2008, we committed to a plan to sell our biologic tissue product practice, including our entire product line relating to the processing, manufacturing, marketing and selling of Osteocel® and Osteocel® XO, an allograft material containing cancellous bone, used in spinal fusion and other surgical procedures. We refer to these assets as our Osteocel asset disposal group. Not included among the Osteocel asset disposal group is Osteocel® XC, our second generation product candidate under development for bone repair, utilizing culture expanded mesenchymal stem cells to create a synthetic version of Osteocel. On May 8, 2008, we entered into a definitive agreement to sell the Osteocel asset disposal group to NuVasive, Inc., a Delaware corporation. Our ability to consummate the sale is subject to, among other things, the expiration of the applicable waiting period (including any extensions) under the U.S. Hart-Scott-Rodino Act. We are also seeking stockholder approval, to satisfy any approvals which may be required in respect of the sale under Delaware law. We expect to close the transaction during the second or third quarter of 2008, recognizing a gain.

The net assets of the Osteocel asset disposal group were as follows, at March 31, 2008 and December 31, 2007:

	2008	2007
Accounts receivable	$ 3,955	$ 4,324
Inventory	4,622	3,983
Other current assets	72	138
Current assets of discontinued operations	8,649	8,445
Property and equipment, net	5,539	4,596
Current liabilities of discontinued operations	3,068	2,552
Net assets of discontinued operations	$ 11,120	$ 10,489

We eliminated the operations of the business components of the Osteocel asset disposal group from our ongoing operations as a result of the disposal transaction and have presented the results of the group s operations as a discontinued operation for all periods. Summarized operating results of the Osteocel asset disposal group are as follows:

	Three Months Ended March 31,	
	2008	2007
Product Sales	$ 7,511	$ 2,000
Cost of goods sold	3,781	901
Gross Profit	3,730	1,099
Failed production runs		2,433
General & administrative expenses	181	103
	181	2,536
Income (loss) from operations of discontinued operations	$ 3,549	$ (1,437)

4. Notes Payable

In March 2008, we issued $8.0 million in convertible promissory notes in a private placement to several non-U.S. investors pursuant to a private placement intended to qualify under Regulation S and Section 4(2) of the Securities Act of 1933, as amended. The notes bear interest at a rate of 2% per annum and become due and payable on November 30, 2008. The notes are convertible at the option of the respective holders at any time, into shares of common stock at conversion prices ranging from $12.04 to $12.17 per share (the respective closing prices on the NASDAQ Global Exchange on the dates of the definitive agreements). The notes provide for redemption at any time at our option, with 30-days prior written notice. The note holders are afforded certain registration rights in respect of any shares issued upon conversion.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

Forward-Looking Information

This report includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Forward-looking statements include statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, compensation arrangements, financing needs, plans or intentions relating to acquisitions, business trends and other information that is not historical information and, in particular, may appear under the headings Risk Factors in our Annual Report 10-K under Part I Item 1A, Part II Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and the other documents we file with the Securities and Exchange Commission, or SEC, including, among others, our quarterly reports on Form 10-Q and any amendments thereto. When used in this Quarterly Report, the words *estimates, expects, anticipates, projects, plans, intends, believes, forecasts* and variations of such words or similar expressions are intended to identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements regarding the following: our product development efforts; our clinical trials and anticipated regulatory requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for mesenchymal stem cells and biologic drug candidates; our cash needs; patents and proprietary rights; ability of our potential products to treat disease; our plans for sales and marketing; our plans regarding facilities; types of regulatory frameworks we expect will be applicable to our potential products; and results of our scientific research. All forward-looking statements, including, without limitation, management s examination of historical operating trends, are based upon our current expectations and various assumptions. Our expectations, beliefs and projections are expressed in good faith and we believe there is a reasonable basis for them. However, there can be no assurance that management s expectations, beliefs and projections will result or be achieved.

You should read the following management s discussion and analysis of our financial condition and results of operations in conjunction with our audited Financial Statements and related notes thereto and other disclosures included as part of our Annual Report on Form 10-K for the year ended December 31, 2007, and our unaudited Condensed Financial Statements for the three months ended March 31, 2008 and other disclosures included in this Quarterly Report on Form 10-Q. Our Condensed Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

There are a number of risks and uncertainties that could cause our actual results to differ materially from the forward-looking statements contained in this report. Some of the important factors that could cause our actual results to differ materially from the forward-looking statements we make in this report are set forth in this report, including under the heading Risk Factors , or in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 under Part I Item 1A Risk Factors. There may be other factors that may cause our actual results to differ materially from the forward-looking statements.

All forward-looking statements attributable to us or persons acting on our behalf apply only as of the date of this Quarterly Report and are expressly qualified in their entirety by the cautionary statements included herein. We undertake no obligation to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances and do not intend to do so.

When we use the terms Osiris, we, us, and our we mean Osiris Therapeutics, Inc., a Delaware corporation.

Introduction and Overview

The following is a discussion and analysis of our financial condition and results of operations for the three month periods ended March 31, 2008 and 2007. You should read this discussion together with the accompanying unaudited condensed financial statements and notes and with our Annual Report on Form 10-K for the year ended December 31, 2007. Historical results and any discussion of prospective results may not indicate our future performance. See Forward Looking Information.

We are a leading stem cell therapeutic company headquartered in Columbia, Maryland and focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic, and cardiovascular areas. We were incorporated in Delaware in April 2002. Our predecessor company was organized in 1992. Our lead biologic drug candidate, Prochymal , is being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease (GvHD) and Crohn s disease, and is the only stem cell therapeutic currently granted both Orphan Drug and Fast Track status by the Food and Drug Administration (FDA). Prochymal is also being developed for the repair of heart tissue following a heart attack and for protection of pancreatic islet cells in patients with type 1 diabetes. Our pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen for osteoarthritis in the knee. We have also partnered with Genzyme Corporation to develop Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies.

Osiris is a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. We have developed an extensive intellectual property portfolio to protect our technology in the United States and a number

of foreign countries including 47 U.S. and 253 foreign patents owned or licensed. We believe that our biologic drug candidates have advantages over other stem cell therapeutics in development for the following reasons:

- **Stem Cell Source.** Our stem cells are obtained from adult bone marrow, a readily available source. The cells are drawn from the hips of volunteer donors between the ages of 18 and 30 years, using a simple needle and syringe aspiration. Because the cells are obtained from consenting adult donors, we are able to largely avoid the ethical controversy surrounding embryonic and fetal stem cell research.

- **Ability to Mass Produce.** Through our proprietary manufacturing methods, we can grow MSCs in a controlled fashion to produce up to 10,000 treatments of our biologic drug candidates from a single bone marrow donation. Our ability to produce a large quantity of treatments from one donation provides us with manufacturing efficiencies and product consistency that are essential to commercialization.

- **Universal Compatibility.** Many stem cell therapies under development can elicit a rejection response in the recipient and therefore require donor-to-recipient matching or potentially harmful immunosuppression. This greatly reduces manufacturing efficiencies and creates a risk of mismatch which can result in an acute inflammatory response and, potentially, in death. Based on our clinical experience, we believe that our biologic drug candidates are not rejected by the patient s immune system and so, like type O negative blood, do not require matching. This universal compatibility allows us to produce a standardized product available to all patients in almost any medical setting.

- **Treatment on Demand.** Our biologic drug candidates can be stored frozen at end-user medical facilities until they are needed. We anticipate that medical facilities will be able to prescribe and dispense these products in much the same way as conventional drugs. In contrast, other stem cell technologies under development require weeks to prepare after a patient s need is identified. This is a key feature of our technology, as many patients in the critical care setting require prompt treatment.

The following table summarizes key information about our biologic drug candidates.

Product/Candidate	Indication	Status
Prochymal	Steroid Refractory Acute GvHD	Phase III
	First Line Treatment of Acute GvHD	Phase III
	Biologics Refractory Crohn s Disease	Phase III
	Type I Diabetes	Phase II
	Acute Myocardial Infarction	Phase II
	Acute Radiation Syndrome	Preclinical
Chondrogen	Osteoarthritis & Cartilage Protection	Phase I/II

We have incurred annual operating losses since inception and expect to incur substantial operating losses in the future in connection with the development of our core products. As of March 31, 2008, we had an accumulated deficit of $257 million.

In addition to our biologic drug candidates, we produce and since July 2005 have marketed Osteocel for regenerating bone in orthopedic indications. Osteocel is our only commercial product and generated revenue of approximately $7.5 million for the three months ended March 31, 2008. We manufacture Osteocel in our Baltimore, Maryland clean-room facilities for distribution by us and others for use in orthopedic indications and spinal procedures. In April 2008, however, we committed to a plan to sell our Osteocel related assets, and on May 8, 2008 entered into an asset purchase agreement to sell those assets, including our entire product line relating to the processing, manufacturing, marketing and selling of Osteocel and Osteocel XO to NuVasive, Inc. Our ability to consummate the sale is subject to a number of risks and uncertainties, and conditions precedent, including the expiration of the applicable waiting period (including any extensions) under the U.S. Hart-Scott-Rodino Act. We are also seeking stockholder approval for the sale and expect to close the transaction during the second or third quarter of 2008, recognizing a gain.

Financial Operations Overview

Revenue

We recognize revenue on collaborative and royalty agreements and a contract with the United States Department of Defense for the development and stockpiling of Prochymal for the treatment of acute radiation syndrome.

Research and Development Costs

Our research and development costs consist of expenses incurred in identifying, developing and testing biologic drug candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for independent

monitoring and analysis of our clinical trials, costs of contract research and manufacturing, costs of facilities, and the costs of manufacturing clinical batches of biologic drug candidates, quality control supplies and material to expand biologic drug candidates.

Consistent with our focus on the development of biologic drug candidates with potential uses in multiple indications, many of our costs are not attributable to a specifically identified project. We use our employee and infrastructure resources across several projects. Accordingly, we do not account for internal research and development costs on a project-by-project basis. As a result, we cannot state precisely the total costs incurred for each of our clinical and preclinical projects on a project-by-project basis. From inception in December 1992 through March 31, 2008, we incurred aggregate research and development costs of approximately $251 million. We expect our research and development expenses to increase substantially in the future, as we expand our clinical trial activity, as our biologic drug candidates advance through the development cycle and as we invest in additional product opportunities and research programs. Clinical trials and preclinical studies are time-consuming and expensive. Our expenditures on current and future preclinical and clinical development programs are subject to many uncertainties. We test our products in several preclinical studies, and we then conduct clinical trials for those biologic drug candidates that we determine to be the most promising. As we obtain results from clinical trials, we may elect to discontinue or delay trials for some biologic drug candidates in order to focus our resources on more promising biologic drug candidates. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, size of trial and intended use of a biologic drug candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the length of time required to enroll trial participants;
- the duration of patient treatment and follow-up;
- the costs of producing supplies of the biologic drug candidates needed for clinical trials and regulatory submissions;
- the efficacy and safety profile of the biologic drug candidate; and
- the costs and timing of, and the ability to secure, regulatory approvals.

As a result of the uncertainties discussed above, we are unable to determine with any significant degree of certainty the duration and completion costs of our research and development projects or when and to what extent we will generate revenues from the commercialization and sale of any of our biologic drug candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of the costs associated with our general management, including salaries, allocations of facilities and related costs, and professional fees such as legal and accounting expenses. In anticipation of the commercialization and bringing our biologic drug candidates to market, we are incurring increases in our general and administrative expense in the areas of business development and intellectual property. We have also incurred increased general and administrative costs for legal and accounting compliance costs, investor relations and other activities associated with operating as a publicly traded company. Continued increases will also likely result from the additional hiring of operational, financial, accounting, facilities engineering and information systems personnel.

Interest Expense, Net

Interest income consists of interest earned on our cash and short-term investments. Interest expense consists of interest incurred on convertible debt, capital leases and other debt financings. We pay interest on our bank loan, capital leases and our convertible long-term debt.

Income Taxes

We have not recognized any deferred tax assets or liabilities in our financial statements since we cannot assure their future realization. Because realization of deferred tax assets is dependent upon future earnings, a full valuation allowance has been recorded on the net deferred tax assets, which relate primarily to net operating loss and research and development carry-forwards. In the event that we become profitable within the next several years, we have net deferred tax assets of approximately $75 million that may be utilized prior to us having to recognize any income tax expense or make payments to the taxing authorities. Utilization of our net operating loss carry-forwards in any one year may be limited under Internal Revenue Code Section 382, and we could be subject to the alternative minimum tax.

Critical Accounting Policies

There have been no material changes in our critical accounting policies, estimates and judgments during the three months ended March 31, 2008 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2007, other than as disclosed herein.

Results of Operations

Comparison of Quarters ended March 31, 2008 and 2007

Revenues (excluding discontinued operations)

Revenues for the three months ended March 31, 2008 totaled $0.4 million, consisting of $0.3 million in contract revenue from the Department of Defense contract and $0.1 million in royalties. Revenues for the three months ended March 31, 2007 were $0.3 million, which consisted primarily of the recognition of license fees from research, development and commercialization collaborative agreements with an international pharmaceutical company. These collaborative agreements were terminated in December 2007 and upon such termination we regained the worldwide rights to Prochymal for cardiac indications.

Research and Development Expenses

Research and development expenses were approximately $16.7 million for the three months ended March 31, 2008 compared to $8.5 million for the comparable period in 2007, reflecting the increase in our clinical trial activities. At March 31, 2008, we are conducting three Phase III clinical trials in several inflammatory disease indications, Phase II clinical trials for acute myocardial infarction and type I diabetes and conducting preclinical research on acute radiation syndrome.

General and Administrative Expenses (excluding discontinued operations)

General and administrative expenses were $2.6 million for the three months ended March 31, 2008 compared to $1.5 million in the corresponding period in fiscal 2007. The increased costs in 2008 include facilities costs associated with leasing and operating plants in Columbia and Baltimore, Maryland (the Baltimore facility is scheduled to close in the third quarter of 2008), increased legal costs associated with our intellectual property and increases in our managerial level staff in anticipation of qualifying and commercializing our biologic drug candidates.

Interest Expense, Net

Interest expense, net was $0.2 million for the three months ended March 31, 2008 compared to $0.3 million in the corresponding period in fiscal 2007.

Income (Loss) from Operations of Discontinued Operations

Income from operations of the Osteocel asset disposal group were $3.5 million for the three months ended March 31, 2008 compared to a loss of $1.4 million for the comparable period in 2007, as follows:

	Three Months Ended March 31,	
	2008	2007
	(Amounts in thousands)	
Product Sales	$ 7,511	$ 2,000
Cost of goods sold	3,781	901
Gross Profit	3,730	1,099
Failed production runs		2,433
General & administrative expenses	181	103
	181	2,536
Income (loss) from operations of discontinued operations	$ 3,549	$ (1,437)

In April 2008, we committed to a plan to sell our biologic tissue product practice, consisting of the Osteocel asset disposal group. On May 8, 2008, we entered into a definitive agreement to sell the Osteocel asset disposal group. We expect to close the transaction during the second or third quarter of 2008, recognizing a gain.

Liquidity and Capital Resources

Liquidity

At March 31, 2008, we had $12.0 million in cash and short-term investments. In addition, in October 2007, we obtained a $30.0 million financing commitment from Friedli Corporate Finance, Inc., which is owned by Peter Friedli who is the Chairman of our Board of Directors and largest shareholder. This financing commitment is for a twelve month term and provides for financing through the issuance by us of common stock issued at a price determined as the basis of market value, or 3-year promissory notes bearing interest at LIBOR plus 4%. Although we control the timing of draws made during the term of the commitment, if any, Friedli Corporate Finance, Inc. determines whether we issue common stock or promissory notes, subject, however to certain limitations as to the aggregate number of shares of common stock that may be issued. We did not incur any fees in connection with this financing commitment and have made no draws under such commitment.

At March 31, 2008, our short-term debt consisted of $4.9 million due in quarterly installments through January 2009 and payable to an international pharmaceutical company and $8.0 million in convertible notes payable to several noteholders, including Mr. Friedli, which mature on November 30, 2008. The convertible notes may be converted into common stock at any time at the discretion of the note holders. The notes also provide for redemption at any time at our option, with 30-days prior written notice.

Cash Flows

Net cash used in operating activities was $11.3 million for the three months ended March 31, 2008, which is comprised of net cash used in continuing operations of $15.3 million, netted against net cash provided by discontinued operations of $3.9 million. Net cash used in operating activities during the three months ended March 31, 2007 was $8.6 million, which is comprised of net cash used in continuing operations of $9.8 million, netted against net cash provided by discontinued operations of $1.2 million.

Net cash used in continuing operations during the first quarter of 2008 reflects the loss from continuing operations of $19.1 million, partially offset by $2.6 million in favorable changes in our working capital and $1.2 million of non-cash charges. Net cash used in continuing operations during the three months ended March 31, 2007 was $9.7 million, reflecting our loss from continuing operations of $10.1 million, netted against unfavorable changes in working capital of $0.6 million and non-cash charges of $1.0 million.

Net cash provided by discontinued operations during the first quarter of 2008 reflects the income from discontinued operations of $3.5 million, increased by favorable changes in working capital of discontinued operations of $0.3 million and non-cash charges of $0.1 million. Net cash provided by discontinued operations during the three months ended March 31, 2007 was $1.2 million and reflects our loss from discontinued operations of $1.4 million offset by favorable changes in working capital of discontinued operations of $2.6 million. The favorable changes in working capital of discontinued operations in the first quarter of 2007 are primarily reductions in accounts receivable and inventory related to the failed production runs associated with the expansion of our Baltimore, MD manufacturing facility.

Net cash provided by investing activities was $9.3 million for the three months ended March 31, 2008, including $1.1 million of capital expenditures spent primarily on our manufacturing facilities in Columbia, Maryland, partially offset by the sale of $10.4 million of short-term investments. Net cash used in investing activity for the three months ended March 31, 2007 was $10.0 million.

Net cash provided by financing activities was $6.1 million for the three months ended March 31, 2008. This includes scheduled payments on our capital leases and notes, offset by the $8.0 million proceeds from the issuance of convertible promissory notes in March 2008. Cash used in financing activities during the three months ended March 31, 2007 was $0.2 million.

Capital Resources

Our future capital requirements will depend on many factors, including, but not limited to:

- the closing of the transaction providing for the sale of the Osteocel asset disposal group and performance under the related manufacturing agreement;

- the scope and results of our research and preclinical development programs;

- the scope and results of our clinical trials, particularly regarding the number of patients required for our Phase III trials for Prochymal;

- the timing of and the costs involved in obtaining regulatory approvals for our biologic drug candidates, which could be more lengthy or complex than obtaining approval for a new conventional drug, given the FDA s limited experience with late-stage clinical trials and marketing approval for stem cell therapeutics;

- the costs of maintaining, expanding and protecting our intellectual property portfolio, including litigation costs and liabilities;

- the costs of repaying our debt; and

- the costs of enlarging our work force consistent with expanding our business and operations and status as a public company, and as necessary to enhance and train our sales network in anticipation of the approval of our biologic drug candidates for commercial sale.

As a result of these and other factors, we will likely need or choose to seek additional funding prior to our becoming cash flow positive on an operational basis. We would likely seek such funding through public or private financings or some combination of them. Although not our current focus, we might also seek funding through collaborative arrangements if determined to be necessary or appropriate.

We are also pursuing government contracts in an effort to help offset the remaining development costs and reduce adoption risks by securing advanced purchase commitments for Prochymal. Additional funding may not be available to us on acceptable terms, or at all. If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our technologies or biologic drug candidates. If we raise capital through the sale of equity, or securities convertible into equity, dilution to our then existing stockholders would result. If we raise additional capital through the incurrence of debt, we would likely become subject to covenants restricting our business activities, and holders of debt instruments would have rights and privileges senior to those of our equity investors. In addition, servicing the interest and repayment obligations under these borrowings would divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

We expect that our available cash and interest income, including the availability under our line-of-credit and financing commitment, will be sufficient to finance currently planned activities through at least 2008. These estimates are based on certain assumptions, which could be negatively impacted by the matters discussed under Risk Factors in this report and our Annual Report on Form 10-K, among other things.

If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, which may have a material adverse affect on our business, financial condition and results of operations. See Risk Factors in this report and our Annual Report on Form 10-K.

Off-Balance Sheet Arrangements.

We have no off-balance sheet financing arrangements and we have not entered into any transactions involving unconsolidated subsidiaries or special purpose entities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Due to the short duration of our investment portfolio and the high quality of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. However, our investment portfolio consists of investment grade auction rate certificates which are presently illiquid at par value. In the event we sold one of these auction rate securities presently in the secondary market, we may experience a loss of between 5% - 15% of the par value. Our portfolio managers are presently unable to provide us with an estimate of how long the credit crisis in the auction rate certificate market will exist.

We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectability and establishment of appropriate allowances in connection with our internal controls and policies.

We do not enter into hedging or derivative instrument arrangements.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures. An evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Quarterly Report on Form 10-Q was made under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (a) are effective to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is timely recorded, processed, summarized and reported and (b) include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. There have not been any changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we receive threats or may be subject to routine litigation matters related to our business. However, we are not currently a party to any material pending legal proceedings.

Item 1A. Risk Factors.

In addition to the risk factors previously disclosed under the heading Risk Factors in Part I Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, filed with the Securities and Exchange Commission on March 17, 2008, you should carefully consider the risk factors described below which relate to our sale of the Ostoecel asset disposal group to NuVasive, Inc. If any of the following risk factors or any of the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 actually occur, our business, financial condition or results of operations could be materially adversely affected.

Risk Factors Regarding the Proposed Sale of the Osteocel Asset Disposal Group.

The proposed sale may not be completed if the conditions to closing are not satisfied or waived.

The proposed sale may not be completed because the conditions to closing may not be satisfied or waived. Conditions which must be satisfied or waived prior to the technology assets closing include obtaining stockholder approval and required consents from third parties such as tissue suppliers and parties to important contracts, and the receipt of requisite approvals or the expiration of applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. If the transaction is not completed, it is possible that we will have difficulty recouping the costs incurred in connection with negotiating the proposed transaction, and our business may be seriously harmed. In addition, depending upon the reason for the termination, pursuant to the asset purchase agreement, we may become obligated upon termination to pay NuVasive a termination fee of $2,000,000, or $350,000 in expense reimbursements.

We may not receive all of the payments available to us under the terms of the asset purchase agreement, and accordingly, we may have less cash available to us to fund our remaining operations.

The terms of the asset purchase agreement provide for an initial payment of $35 million dollars in cash and allow for the prospect of additional milestone payments, of up to approximately an additional $50 million dollars in the aggregate. In addition, pursuant to the terms of a manufacturing agreement to be entered into concurrent with the initial closing under the asset purchase agreement, we will have the ability to earn fee revenues related to the production of Osteocel for supply to NuVasive over a period of approximately eighteen months following the initial closing of the transaction. The manufacturing agreement imposes minimum purchase order obligations on NuVasive which, if satisfied by us result in potential fee revenues of approximately $52 million. Our ability to earn these milestone payments or fee revenues is, however,

subject to a number of conditions and uncertainties, and we have no assurances that these amounts will, in fact, be paid to or be received by us in full. If we do not receive these payments, we will have less cash available to fund our remaining operations and to support the continued development and pursuit of FDA approval for our biologic drug candidates, including Prochymal.

The asset purchase agreement will expose us to contingent liabilities which could adversely affect our ability to pursue our core business focused on the development and marketing approval for our biologic drug candidates, including Prochymal.

In the asset purchase agreement we have made customary representations and warranties and the parties have agreed to indemnify each other for breaches of representations, warranties and covenants contained in the asset purchase agreement, and we have agreed to indemnify NuVasive for certain excluded liabilities. Should we incur liability for breach of these representations or warranties, our ability to pursue our core business focused on the development and marketing approval for our biologic drug candidates, including Prochymal, could be materially and adversely affected.

The failure to complete the proposed sale may result in a decrease in the market value of our common stock and may impair our ability to achieve our objectives of developing, obtaining FDA approval and marketing our biologic drug candidates, including Prochymal.

The failure to complete the proposed sale may result in a decrease in the market value of our common stock and may impair our ability to achieve our objectives of becoming profitable as quickly as possible and enhancing the value of our assets to our stockholders.

If our stockholders fail to approve the proposed sale, or if the proposed sale is not completed for any other reason, we will not receive the benefits of the transaction, which may substantially limit our ability to implement our strategy of pursuing the continued development, FDA approval and marketing of our biologic drug candidates, including Prochymal.

By completing the proposed sale, we will be selling the assets that have historically generated substantially all of our revenue.

Pursuant to the proposed sale, we will be selling our entire product line relating to the processing, manufacturing, marketing and selling of Osteocel and Osteocel XO. This business has historically been the source of a significant percentage of our revenue. Although we expect to receive continued revenues for the supply of product pursuant to the manufacturing agreement, these revenues will not be long term and will likely cease within eighteen months after the initial closing under the asset purchase agreement. Although our business related to the development, obtaining FDA approval and marketing of our biologic drug candidates, including Prochymal, will remain, this business has generated no appreciable revenue and has caused us to incur significant operating expenses and resulted in the incurrence of substantial losses in each year since our inception. We expect to continue to incur operating expenses and anticipate our expenses and losses will increase in the foreseeable future as we continue our efforts to develop, obtain FDA approval and market our biologic drug candidates, including Prochymal. Even in the event that all milestone payments are received by us under the asset purchase agreement, these funds and the funds available under the manufacturing agreement may not collectively be sufficient to fund our anticipated losses and expenses. Accordingly, we may need to seek additional funding prior to our becoming cash flow positive on an operational basis. We would likely seek such funding through public or private financing or some combination of them. Additional funding may not be available to us on acceptable terms, or at all.

Our long term business prospects will depend primarily on the success of our biologic drug candidates business.

Although we will continue to manufacture Osteocel for approximately eighteen months after the initial closing under the asset purchase agreement, our biologic drug candidate business will be the primary focus of our business. Our long term business prospects will, therefore, be dependent almost solely on the success of our biologic drug candidate business. This business is based on novel technologies and involves significant risks and challenges in regards to product development and optimization, manufacturing, government regulation, intellectual property, third-party reimbursement and market acceptance, among other risks previously disclosed by us.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Note Conversion

In January 2008, we induced the conversion of $1.2 million of our 10% convertible promissory notes, together with accrued interest, into 89,380 shares of common stock at the conversion price of $14.00 per share. The notes were held by institutional and accredited investors based outside of the U.S. The debt conversion was arranged for us by Friedli Corporate Finance, Inc., of which Peter Friedli, our Chairman of the Board of Directors and largest shareholder, is President and sole owner. The securities issued as a result of the debt conversion were issued pursuant to exemptions from registration, as provided for under Regulation S and Regulation D promulgated under Securities Act of 1933, as amended. In January 2008, we filed a Registration Statement on Form S-3 to register the resale of these shares by the respective holders.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

Item 5. **Other Information**.

None.

Item 6. **Exhibits**.

Exhibit Number	Description of Exhibit
10.1	Form of Subscription Agreements, entered into on March 19 and March 24, 2008, by a between the Registrant and certain non-U.S. Purchasers in connection with the issuance and sale of $8.0 million in Convertible Promissory Notes in the aggregate.
10.2	Form of 2% Convertible Promissory Notes of the Registrant, dated March 19 and March 24, 2008, issued in the aggregate principal amount of $8 million to certain non-U.S. Purchasers.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15D-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002).
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15D-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002).
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

The certification attached as Exhibit 32 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Osiris Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Osiris Therapeutics, Inc.

Date: May 12, 2008

/s/ PHILIP R. JACOBY, JR.
Philip R. Jacoby, Jr.
Interim Chief Financial Officer

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

Amendment No.1

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2008

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 001-32966

OSIRIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**71-0881115**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

7015 Albert Einstein Drive, Columbia, Maryland 21046

(Address of principal executive offices) (Zip Code)

443-545-1800

(Registrant s telephone number, including area code)

None

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Class	**Outstanding at May 9, 2008**
Common Stock, par value $0.001 per share	31,765,941

AMENDMENT NO. 1 TO FORM 10-Q

This Amendment No. 1 on Form 10-Q/A (the Amendment) amends our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 as originally filed with the Securities and Exchange Commission on May 12, 2008 (the Original Filing). This Amendment relates solely to Part II, Item 6 of the Original Filing, and solely amends paragraph 4 of Exhibits 31.1 and 31.2, certification of principal executive officer and principal financial officer, respectively. The text of Part II, Item 6 of the Original Filing, solely as it relates to Exhibits 31.1 and 31.2, respectively, is included herewith, and Exhibits 31.1 and 31.2, as so amended are filed herewith in their entirety, in each case for ease of reference.

Except for the revisions described above, this Amendment does not amend, modify or update the Original Filing in any respect. Without limiting the foregoing, this Amendment does not amend or modify Part II, Item 6 of the Original Filing as it relates to any exhibit included therewith, other than Exhibits 31.1 and 31.2. This Amendment does not reflect events that have occurred subsequent to the filing of the Original Filing and, accordingly, this Amendment should be read in conjunction with our filings made with the Securities and Exchange Commission subsequent to the date of the Original Filing.

PART II OTHER INFORMATION

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Item 6. **Exhibits**.

Exhibit Number	Description of Exhibit
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15D-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002).
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15D-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Osiris Therapeutics, Inc.

Date: May 22, 2008

/s/ PHILIP R. JACOBY, JR.
Philip R. Jacoby, Jr.
Interim Chief Financial Officer

United States
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 4, 2008

OSIRIS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-32966**	**71-0881115**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

7015 Albert Einstein Drive, Columbia, Maryland	**21046**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(443) 545 - 1800**

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Stockholders Approve Amended and Restated 2006 Omnibus Plan and Re-elect Directors at Annual Meeting

At the Annual Meeting of Stockholders held on June 4, 2008, the stockholders of Osiris Therapeutics, Inc. (the Company), by the affirmative vote of approximately 66 % of the votes entitled to be cast, approved the amendment and restatement of the Company s 2006 Omnibus Plan to, among other things, increase the number of shares authorized for issuance at any time under the 2006 Omnibus Plan from 850,000 to 1,450,000 shares. In addition, the stockholders re-elected C Randal Mills, Ph.D and Felix Gutzwiller to the Board of Directors for three year terms expiring at the annual meeting to be held in 2011 and until their respective successors are duly elected and qualify. Dr. Mills also serves as President and Chief Executive Officer of the Company. The amendment and restatement of the 2006 Omnibus Plan (as so amended and restated, the Amended and Restated Plan) was previously approved by the Board of Directors of the Company on April 17, 2008, subject to and to become effective only upon approval by the stockholders of the Company.

The Amended and Restated Plan is the sole equity compensation plan under which grants and awards are made to employees and directors of the Company. The Company formerly made grants under the Amended and Restated 1994 Stock Incentive Plan, but the ability to make awards thereunder has expired. All non-employee directors and all employees (including officers) of the Company or its subsidiaries are eligible to receive awards under the Amended and Restated Plan. The Amended and Restated Plan contains provisions for making various stock-based awards, including non-qualified stock options, incentive stock options as defined in Section 422 of the Internal Revenue Code of 1986, as amended, stock appreciation rights, restricted stock awards, and performance shares and in some cases performance units. In no event is any individual employee or director eligible to receive in any calendar year awards under the Amended and Restated Plan involving more that 125,000 shares of our common stock (or 50,000 shares in the case of performance share awards), as adjusted due to a merger, reorganization or similar event. Unless extended upon subsequent Board and stockholder approval, the Amended and Restated Plan expires on April 16, 2016, and no awards may be made after that date. Awards made before that date will remain outstanding in accordance with their terms, notwithstanding expiration of the Amended and Restated Plan.

The Compensation Committee of the Board of Directors administers the Amended and Restated Plan and has the authority, subject to the terms of the Amended and Restated Plan, to determine and designate the employees and directors to whom awards will be made and the terms, conditions and restrictions applicable to each award (including, but not limited to, the option price, any restriction or limitation, any vesting schedule or acceleration thereof, any forfeiture restrictions and performance goals and criteria).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OSIRIS THERAPEUTICS, INC.

Dated: June 10, 2008	By:	/s/ PHILIP R. JACOBY, JR. Philip R. Jacoby, Jr. Interim Chief Financial Officer

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **June 12, 2008**

OSIRIS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-32966**	**71-0881115**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

7015 Albert Einstein Drive, Columbia, MD	**21046**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(443) 545-1800**

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 1.01. Entry Into Material Definitive Agreement

Promissory Notes

On June 12, 2008, our Board of Directors approved the issuance of up to $10.0 million of six-month promissory notes (the Notes) accruing interest at ten percent (10%) semi-annually and redeemable by the Company with ten days prior notice on any of the monthly anniversary dates of the Notes. Also on June 12, 2008, the Company entered into definitive agreements with two investors who subscribed for an aggregate of $4.5 million of the Notes, as further described in Item 2.03 below of this Form 8-K, which item is incorporated by reference into this Item 1.01.

ITEM 2.03. Creation of a Direct Financial Obligation or an Obligation Under an Off-Balance Sheet Arrangement of a Registrant

On June 12, 2008, the Company accepted a subscription agreement for a $3.0 million promissory note from Peter Friedli, the Chairman of our Board of Directors and largest shareholder, pursuant to a private placement intended to qualify under Regulation S and Section 4(2), of the Securities Act of 1933, as amended. Also on June 12, 2008, we accepted a subscription agreement for a $1.5 million promissory note from a Swiss pension fund. The Notes accrue interest at a rate of ten percent (10%) semi-annually, payable upon maturity on the six month anniversary of issuance. The Notes are not convertible, but are redeemable by the Company on any monthly anniversary date, with ten days prior notice. The Notes were funded on June 16 and June 12, 2008, respectively. Our Board of Directors, including all of the Company s independent directors, but with Mr. Friedli abstaining, together with the audit committee, unanimously approved the offering and sale of the Notes and the sale of the $3.0 million Note to Mr. Friedli.

The net proceeds to the Company from the offering and sale of the Notes are to be used to further the Company s clinical trial activities and for general corporate purposes. The Company expects to repay these short-term promissory notes with a portion of the proceeds anticipated to be received by the Company at the technology assets closing under the Asset Purchase Agreement dated May 8, 2008, between the Company and NuVasive, Inc. for the sale to NuVasive of the Company s Osteocel and Osteocel XO product line, and related business assets. The technology assets closing is anticipated to occur during the third quarter of fiscal 2008. The consummation of the technology assets closing is, however, subject to satisfaction of customary conditions for transactions of this type, including approval of the Asset Purchase Agreement by the Company s stockholders and therefore no assurances can be given as to when if ever the technology assets closing will occur.

Information presented in this Current Report on Form 8-K may contain forward-looking statements and certain assumptions upon which such forward-looking statements are in part based. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Risks and uncertainties related to the proposed sale of our assets related to Osteocel include the risk that the conditions relating to the closing of the sale transaction may not be satisfied, or may be delayed, or that the terms may be altered for any reason. Additional factors that could cause our actual results to differ materially from those anticipated in forward-looking statements, include the factors described in the section entitled Risk Factors in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission. You should not unduly rely in forward-looking statements.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, Osiris has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OSIRIS THERAPEUTICS, INC.

Dated: June 17, 2008

By: /s/ Philip R. Jacoby, Jr.
Philip R. Jacoby, Jr.
Interim Chief Financial Officer

APPENDIX F

Reports filed by NuVasive

- Annual Report on Form 10-K for the fiscal year ended December 31, 2007
- Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2008

[SEE PAGES FOLLOWING]

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2007

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 000-50744

NUVASIVE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0768598**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4545 Towne Centre Court, San Diego, California	**92121**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code:

(858) 909-1800

Securities registered pursuant to Section 12(b) of the Act

Title of Each Class:		Name of Each Exchange on which Registered:
Common Stock, par value $0.001 per share		**The NASDAQ Global Market LLC**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933, as amended. YES x NO o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended. YES o NO x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $795.1 million as of the last business day of the registrant s most recently completed second fiscal quarter (i.e. June 29, 2007), based upon the closing sale price for the registrant s common stock on that day as reported by the NASDAQ Global Market. Shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates.

There were 35,413,933 shares of the registrant s common stock issued and outstanding as of February 22, 2008.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Form 10-K incorporates information by reference to the registrant s definitive Proxy Statement for the Annual Meeting of Stockholders to be held on May 22, 2008.

NuVasive, Inc.

Form 10-K for the Fiscal Year ended December 31, 2007

PART I

This Annual Report on Form 10-K, particularly in Item 1. Business and Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations , and the documents incorporated by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding our future financial position, business strategy and plans and objectives of management for future operations. When used in this Annual Report, the words believe, may, could will, estimate, continue, anticipate, intend, expect and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to certain risks and uncertainties that could cause our actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this report, and in particular, the risks discussed under the heading Risk Factors and those discussed in other documents we file with the Securities and Exchange Commission. Except as required by law, we do not intend to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report and in the documents incorporated in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on such forward-looking statements.

Item 1. ***Business.***

Overview

We are a medical device company focused on the design, development and marketing of products for the surgical treatment of spine disorders. Our currently-marketed product portfolio is focused on applications for spine fusion surgery, a market estimated to exceed $4.2 billion in the United States in 2008. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS , as well as a growing offering of cervical and motion preservation products. Our currently-marketed products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. We focus significant research and development efforts on both MAS and motion preservation products in the areas of (i) fusion procedures in the lumbar and thoracic spine, (ii) cervical fixation products, and (iii) motion preservation initiatives such as total disc replacement and nucleus-like cervical disc replacement. We dedicate significant resources toward training spine surgeons on our unique technology and products. Currently, we are training approximately 400 to 500 surgeons annually.

Our MAS platform combines three categories of our product offerings:

- NeuroVision® a proprietary software-driven nerve avoidance system;
- MaXcess® a unique split-blade design retraction system providing enhanced surgical access to the spine; and
- Specialized implants includes our SpheRx® pedicle screw system, and CoRoent® suite of implants.

We believe our MAS platform provides a unique and comprehensive solution for safe and reproducible minimally disruptive surgical treatment of spine disorders by enabling surgeons to access the spine in a manner that affords direct visibility and avoidance of critical nerves. The fundamental difference between our MAS platform and what has been previously named MIS, or minimally invasive surgery, is the ability to customize safe and reproducible access to the spine while allowing surgeons to continue to use instruments that are familiar to them. Simply stated, the MAS platform does not force surgeons to reinvent approaches that add complexity and

undermine safety, ease and efficacy. An important ongoing objective has been to maintain a leading position in access and nerve avoidance, as well as being the leader and pioneer in lateral surgery. Our MAS platform, with the unique advantages provided by NeuroVision, enables an innovative lateral procedure known as eXtreme Lateral Interbody Fusion, or XLIF ® , in which surgeons access the spine for a fusion procedure from the side of the patient s body, rather than from the front or back. Our MaXcess instruments provide access to the spine in a manner that affords direct visibility and our NeuroVision system allows surgeons to avoid critical nerves. We believe that the procedures facilitated by our MAS platform reduce operating times, decrease trauma and blood loss, and lead to faster overall patient recovery times compared to open spine surgery.

We also offer a suite of traditional spine surgery products, including certain CoRoent® suite of implants, a titanium surgical mesh system, a line of precision-machined cervical and lumbar allograft implants, and related instrumentation. Our Triad ® and Extensure lines of bone allograft, in our patented saline packaging, is human bone that has been processed and precision shaped for transplant. We also offer fusion fixation products that offer unique technological benefits such as our Gradient Plus cervical plate and SpheRx pedicle screw system.

Our corporate headquarters are located in a 62,000 square foot, facility in San Diego, California. This facility has a six-suite state-of-the-art cadaver operating theatre designed to accommodate the training of spine surgeons. We recently signed a lease to relocate our corporate headquarters to a new facility in San Diego, which we intend to occupy during 2008. In 2006, we relocated our primary distribution and warehousing operations to a facility we purchased in Memphis, Tennessee. Our business requires overnight delivery of products and surgical instruments for almost all surgeries involving our products. Because of its location and proximity to overnight third-party transporters, our Memphis facility has greatly enhanced our ability to meet demanding delivery schedules and provide a greater level of customer service.

Recent Product Introductions

In the last several years, we have introduced numerous new products and product enhancements that have significantly expanded our MAS platform, marked our entrance into the growing motion preservation market and increased our revenue opportunities for each surgery performed using our products. We have also acquired complementary and strategic assets and technology. Our newly-launched products are exemplified by the following categories:

- *Implants* our implant products have historically focused on the lumbar spine; with our recent and planned product introductions, we will increasingly address the cervical and thoracic spine as well. These products include:
- *SpheRx II & DBR II Pedicle Screw Systems* pedicle screw systems designed for a posterior approach, which has been enhanced with a Dual Ball Rod feature to allow for instrument-free compression of the vertebrae, as well as minimally disruptive rod delivery features that minimize the incidence of associated tissue trauma. Additionally there is no rod-overhang affecting anatomic structures adjacent to the fusion construct.
- *XLP* Lateral Plate is a fixation plate designed for placement through the same incision used in an XLIF procedure and that is designed to perform a similar fixation function as pedicle screws without the need for an additional incision or to reposition the patient. This single approach fixation saves the patient the morbidity of another approach to the spine for adjunctive fixation. Additionally, the surgeon and hospital save significant time and money related to applying posterior fixation.
- *Thoracic XLIF* the thoracic spine can now be accessed in the same safe and reproducible way XLIF has demonstrated in the lumbar spine.
- *Gradient Plus* continued evolution of our cervical plating system that provides construct options (constrained, semi-constrained, or translational) that best satisfy the patient specific requirements. Whether using controlled translation that allows the plate to settle in concert with the eventual allograft implant or a fixed construct for trauma application, Gradient

Plus provides the benefit of intraoperative choice when selecting the construct that best satisfies patient need.

- *Helix ACP* is a fixation plate designed for the anterior approach in cervical surgeries. The plate features a one step canted coil locking mechanism for surgical ease and efficiency.

- *CoRoent Offering* designed in response to the demand from spine surgeons for implants with superior anatomical fit that are simple to position and align. The CoRoent family of products consists of multiple shapes and sizes, several designed to be inserted using a patented Insert and Rotate technique, which minimizes damage to the surrounding bone. Each of these CoRoent products is made of PEEK OPTIMA ® , a biocompatible polymer commonly used in implantable devices.

- *Access* a key element of our MAS platform is the safe and customizable access it affords to the spine. The core of this offering is our MaXcess retractor system. We seek to maintain a competitive advantage through the introduction of our MaXcess products.

We have launched two completely revised versions of our MaXcess retractor system over the last 3 years, with the current version being MaXcess III. MaXcess III maintains the split-blade design of the original product and incorporates our NeuroVision nerve avoidance technology within the posterior retraction blade. MaXcess III also adds a removable fourth blade, which provides greater posterior surgical options and incorporates an improved tilted blade-locking mechanism. MaXcess Micro-Access System the smallest, lightest version of our MaXcess retractor systems, is designed to provide access during posterior lumbar and cervical decompression surgeries.

- *NeuroVision* the key ingredient for the XLIF procedure, NeuroVision utilizes proprietary technology and hunting algorithms to locate and avoid critical nerves during surgery. We continually advance and enhance the system, with new features such as:

- *Full Spinal Cord Monitoring* NeuroVision now incorporates multiple monitoring modalities, allowing monitoring of the entire spinal cord.

- *Remote Monitoring* NeuroVision has also been updated to allow for Remote Monitoring, providing the ability to monitor surgeries both intraoperatively and remotely, allowing for more efficient case coverage.

- *System updates* A software update providing a new graphical user interface that allows for greater ease of use by the surgical staff. NeuroVision has also been given a new harness and dual electrodes, or redesigned connectors, to streamline the application of surface electrodes that relay muscle activity to the monitoring system.

- *Motion Preservation* We also made significant progress in 2007 on our research and development initiatives related to motion preservation. The NeoDisc ® clinical trial is a prospective, randomized, controlled, multi-center clinical trial to evaluate the safety and efficacy of NeoDisc by comparing the outcomes of patients to traditional anterior cervical discectomy and fusion. Enrollment began in the third quarter of 2006 and we look forward to analyzing the data collected. Over 70% were enrolled through the end of 2007.

Our motion preservation product development efforts include our mechanical lateral total disc replacement (TDR), and our elastomeric lateral TDR, which is based on an embroidery design. We filed for Investigational Device Exemptions, or IDEs, on the mechanical lateral TDR as well as our ceramic-on-ceramic cervical TDR CerPass in late 2007.

Our Strategy

Our objective is to become a leading provider of creative medical products that provide comprehensive solutions for the surgical treatment of spine disorders. We are pursuing the following business strategies in order to achieve this objective:

- *Establish our MAS Platform as a Standard of Care.* We believe our MAS platform has the potential to become the standard of care for minimally invasive spine surgery as spine surgeons continue to adopt our products and recognize their benefits. We

also believe that our MAS platform has the potential to dramatically improve the clinical results of minimally invasive spine surgery. We dedicate significant

resources to educating spine surgeons on the clinical benefits of our products, and we intend to capitalize on patient demand for minimally disruptive surgical alternatives.

- *Continue to Introduce New Creative Products.* One of our core competencies is our ability to develop and commercialize creative spine surgery products. In the recent past, we have introduced more than 30 new products and product enhancements. We have several additional products currently under development that should expand our presence in fusion surgery as well as provide an entry into the motion preservation market segment. We intend to accomplish this with an unwavering commitment to our MAS platform and building on our core technology. We believe that these additional products will allow us to generate, on average, greater revenues per spine surgery procedure while improving patient care.

- *Establish Exclusive Sales Force with Broad Reach.* We believe that having a sales force dedicated to selling only our spine surgery products is critical to achieve continued growth across product lines, greater market penetration and increased sales. In 2006, we completed our transition to an exclusive sales force, and we have seen the benefits of that effort. Our sales force is achieving deeper penetration in our accounts and further establishing NuVasive as a technology leader in the spine industry. Our exclusive sales force is comprised of Sales Directors, each of whom is responsible for a geographic region of the country. Each Sales Director is responsible for Area Business Managers, or ABMs, who are NuVasive shareowners (our employees) responsible for a defined territory. The remainder of the sales force are both direct (our shareowners) and exclusive independent sales representatives or an exclusive distributor agent, each acting as our sole representative and selling only NuVasive spine products in a given territory.

- *Provide Tailored Solutions in Response to Surgeon Needs.* Responding quickly to the needs of spine surgeons, which we refer to as Absolute Responsiveness ® , is central to our corporate culture, critical to our success and, we believe, differentiates us from our competition. We solicit information and feedback from our surgeon customers and clinical advisors regarding the utility of and potential improvements to our products. For example, we have an on-site machine shop to allow us to rapidly manufacture product prototypes and a state-of-the-art cadaver operating theatre to provide clinical training and validate new ideas through prototype testing.

- *Selectively License or Acquire Complementary Spine Products and Technologies.* In addition to building our company though internal product development efforts, we intend to selectively license or acquire complementary products and technologies. By acquiring complementary products, we believe we can leverage our expertise at bringing new products to market and provide additional selling opportunities for our sales force. We have acquired complementary and strategic assets, including (i) cervical plate technology, which we re-launched as our SmartPlate Gradient CLP product; (ii) surgical embroidery technology, including the NeoDisc investigational nucleus-like cervical disc replacement; and (iii) our FormaGraft ® bone graft product for use in fusion surgeries. We will continue to be opportunistic in this regard as we seek to expand our market share.

Industry Background and Market

The spine is the core of the human skeleton, and provides a crucial balance between structural support and flexibility. It consists of 29 separate bones called vertebrae that are connected together by connective tissue to permit a normal range of motion. The spinal cord, the body s central nerve conduit, is enclosed within the spinal column. Vertebrae are paired into what are called motion segments that move by means of three joints: two facet joints and one spine disc. The four major categories of spine disorders are degenerative conditions, deformities, trauma and tumors. The largest market and the focus of our business is degenerative conditions of the facet joints and disc space. These conditions can result in instability and pressure on the nerve roots as they exit the spinal column, causing back pain or radiating pain in the arms or legs.

The prescribed treatment for spine disorders depends on the severity and duration of the disorder. Initially, physicians will prescribe non-operative procedures including bed rest, medication, lifestyle modification, exercise, physical therapy, chiropractic care and steroid injections. In most cases, non-operative treatment options are effective; however, many patients require spine surgery. It is estimated that in excess of one million patients undergo spine surgery each year in the United States. The most common spine surgery procedures are: discectomy, the

removal of all or part of a damaged disc; laminectomy, the removal of all or part of a lamina, or thin layer of bone, to relieve pinching of the nerve and narrowing of the spinal canal; and fusion, where two or more adjoining vertebrae are fused together to provide stability. All three of these procedures require access to the spine. Traditional open surgical approaches require large incisions to be made in the back so that surgeons can see the spine and surrounding area. Most open procedures are invasive, lengthy and complex, and may result in significant blood loss, extensive dissection of tissue and lengthy hospitalization and rehabilitation.

Back pain is one of the number one causes of healthcare expenditures in the United States, with a direct cost of more than $50 billion annually for diagnosis, treatment and rehabilitation. The U.S. market for lumbar and cervical spine fusion, the focus of our business, was estimated to be over $3 billion in 2006, over $3.6 billion in 2007, and is estimated to grow over $4.2 billion in 2008.

We believe that the implant market for spine surgery procedures will continue to grow because of the following market dynamics:

- *Increased Use of Implants.* The use of implants has evolved into the standard of care in spine surgery. Over the past five years, there has been a significant increase in the percentage of spine fusion surgeries using implants and it is estimated that over 85% of all spine fusion surgeries now involve implants.
- *Demand for Minimally Invasive Alternatives.* As with other surgical markets, we anticipate that the broader acceptance of minimally invasive spine surgery will result in increased demand for these types of surgical procedures.
- *Increasing demand for motion-preserving treatments with potentially earlier intervention in the degenerative disease process for many patients.*
- *Favorable Demographics.* The population segment most likely to experience back pain is expected to increase as a result of aging baby boomers, people born between 1946 and 1965. We believe this population segment will demand a quicker return to activities of daily living following surgery.

Minimally Invasive Surgical Procedures

The benefits of minimally invasive surgery procedures in other areas of orthopedics have significantly contributed to the strong and growing demand for minimally invasive surgery of the spine. Surgeons and hospitals seek spine procedures that result in fewer operative complications, shorter surgery times and decreased hospitalization. At the same time, patients seek procedures that cause less trauma and allow for faster recovery times. Despite these benefits, the rate of adoption of minimally invasive surgical procedures has been relatively slow with respect to the spine.

We believe the two principal factors contributing to spine surgeons slow adoption of minimally invasive alternatives are: (i) the limited or lack of direct access to and visibility of the surgical anatomy, as well as (ii) the associated complex instruments that have been required to perform these procedures. Most minimally invasive systems do not allow the surgeon to directly view the spine and provide only restrictive visualization through a camera system or endoscope, while also requiring the use of complex surgical techniques. In addition, most minimally invasive systems use complex or highly customized surgical instruments that require special training and the completion of a large number of trial cases before the surgeon becomes proficient using the system.

The NuVasive Solution Maximum Access Surgery (MAS)

Our MAS platform allows surgeons to perform a wide range of minimally disruptive procedures, while overcoming the shortcomings of alternative minimally invasive surgical techniques. We believe our products improve clinical results and have both the potential to expand the number of minimally disruptive procedures performed and become a standard of care in spine fusion and non-fusion surgery.

Our MAS platform combines 3 product categories: NeuroVision, MaXcess, and specialized implants. NeuroVision enables surgeons to navigate around nerves while MaXcess affords direct customized access to the spine for implant delivery. MaXcess also allows surgeons to use well-established traditional instruments in a

minimally disruptive and less traumatic manner. We also offer a variety of specialized implants that enable sufficient structural support while conforming to the anatomical requirements of the patient.

Our products facilitate minimally disruptive applications of the following spine surgery procedures, among others:

- Lumbar fusion procedures in which the surgeon approaches the spine through the patient s back or abdomen;
- Decompression, which is removal of a portion of bone over the nerve root or disc from under the nerve root to relieve pinching of the nerve; and
- Procedures designed to correct and/or stabilize the spine while simultaneously maintaining motion.

Importantly, our products also enable innovative procedures such as the XLIF. The XLIF procedure, which we developed with leading spine surgeons, allows surgeons to access the spine from the side of the patient s body rather than from the front or back, which results in less operating time and reduced patient trauma and blood loss.

We believe procedures enabled by our MAS platform have significant benefits. A multi-center evaluation study of 145 XLIF procedures performed in 2003 and 2004 and subsequent reports and publications presented at multiple meetings through 2007 support our belief that our MAS platform provides the following benefits:

- *Reduced Surgery Times.* XLIF procedures utilizing our MAS platform, which we refer to as MAS XLIF, have averaged about 1 hour to perform which we believe is substantially shorter than it takes to perform an equivalent open procedure.
- *Reduced Hospital Stays.* Hospital stays following a MAS XLIF procedure have averaged one to two days which we believe is substantially shorter than the hospital stays associated with an equivalent open procedure.
- *Reduced Pain and Recovery Times.* Due to smaller incisions and less trauma and blood loss for the patient, we believe that the pain and recovery time for patients following a MAS XLIF procedure is significantly less than with an equivalent open procedure. In most cases, patients are walking the same day as surgery following a MAS XLIF.

MAS NeuroVision

NeuroVision utilizes electromyography, or EMG, and proprietary software algorithms and graphical user interfaces to provide surgeons with an enhanced nerve avoidance system. Our system functions by monitoring changes in electrical signals across muscle groups, which allows us to detect underlying changes in nerve activity. We connect the instruments that surgeons use to a computer system that provides real time feedback during surgery. Our system analyzes and then translates complex neurophysiologic data into simple, useful information to assist the surgeon s clinical decision-making process. In addition, during a pedicle screw test, in which the integrity of the bone where the implant is placed is tested, if the insertion of a screw results in a breach of the bone, a red light and corresponding numeric value will result so that the surgeon may reposition the implant to avoid potential nerve impingement or irritation. If no breach of the bone occurs, a green light and corresponding numeric value will result. The initial application of NeuroVision, Screw Test with our INS-1 ® system, was cleared by the FDA in November 2000 and commercially launched in 2001.

Surgeons can dynamically link familiar surgical instruments to NeuroVision, thus creating an interactive set of instruments that enable the safe navigation of neural anatomy. The connection is accomplished using a clip that is attached to the instrument, effectively providing the benefits of NeuroVision through an instrument already familiar to the surgeon. The system s proprietary software and easy to use graphical user interface enables the surgeon to make critical decisions in real time resulting in safer and faster procedures with the potential for improved patient outcomes. We have recently introduced significant enhancements to NeuroVision in the form of MEP technology, remote reading capability, a software update and improved nerve monitoring capabilities. The data developed using NeuroVision can now be ported to health care professionals for additional interpretation of interoperative information.

MAS MaXcess

Our MaXcess system consists of instrumentation and specialized implants that provide maximum access to the spine with minimal soft tissue disruption. MaXcess has a split blade design consisting of three blades that can be positioned to build the surgical exposure in the shape and size specific to the surgical requirements rather than the fixed tube design of other minimally invasive surgical systems. MaXcess split blade design also provides expanded access to the spine, which allows surgeons to perform surgical procedures using instruments that are similar to those used in open procedures but with a significantly smaller incision. The ability to use familiar instruments reduces the learning curve and facilitates the adoption of our products. Our system s illumination of the operative corridor aids in providing surgeons with direct visualization of the patient s anatomy, without the need for additional technology or other special equipment. During the fourth quarter of 2004, we introduced an extension of our MaXcess product with our MaXcess-Micro Access System. This product brings all of the benefits of minimally disruptive surgery to both the cervical spine for posterior application and the lumbar spine for decompression.

In 2005, we introduced MaXcess II, a second generation of our MaXcess retractor that incorporates NeuroVision within the posterior retraction blade, providing built-in nerve monitoring capabilities. MaXcess II features superior and inferior blades that kick-out at an angle to spread the tissue closest to the pathology point further than original MaXcess.

In 2006, we launched MaXcess III, our most advanced retractor system. MaXcess III is a further enhancement of the MaXcess and MaXcess II systems, with the addition of several features that improve access to the spine. MaXcess III maintains the split-blade design and continues to incorporate NeuroVision nerve avoidance technology within the posterior retraction blade. MaXcess III adds a removable fourth blade, which provides greater posterior surgical options and incorporates an improved tilted blade-locking mechanism.

In 2007, our MaXcess products have been used in the thoracic region of the spine as the lateral approach has broadened from the lumbar to the thoracic region as well as into adult degenerative scoliosis procedures.

MAS Specialized Implants

We have a number of implants designed to be used with our MAS platform. These implants are used for interbody disc height restoration for fusion, partial vertebral body replacement and stabilization of the spine. These implants include our SpheRx, SpheRx II and SpheRx II DBR pedicle screw systems, our CoRoent family of unique implants for partial vertebral body replacement and interbody implants, precision-machined allograft, as well as numerous new implants currently under development.

Our implants are available in a variety of shapes and sizes to accommodate the anatomical requirements of the patient and the particular fusion procedure. Our implants are designed for insertion into the smallest possible space while maximizing surface area contact for fusion.

Our fixation systems have been uniquely designed to be delivered through our MaXcess system to provide stabilization of the spine. These systems enable minimally disruptive placement of implants and are intended to reduce operating time and patient morbidity, often through a single approach.

We have developed a suite of traditional spine surgery products, including a line of precision-machined cervical and lumbar allograft implants, a titanium surgical mesh system, and related instrumentation. Allograft implant tissue is recovered from deceased human donors, which is processed into specified sizes and shapes and sterilized for implantation. Unlike other suppliers of allograft implants, our patented packaging process allows us to provide a ready-to-use structural graft eliminating the need for refrigeration and re-hydration. We package all of our allograft implants in a sterile saline solution. In addition, our allograft packaging and instrumentation are color-coded to assist the surgeon in selecting the proper size implant for use with the appropriate size instrument.

Our traditional product offerings also include fusion plates such as our SmartPlate Gradient CLP, a dynamic cervical plate that encompasses a gradient locking mechanism which gradually loads the screws based upon the anatomic requirements. This allows the plate to settle in concert with the allograft implant settling that occurs within the disc space over time, offering a better anatomical fit.

Development Projects

We are developing proprietary total disc replacement devices for lateral lumbar spine applications and separately for cervical spine applications. These devices are intended to allow surgeons to address a patient s pain and dysfunction while maintaining normal range of motion and avoiding future adjacent level degeneration that can occur after spine fusion. Commercialization of these devices, including NeoDisc, will require premarket approval rather than 510(k) clearance. NeoDisc is currently undergoing a clinical trial. NeoDisc is a nucleus-like cervical disc replacement device designed to preserve motion in the cervical region of the spine and provide an alternative pre-surgical treatment and mechanical total disc replacement (TDR) or spinal fusion. The NeoDisc design has an elastomeric core with a novel embroidered jacket to envelop the core in a similar manner as the annulus with anterior fixation flanges which simulate the anterior longitudinal ligament. We believe that NeoDisc could be attractive for use in broad indications and pathologies because of the relatively simple surgical placement procedure and the easily revisable nature of the implant.

In addition to the motion preservation platform, we have many product development projects that are intended to broaden surgical applications and increase fixation options for greater vertical integration of our MAS techniques. Additionally, we are expanding our cervical fixation product portfolio to provide for a comprehensive cervical offering that will include segmentation of both fixation and motion markets.

In January 2007, we also completed the acquisition of certain rights to a biologic product we call FormaGraft. This synthetic bone void filler is designed to aid in bone growth with fusion procedures.

Research and Development

Our research and development efforts are primarily focused on developing further enhancements to our existing products, launching new product categories, as well as developing our total disc products. Our research staff consists of 18 shareowners, including four who hold Ph.D. degrees and three who hold other advanced degrees. Our research and development group has extensive experience in developing products to treat spine pathology and this group continues to work closely with our clinical advisors and spine surgeon customers to design products that are intended to improve patient outcomes, simplify techniques, shorten procedures, reduce hospitalization and rehabilitation times and, as a result, reduce costs.

Sales and Marketing

We currently sell our products through a combination of exclusive independent sales agencies and direct sales representatives employed by us. Importantly, both our direct sales representatives as well as our independent sales agencies are exclusive and sell only NuVasive spine surgery products. Our sales force is comprised either of sales professionals, who are NuVasive shareowners responsible for a defined territory or independent sales representatives, each acting as our sole representative in a given territory. The determination of whether to engage a directly-employed shareowner or exclusive distributor is made on a territory by territory basis, with a focus on the candidate who brings the best skills, experience and contacts. Currently, the split between directly-employed and independent sales agents in our sales force is roughly equal. Our sales force is managed by a Senior Vice President of U.S. Sales and 11 Sales Directors. Each Sales Director is responsible for a portion of the United States and manages the directly-employed and independent sales agents engaged in that territory.

The transition to an exclusive sales force has been a very positive contributor to our growth in sales. There are many reasons that we believe strongly in an exclusive sales force, none more important than having a sales force that is properly trained and incentivized to sell and represent only our portfolio of products.

Surgeon Training and Education

NuVasive devotes significant resources to training and educating surgeons regarding the safety and reproducibility of our surgical techniques and our complimentary instruments and implants. We maintain a state-of-the-art cadaver operating theatre and training facility at our corporate headquarters to help promote adoption of our products. Currently, we are training approximately 400 to 500 surgeons annually in the XLIF ® technique and our other Maximum Access Surgery, or MAS platform products including: NeuroVision, MaXcess and SpheRx DBR.

NuVasive has also helped to establish SOLAS™, the Society of Lateral Access Surgery, a group of spine surgeons dedicated to the development and expanded application of lateral spine surgery techniques that offer significant patient benefits and improved clinical outcome through peer-to-peer communication, clinical education efforts, and research.

Manufacturing and Supply

We rely on third parties for the manufacture of our products and their components and servicing, and we do not currently maintain alternative manufacturing sources for some components of NeuroVision, MaXcess, and SpheRx, as well as some of our other finished goods products. We are in the process of identifying and qualifying alternative suppliers for our highest volume products to maintain consistent supply to our customers. Our outsourcing strategy is targeted at companies that meet FDA, International Organization for Standardization, or ISO, and quality standards supported by internal policies and procedures. Supplier performance is maintained and managed through a corrective action program intended to ensure that all product requirements are met or exceeded. We believe these manufacturing relationships minimize our capital investment, help control costs, and allow us to compete with larger volume manufacturers of spine surgery products.

Following the receipt of products or product components from our third-party manufacturers, we conduct inspection and packaging and labeling, as needed, at either our headquarters facility or our distribution facility. Under our existing contracts, we reserve the exclusive right to inspect and assure conformance of each product and product component to our specifications. In the future, we may consider manufacturing certain products or product components internally, if and when demand or quality requirements make it appropriate to do so.

We currently rely on Tissue Banks International, Inc. and AlloSource, Inc. as our only suppliers of allograft implants. Our agreements with each of these suppliers automatically renew for successive one-year terms unless otherwise terminated by either party in accordance with the terms of the respective agreement.

In August 2005, we acquired NeoDisc, an investigational nucleus-like cervical disc replacement device, from Pearsalls Limited. NeoDisc is currently the subject of a clinical trial, and our supply of the product comes solely from Pearsalls Limited. We are in the process of determining whether to establish alternate suppliers.

Also, in January 2007, we acquired certain rights to FormaGraft®, a ceramic/collagen bone graft matrix used to promote spinal fusion, from Radius Medical, LLC. Our supply of the product comes solely from Maxigen Biotech. We are in the process of determining whether to establish alternate suppliers.

We and our third-party manufacturers are subject to the FDA s quality system regulations, state regulations, such as the regulations promulgated by the California Department of Health Services, and regulations promulgated by the European Union. For tissue products, we are FDA registered and licensed in the States of California, New York and Florida. For our implants and instruments, we are FDA registered, California licensed, CE marked and ISO certified. CE is an abbreviation for European Compliance. Our facility and the facilities of our third-party manufacturers are subject to periodic unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state agencies. The FDA may impose enforcement, inspections or audits at any time.

Loaner Equipment

We seek to deliver surgical instrument sets just in time to fulfill our customer obligations to meet surgery schedules. In most cases once the surgery is finished, the instrument sets are returned to us and we prepare them for shipment to meet future surgeries. This strategy minimizes backlogs, while increasing asset turns and maximizing cash flow. Our pool of surgical equipment that we loan to or place with hospitals continues to increase as we expand our distribution channels and increase market penetration of our products. These loaners are important to the growth of our business and we anticipate additional investments in our loaner assets.

Intellectual Property

We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure agreements and other measures to protect our intellectual property rights. We believe that in order to

have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. We require our shareowners, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us. We also require our shareowners, consultants and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived during the work day, using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

Patents

As of December 31, 2007 we had 50 issued U.S. patents, 31 foreign national patents, and 229 pending patent applications, including 168 U.S. applications, 7 international (PCT) applications and 54 foreign national applications. Our issued and pending patents cover, among other things:

- Embroidery technology including the NeoDisc and additional advanced applications of the embroidery platform technology;
- Motion preservation products;
- MAS surgical access and spine systems;
- Neurophysiology enabled instrumentation and methodology, including pedicle screw test systems, navigated guidance, and surgical access systems; and
- Implants and related instrumentation and targeting systems.

Our issued patents begin to expire in 2018. We have multiple patents covering unique aspects and improvements for many of our products. We do not believe that the expiration of any single patent is likely to significantly affect our intellectual property position.

We have undertaken to protect our neurophysiology platform, including NeuroVision®, through a comprehensive strategy covering various important aspects of our neurophysiology-enabled instrumentation, including, screw test, navigated guidance, surgical access and related methodology. Our NeuroVision patent portfolio includes 10 issued U.S. patents, 43 U.S. patent applications (including 37 U.S. utility patent applications, 5 U.S. provisional applications, and 1 U.S. design application), 8 issued foreign national patents, 3 international (PCT) patent applications, and 26 foreign national applications on this system and related instrumentation.

We have also undertaken to protect our XLIF® franchise, including methodology, implants, and systems used during XLIF procedures. In 2007, we obtained a U.S. Patent covering the use of neurophysiology (such as our NeuroVision system) and a split-blade retractor (such as our MaXcess retractor) to perform lateral access surgery. In addition to this issued patent, as well as 1 issued foreign patent, our XLIF patent portfolio includes 26 U.S. utility patent applications, 8 U.S. provisional patent applications, 2 international (PCT) patent applications, and 15 foreign national patent applications covering various additional aspects of XLIF methodology, implants, and systems.

We obtained a U.S. Patent with broad claims protecting our SpheRx® pedicle screw system, including SpheRx DBR. In addition to this issued patent, we have several patent applications pending on the SpheRx pedicle screw system and related instrumentation, including 9 U.S. utility applications, 1 U.S. provisional applications, 1 issued foreign national patent, and 3 foreign national applications.

We acquired a substantial intellectual property portfolio as part of our purchase of the NeoDisc® investigational device from Pearsalls Limited. This portfolio has been expanded since acquisition and now includes 2 issued U.S. patents, 27 U.S. applications (including 15 U.S. utility applications and 12 U.S. provisional applications), 21 issued foreign national patents, 2 international (PCT) applications, and 13 foreign national applications, directed at both NeoDisc as well as additional applications of the embroidery technology.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages. Even if we were to prevail, any litigation could be costly and

time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to protect our intellectual property rights.

As the number of entrants into our market increases, the possibility of a patent infringement claim against us grows. While we take extensive efforts to ensure that our products do not infringe other parties patents and proprietary rights, our products and methods may be covered by patents held by our competitors. In addition, our competitors may assert that future products we may market infringe their patents.

A patent infringement suit brought against us or any strategic partners or licensees may force us or any strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party s intellectual property, unless that party grants us or any strategic partners or licensees rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if any strategic partners, licensees or we were able to obtain rights to the third party s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

Trademarks

As of December 31, 2007, we have 64 trademark registrations, both domestic and foreign, including the following U.S. trademarks: NuVasive, NeuroVision, MaXcess, XLIF, SpheRx, DBR, CoRoent, SmartPlate, Creative Spine Technology, Triad, InStim, NeoDisc, ExtenSure, FormaGraft, and Absolute Responsiveness. We have 19 trademark applications pending, both domestic and foreign, including the following trademarks: MAS, ExtenSure, CerPass, Nerve Avoidance Leader, XLP, Halo, VuePoint, Embrace, Embody, and Envoy.

Competition

We are aware of a number of major medical device companies that have developed or plan to develop products for minimally invasive spine surgery in each of our current and future product categories.

Our currently marketed products are, and any future products we commercialize will be, subject to intense competition. Many of our current and potential competitors have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. In addition, many of these competitors have significantly greater operating history and reputations than we do in their respective fields. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate reimbursement and are safer, less invasive and less expensive than alternatives available for the same purpose. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing competing products. Below are our primary competitors grouped by our product categories.

Our NeuroVision system competes with the conventional nerve monitoring systems offered by Medtronic Sofamor Danek, Nicolet Biomedical and Axon Systems. We believe our system competes favorably with Nicolet s and Axon s systems on both price and ease of use for the spine surgeon, with the added advantage that our NeuroVision System was designed to support surgeon directed applications. Medtronic s neuromonitoring system, while surgeon directed, requires manual interpretation for neuromonitoring. Several companies offer products that compete with our MaXcess system, SpheRx pedicle screw system and implants, including competitive offerings by DePuy Spine, Inc., a Johnson & Johnson company, Medtronic Sofamor Danek and Stryker Spine.

Competition is intense in the fusion product market. We believe that our most significant competitors are Medtronic Sofamor Danek, DePuy Spine, Stryker Spine and Synthes, Inc., each of which has substantially greater

sales and financial resources than we do. Medtronic Sofamor Danek, in particular, has a broad classic fusion product line. We believe our differentiation in the market is an innovative portfolio of products elegantly delivered through our MaXcess system as well as through our XLIF approach, complemented by additional innovative and pull-though products along the entirety of the spine. Our allograft is packaged in a saline solution, which allows the product to be used immediately and does not require specialized handling, representing a unique product in the allograft market.

Competition in the motion preservation segment is increasing, with Medtronic, DePuy, Stryker and Synthes all investing in this rapidly growing market. In the cervical total disc replacement (TDR) segment, our NeoDisc currently in clinical trials, if approved, will face competition from several products that received FDA approval in 2007 including Medtronic s Prestige and Bryan TDRs as well as Synthes ProDisc TDR. Competition in the dynamic stabilization space is also increasing, accompanied by acquisition activity including Kyphon s acquisition of St. Francis in 2007, followed by Medtronic s acquisition of Kyphon.

We also face competition from a growing number of smaller companies with more limited product offerings and geographic reach than our larger competitors. These companies, who represent intense competition in specified markets, include Abbott Spine, Inc. (an Abbott Laboratories company), Orthofix International N.V. (Blackstone Medical, Inc.), Alphatec Spine Inc., Globus Medical, Inc., and others.

Government Regulation

Our products are medical devices and tissues subject to extensive regulation by the FDA and other regulatory bodies. FDA regulations govern, among other things, the following activities that we or our partners perform and will continue to perform:

- product design and development;
- product testing;
- product manufacturing;
- product labeling;
- product storage;
- premarket clearance or approval;
- advertising and promotion; and
- product sales and distribution.

FDA s Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement.

Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device are placed in class III, requiring premarket approval.

510(k) Clearance Pathway

To obtain 510(k) clearance, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of premarket approval applications. The FDA s 510(k) clearance pathway usually takes from three to twelve months from the date the application is completed, but it can take significantly longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer s determination. If the FDA disagrees with a manufacturer s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties. We have made and plan to continue to make additional product enhancements that we believe do not require new 510(k) clearances.

Premarket Approval Pathway

A premarket approval (PMA) application must be submitted if the device cannot be cleared through the 510(k) process. A premarket approval application must be supported by extensive data including, but not limited to, technical information, preclinical data, clinical trial data, manufacturing data and labeling to demonstrate to the FDA s satisfaction the safety and efficacy of the device for its intended use.

Once a complete PMA application is submitted, the FDA begins an in-depth review which generally takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New PMAs or PMA supplements are required for significant modifications to the manufacturing process, labeling or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Human Cell, Tissue, and Cellular and Tissue Based Products

Our allograft implant products are regulated by FDA as Human Cell, Tissue, and Cellular and Tissue Based Products. FDA regulations do not currently require products regulated as minimally manipulated human tissue-based products to be 510(k) cleared or PMA approved before they are marketed. We are, however, required to register our establishment, list these products with the FDA and comply with Current Good Tissue Practices for Human Cell, Tissue, and Cellular and Tissue Based Product Establishments. The FDA periodically inspects tissue processors to determine compliance with these requirements. Violations of applicable regulations noted by the FDA during facility inspections could adversely affect the continued marketing of our products. We believe we comply with all aspects of the Current Good Tissue Practices, although there can be no assurance that we will comply, or will comply on a timely basis, in the future. Entities that provide us with allograft bone tissue are responsible for performing donor recovery, donor screening and donor testing and our compliance with those aspects of the Current Good Tissue Practices regulations that regulate those functions are dependent upon the actions of these independent entities.

The procurement and transplantation of allograft bone tissue is subject to U.S. federal law pursuant to the National Organ Transplant Act, or NOTA, a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for valuable consideration. NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. With the exception of removal and implantation, we provide services in all of these areas. We make payments to vendors in consideration for the services they provide in connection with the recovery and screening of donors. Failure to comply with the requirements of NOTA could result in enforcement action against us.

The procurement of human tissue is also subject to state anatomical gift acts and some states have statutes similar to NOTA. In addition, some states require that tissue processors be licensed by that state. Failure to comply with state laws could also result in enforcement action against us.

Clinical Trials

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. These trials generally require approval of a submitted application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the responsible institutional review boards. Future clinical trials of our motion preservation designs and interbody implants will likely require that we obtain IDEs from the FDA prior to commencing clinical trials. We have gained IDE approval from the FDA to begin a clinical trial relating to NeoDisc ® , our embroidery cervical disc replacement device, and are currently enrolling patients in this trial. We have also filed an IDE for our CerPass device, our other cervical total disc replacement device. Our clinical trials must be conducted in accordance with FDA regulations and other federal regulations concerning human subject protection and privacy and must be publicly registered. The results of our clinical trials may not be sufficient to obtain approval of our product. There are numerous risks associated with conducting such a clinical trial, including the high costs and uncertain outcomes. For a complete discussion of these risks, please see the Risk Factors section of this Annual Report.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include, but are not limited to:

- quality system regulation, which requires manufacturers to follow design, testing, process control, and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling; and
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- fines, injunctions, and civil penalties;
- recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or premarket approval of new products;
- withdrawing 510(k) clearance or premarket approvals that are already granted; and
- criminal prosecution.

We are subject to unannounced device inspections by the FDA and the California Food and Drug Branch, as well as other regulatory agencies overseeing the implementation and adherence of applicable state and federal tissue licensing regulations. These inspections may include our subcontractors facilities.

International

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ.

The European Union, which consists of 25 of the major countries in Europe, has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a Notified Body. This third-party assessment consists of an audit of the manufacturer s quality system and technical review of the manufacturer s product. We have now successfully passed several Notified Body audits since our original certification in 2001, granting us ISO registration and allowing the CE conformity marking to be applied to certain of our devices under the European Union Medical Device Directive. We have expanded our certification scope and are now working with two different Notified Bodies overseeing our currently released, as well as forthcoming, product development projects.

Third-Party Reimbursement

We expect that sales volumes and prices of our products will continue to be largely dependent on the availability of reimbursement from third-party payers, such as governmental programs, for example, Medicare and Medicaid, private insurance plans and managed care programs. These third-party payers may deny reimbursement if they feel that a device is not the most cost-effective treatment available, or was used for an unapproved indication. Also, third-party payers are increasingly challenging the prices charged for medical products and services. In international markets, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific product lines. There can be no assurance that our products will be considered cost-effective by third-party payers, that reimbursement will be available or, if available, that the third-party payers reimbursement policies will not adversely affect our ability to sell our products profitably.

Particularly in the United States, third-party payers carefully review, and increasingly challenge, the prices charged for procedures and medical products. In addition, an increasing percentage of insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Many managed care programs are paying their providers on a capitated basis, which puts the providers at financial risk for the services provided to their patients by paying them a predetermined payment per member per month. The percentage of individuals covered by managed care programs is expected to grow in the United States over the next decade.

We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. There can be no assurance that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation, or reimbursement policies of third-party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third-party payer coverage or reimbursement could have a material adverse effect on our business, operating results and financial condition.

Healthcare Fraud and Abuse

Healthcare fraud and abuse laws apply to our business if a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or most other federally-funded health care programs. The federal Anti-Kickback Law prohibits unlawful inducements for the referral of business reimbursable under federally-funded health care programs, such as remuneration provided to physicians to induce them to use certain tissue products or medical devices reimbursable by Medicare or Medicaid. The Anti-Kickback Law is subject to evolving interpretations. Some states also have anti-kickback laws which establish similar prohibitions. If a governmental authority

were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigations of health care providers, suppliers and manufacturers throughout the country for a wide variety of Medicare billing practices, and has obtained multi-million dollar settlements. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating health care providers , suppliers , and manufacturers compliance with the health care billing, coverage and reimbursement rules and fraud and abuse laws.

Shareowners (our employees)

We refer to our employees as shareowners. As of December 31, 2007, we had 345 shareowners, of which 35 were employed in research and development, 34 in clinical and regulatory, 128 in general and administrative and operations and 148 in sales and marketing. None of our shareowners are represented by a labor union and we believe our shareowner relations are good.

Corporate Information

Our business was incorporated in Delaware in July 1997. Our principal executive offices are located at 4545 Towne Centre Court, San Diego, California 92121, and our telephone number is (858) 909-1800. Our website is located at *www.nuvasive.com.*

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to those reports, electronically with the Securities and Exchange Commission (the Commission). We make these reports available free of charge on our website under the investor relations page as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Commission. All such reports were made available in this fashion during 2007.

This report may refer to brand names, trademarks, service marks or trade names of other companies and organizations, and these brand names, trademarks, service marks and trade names are the property of their respective holders.

Item 1A. ***Risk Factors***

Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below and elsewhere in this report. If any of the following risks actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the

trading price of our common stock could decline, and you may lose all or part of your investment. Further, additional risks not currently known to us or that we currently believe are immaterial also may impair our business, operations, liquidity and stock price materially and adversely.

Risks Related to Our Business and Industry

Pricing pressure from our competitors and sources of medical reimbursement may impact our ability to sell our products at prices necessary to expand our operations and reach profitability.

The market for spine surgery products is large and growing at a significant rate. This has attracted numerous new companies and technologies, and encouraged more established companies to intensify competitive pressure. New entrants to our markets include numerous niche companies with singular product focus, as well as companies owned partially by spine surgeons, who have significant market knowledge and access to the surgeons who use our

products. As a result of this increased competition, we believe there will be growing pricing pressure in the near future. If competitive forces drive down the price we are able to charge for our products, our profit margins will shrink, which will hamper our ability to invest in and grow our business and achieve profitability.

Further, sales of our products will depend on the availability of adequate reimbursement from third-party payors. Healthcare providers, such as hospitals that purchase medical devices for treatment of their patients, generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these devices. Spine surgeons are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of their involvement in the surgical procedures. We also believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for our existing products or our products currently under development and limit our ability to sell our products on a profitable basis.

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance.

We are in a highly competitive market segment and face competition from large, well-established medical device manufacturers as well as new market entrants.

The market for spine surgery products and procedures is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. With respect to NeuroVision, our nerve avoidance system, we compete with Medtronic Sofamor Danek, Inc., a wholly owned subsidiary of Medtronic, Inc., and Nicolet Biomedical, a VIASYS Healthcare company, both of which have significantly greater resources than we do, as well as numerous regional nerve monitoring companies. With respect to MaXcess, our minimally disruptive surgical system, our largest competitors are Medtronic Sofamor Danek, Inc., DePuy Spine, Inc., a Johnson & Johnson company, and Synthes-Stratec, Inc. We compete with many of the same companies with respect to our other products. We also compete with numerous smaller companies with respect to our implant products, many of whom have a significant regional market presence. At any time, these companies may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products.

Many of our larger competitors are either publicly traded or divisions or subsidiaries of publicly traded companies, and enjoy several competitive advantages over us, including:

- significantly greater name recognition;
- established relations with a greater number of spine surgeons, hospitals, other healthcare providers and third-party payors;
- larger and more well established distribution networks with significant international presence;
- products supported by long-term clinical data;
- greater experience in obtaining and maintaining United States Food and Drug Administration, or FDA, and other regulatory approvals or clearances for products and product enhancements;

- more expansive portfolios of intellectual property rights; and
- greater financial and other resources for product research and development, sales and marketing and litigation.

In addition, the spine industry is becoming increasingly crowded with new market entrants, including companies owned at least partially by spine surgeons. Many of these new competitors focus on a specific product or market segment, making it more difficult for us to expand our overall market position. If these companies become successful, we expect that competition will become even more intense, leading to greater pricing pressure and making it more difficult for us to expand.

To be commercially successful, we must convince spine surgeons that our products are an attractive alternative to existing surgical treatments of spine disorders.

We believe spine surgeons may not widely adopt our products unless they determine, based on experience, clinical data and published peer reviewed journal articles, that our products provide benefits or an attractive alternative to conventional modalities of treating spine disorders. Surgeons may be slow to change their medical treatment practices for the following reasons, among others:

- lack of experience with our products;
- lack of evidence supporting additional patient benefits;
- perceived liability risks generally associated with the use of new products and procedures;
- limited availability of reimbursement within healthcare payment systems;
- costs associated with the purchase of new products and equipment; and
- the time that must be dedicated for training.

In addition, we believe recommendations and support of our products by influential surgeons are essential for market acceptance and adoption. If we do not receive support from such surgeons or have favorable long-term data, surgeons and hospitals may not use our products. In such circumstances, we may not achieve expected revenues and may never become profitable.

Our future success depends on our ability to timely develop and introduce new products or product enhancements that will be accepted by the market.

It is important to our business that we continue to build a more complete product offering to surgeons and hospitals, and enhance the products we currently offer. As such, our success will depend in part on our ability to develop and introduce new products and enhancements to our existing products to keep pace with the rapidly changing spine market. We cannot assure you that we will be able to successfully develop, obtain regulatory approval for or market new products or that any of our future products or enhancements will be accepted by the surgeons who use our products or the payors who financially support many of the procedures performed with our products.

The success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- develop products based on technology that we acquire, such as the technology acquired from Pearsalls Limited and RSB Spine LLC;
- avoid infringing upon the intellectual property rights of third parties;

- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- provide adequate training to potential users of our products;
- receive adequate reimbursement; and
- develop an effective and dedicated marketing and distribution network.

If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these products or enhancements, our results of operations may suffer.

We may encounter difficulties in integrating acquired products, technologies or businesses, which could adversely affect our business.

We acquired products and/or assets from each of Radius Medical, LLC, Pearsalls Limited, RSB Spine LLC, and RiverBend Design LLC, and may in the future acquire technology, products or businesses related to our current or future business. We have limited experience in acquisition activities and may have to devote substantial time and resources in order to complete any future acquisitions. Further, these past and potential acquisitions entail risks, uncertainties and potential disruptions to our business, especially where we have little experience as a company developing or marketing a particular product or technology (as is the case with the biologic product rights we acquired from Radius Medical, LLC). For example, we may not be able to successfully integrate an acquired company s operations, technologies, products and services, information systems and personnel into our business. Further, products we acquire, such as the biologic product we acquired from Radius Medical, LLC or the cervical plate we acquired from RSB Spine LLC, may not provide the intended complementary fit with our existing products. In addition, certain acquired technology, such as that acquired from Pearsalls Limited, may require significant additional development work and efforts to obtain regulatory clearance or approval. An acquisition may further strain our existing financial and managerial controls, and divert management s attention away from our other business concerns. In connection with in-process research and development activities, we would likely experience an increase in development expenses and capital expenditures. We may also fail to retain the employees that are critical to the success of the acquired business. There may also be unanticipated costs and liabilities associated with an acquisition that could adversely affect our operating results.

Our reliance on single source suppliers could limit our ability to meet demand for our products in a timely manner or within our budget.

We rely on third-party suppliers and manufacturers to manufacture and supply our products. To be successful, our contract manufacturers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our anticipated growth could strain the ability of suppliers to deliver an increasingly large supply of products, materials and components. If we are unable to obtain sufficient quantities of high quality components to meet customer demand on a timely basis, we could lose customers, our reputation may be harmed and our business could suffer.

We currently use one or two manufacturers for each of our devices or components. Our dependence on one or two manufacturers involves several risks, including limited control over pricing, availability, quality and delivery schedules. If any one or more of our manufacturers cease to provide us with sufficient quantities of our components in a timely manner or on terms acceptable to us, or cease to manufacture components of acceptable quality, we would have to seek alternative sources of manufacturing. We could incur delays while we locate and engage alternative qualified suppliers and we might be unable to engage alternative suppliers on favorable terms. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate revenue.

Invibio, Inc. is our exclusive supplier of polyetheretherketone, which comprises our PEEK partial vertebral body product called CoRoent. We have a supply agreement with Invibio, pursuant to which we have agreed to purchase our entire supply of polyetheretherketone from Invibio. We also have an exclusive supply arrangement with Peak Industries, Inc., pursuant to which Peak Industries is our exclusive supplier of NeuroVision systems. In the event we experience delays, shortages, or stoppages of supply with either supplier, we would be forced to locate a suitable alternative supplier which could take significant time and result in significant expense. Any inability to meet our customers demands for these products could lead to decreased sales, harm our reputation and result in the loss of customers to our competitors, which could cause the market price of our common stock to decline.

Maxigen Biotech, Inc., or MBI, is our exclusive supplier of our FormaGraft product. We are party to a supply agreement with MBI, pursuant to which we have agreed to purchase our entire supply of FormaGraft from MBI. We will require that MBI significantly expand its manufacturing capacity to meet our forecasted needs, and no assurance can be given that MBI will be able to meet our requirements. If we experience difficulties in dealing with

MBI we may not be able to secure an adequate source of supply of FormaGraft, which could adversely affect our operational results.

Further, Tissue Banks International, Inc. and AlloSource, Inc. collectively supply us with all of our allograft implants, and will continue to be our only sources for the foreseeable future. The processing of human tissue into allograft implants is very labor intensive and it is therefore difficult to maintain a steady supply stream. In addition, due to seasonal changes in mortality rates, some scarce tissues used for our allograft implants are at times in particularly short supply. We cannot be certain that our supply of allograft implants from Tissue Banks International and AlloSource, Inc. will be available at current levels or will be sufficient to meet our needs. If we are no longer able to obtain allograft implants from these sources in amounts sufficient to meet our needs, we may not be able to locate and engage replacement sources of allograft implants on commercially reasonable terms, if at all. Any interruption of our business caused by the need to locate additional sources of allograft implants could reduce our revenues.

We are dependent on the services of Alexis V. Lukianov and Keith Valentine, and the loss of either of them could harm our business.

Our continued success depends in part upon the continued service of Alexis V. Lukianov, our Chairman and Chief Executive Officer, and Keith Valentine, our President and Chief Operating Officer, who are critical to the overall management of NuVasive as well as to the development of our technology, our culture and our strategic direction. We have entered into employment agreements with Messrs. Lukianov and Valentine, but neither of these agreements guarantees the service of the individual for a specified period of time. The loss of either Messr. Lukianov or Valentine could have a material adverse effect on our business, results of operations and financial condition. We have not obtained and do not expect to obtain any key-person life insurance policies.

If we fail to properly manage our anticipated growth, our business could suffer.

The rapid growth of our business has placed a significant strain on our managerial, operational and financial resources and systems. To execute our anticipated growth successfully, we must:

- generate higher revenues to cover a higher level of operating expenses, and our ability to do so may depend on factors that we do not control;
- attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel;
- assimilate new staff members and we will need to manage complexities associated with a larger, faster growing and more geographically diverse organization ;
- expand our clinical development resources to manage and execute increasingly global, larger and more complex clinical trials;
- expand our sales and marketing resources to launch an increasing number of new products from our product pipeline;
- accurately anticipate demand for the products we manufacture and maintain adequate manufacturing capacity for both commercial and clinical supply while maintaining quality standards; and
- upgrade our internal business processes and capabilities (e.g., information technology platform and systems, product distribution and tracking) to create the scalability that a growing business demands.

We are implementing an enterprise resource planning system to support our increasingly complex business and business processes and such implementation is costly and carries substantial operations risk, including loss of data or information, unanticipated increases in costs, disruption of operations or business interruption.

Further, our anticipated growth will place additional strain on our suppliers and manufacturers, resulting in increased need for us to carefully monitor quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

If clinical trials of our current or future product candidates do not produce results necessary to support regulatory approval in the United States, we will be unable to commercialize these products.

Several investigational devices in our development pipeline, including our NeoDisc cervical disc replacement device, Cerpass cervical total disc replacement, or TDR, and lateral lumbar TDR, will require premarket approval, or PMA, from the FDA. A PMA application must be submitted if the device cannot be cleared through the less rigorous 510(k) process. A PMA application must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA s satisfaction the safety and effectiveness of the device for its intended use.

As a result, to receive regulatory approval for NeoDisc, Cerpass or other devices requiring PMA approval, we must conduct, at our own expense, adequate and well controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. Our failure to adequately demonstrate the efficacy and safety of any of our devices would prevent receipt of regulatory approval and, ultimately, the commercialization of that device.

If we fail to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market our products could suffer.

Our medical devices are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA s satisfaction the safety and efficacy of the device for its intended use. To date, all of our products, unless exempt, have been cleared through the 510(k) process. We have no experience in obtaining premarket approval.

Our failure to comply with such regulations could lead to the imposition of injunctions, suspensions or loss of regulatory approvals, product recalls, termination of distribution, or product seizures. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible.

Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Certain of our products may be used by physicians for indications other than those cleared or approved by the FDA, but we cannot promote the products for such off-label uses. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products in foreign countries, we may be subject to rigorous regulation in the future. In such circumstances, we would rely significantly on our foreign independent sales agencies to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

The safety of our products is not yet supported by long-term clinical data and our products may therefore prove to be less safe and effective than initially thought.

We obtained clearance to offer almost all of our products that require FDA clearance or approval through the FDA s 510(k) clearance process. The FDA s 510(k) clearance process is less rigorous than the PMA process and requires less supporting clinical data. As a result, we currently lack the breadth of published long-term clinical data supporting the safety of our products and the benefits they offer that might have been generated in connection with the PMA process. For these reasons, spine surgeons may be slow to adopt our products, we may not have comparative data that our competitors have or are generating and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would reduce demand for our products, significantly reduce our ability to achieve expected revenues and could prevent us from becoming profitable. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability and harm to our business reputation. The spine medical device market has been particularly prone to costly product liability litigation.

If we or our suppliers fail to comply with the FDA s quality system regulations, the manufacture of our products could be delayed.

We and our suppliers are required to comply with the FDA s quality system regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the quality system regulation through inspections. If we or one of our suppliers fail a quality system regulations inspection or if any corrective action plan is not sufficient, the manufacture of our products could be delayed. We underwent an FDA inspection in April 2005 regarding our allograft implant business and another FDA inspection in June 2007 regarding our medical device activities. We underwent an FDA inspection in August 2003 regarding our allograft implant business, and another FDA inspection in April 2004 regarding our medical device activities. In connection with these inspections, the FDA requested minor corrective actions, which we have taken to satisfy the corrective actions. There can be no assurance the FDA will not subject us to further enforcement action and the FDA may impose additional inspections or audits at any time.

Modifications to our marketed products may require new 510(k) clearances or premarket approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, premarket approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer s decision. The FDA may not agree with any of our decisions regarding whether new clearances or approvals are necessary. If the FDA requires us to seek 510(k) clearance or premarket approval for any modification to a previously cleared product, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in delays, fines, costs associated with modification of a product, loss of revenue, harm to our reputation and loss of customers and potential operating restrictions imposed by the FDA.

Risks Related to Our Financial Results and Need for Financing

We have a limited operating history, have incurred significant operating losses since inception and expect to continue to incur losses, and we cannot assure you that we will achieve profitability.

We were incorporated in Delaware in 1997, began commercial sales in 2001 and have multiple products. We have yet to demonstrate that we can generate ongoing sufficient sales of our products to become profitable. The extent of our future operating losses and the timing of profitability, if at all, are difficult to predict. At December 31, 2007, we had an accumulated deficit of approximately $168.0 million, and cash, cash equivalents and short and long

term investments totaling approximately $89.7 million, compared to approximately $117.4 million as of December 31, 2006. Our net loss for the twelve months ended December 31, 2007 was approximately $11.3 million. Even if we do achieve profitability as planned, we may not be able to sustain or increase profitability on an ongoing basis.

Our quarterly financial results are likely to fluctuate significantly because our sales prospects are uncertain.

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period, particularly because our sales prospects are uncertain. These fluctuations may also affect our annual operating results and may cause those results to fluctuate unexpectedly from year to year. The level of our revenues and results of operations at any given time will be based primarily on the following factors:

- our ability to increase sales of our products to hospitals and surgeons;
- our ability to expand and maintain an effective and dedicated sales force;
- pricing pressure applicable to our products, including adverse third-party reimbursement outcomes;
- results of clinical research and trials on our existing products and products in development and our ability to obtain FDA approval or clearance;
- the mix of our products sold (i.e., profit margins differ between our products);
- timing of new product launches, acquisitions, licenses or other significant events by us or our competitors;
- the ability of our suppliers to timely provide us with an adequate supply of materials and components and meet our quality requirements;
- the evolving product offerings of our competitors and the potential introduction of new and competing technologies;
- regulatory approvals and legislative and reimbursement policy changes affecting the products we may offer or those of our competitors; and
- interruption in the manufacturing or distribution of our products.

Many of the products we may seek to develop and introduce in the future will require FDA approval or clearance, without which we cannot begin to commercialize them in the United States, and commercialization of them outside of the United States would likely require other regulatory approvals and import licenses. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we build our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly losses. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors.

After we relocate to our new headquarters, we may not be able to sublease our current headquarters or receive rental income on any such sublease to cover our lease obligations.

In November 2007, we entered into a 15 year lease of a two-building campus style complex in San Diego, California to serve as our new headquarters. Relocation to the new facility is expected to be completed in phases in the second and third quarters of 2008. Subsequent to the

relocation dates, we expect to sublease our current facility through August 2012, the date on which the related lease agreement expires. We may encounter significant difficulties or delays in subleasing our current headquarters and may not be able to sublease it for rents equal to or greater than those which we are obligated to pay. To the extent that we are unable to sublease our current headquarters at an amount equal to our rent obligations for that facility or to the extent sublessees fail to perform their obligations to pay rent, we could incur greater operating expenses than we have planned. Such increases in operating expenses in a period could cause us to exceed our planned expense levels and adversely affect our financial results for that period. Furthermore, inability to sublease such facility may adversely affect our liquidity and capital resources.

Risks Related to Our Intellectual Property and Potential Litigation

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our pending U.S. and foreign patent applications may not issue as patents in a form that will be advantageous to us or may issue and be subsequently successfully challenged by others and invalidated. In addition, our pending patent applications include claims to material aspects of our products and procedures that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may be able to design around our patents or develop products which provide outcomes which are comparable to ours. Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with our officers, shareowners, consultants and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

In addition, there are numerous proposed changes to the patent laws and rules of the US Patent and Trademark Office which, if enacted, may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, proposed changes to the patent rules of the US Patent and Trademark Office were scheduled to take effect on November 1, 2007 which would have significantly limited the right to pursue continuation applications. On October 31, 2007, a temporary injunction was granted in a lawsuit against the US Patent and Trademark Office which served to stay the application of the proposed rules. However, the court has yet to rule on whether to make the injunction permanent. If the injunction is lifted, the proposed rules may take effect and may adversely impact our ability to prevent others from designing around our existing patents. Moreover, Congress is considering several significant changes to the US patent laws, including (among other things) changing from a first to invent to a first inventor to file system, requiring that patent lawsuits be brought in the forum of the defendant, requiring the apportionment of patent damages, and creating a post-grant opposition process to challenge patents after they have issued.

In the event a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time consuming and could divert our management s attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge.

In addition, certain product categories, including pedicle screws, have been the subject of significant patent litigation in recent years. Since we sell pedicle screws and recently introduced our SpheRx II pedicle screw system, any related litigation could harm our business.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. It is not unusual for parties to exchange letters surrounding allegations of intellectual property infringement and licensing arrangements. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages, including treble damages in some cases. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of such potential

products could be severely restricted or prohibited. In addition, our competitors may independently develop technologies similar to ours.

Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to adequately protect our intellectual property rights.

As the number of entrants into our market increases, the possibility of a patent infringement claim against us grows. While we make an effort to ensure that our products do not infringe other parties patents and proprietary rights, our products and methods may be covered by patents held by our competitors. In addition, our competitors may assert that future products we may market infringe their patents.

A patent infringement suit brought against us or any strategic partners or licensees may force us or any strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party s intellectual property, unless that party grants us or any strategic partners or licensees rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all and any licenses may require substantial royalties or other payments by us. Even if any strategic partners, licensees or we were able to obtain rights to the third party s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for spine surgery procedures. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. In addition, we sell allograft implants, derived from cadaver bones, which pose the potential risk of biological contamination. If any such contamination is found to exist, sales of allograft products could decline and our reputation would be harmed.

Currently, we maintain product liability insurance in the amount of $10 million. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, if our product liability insurance proves to be inadequate to pay a damage award, we may have to pay the excess out of our cash reserves which may harm our financial condition. If longer-term patient results and experience indicate that our products or any component cause tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. Finally, even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and could result in the diversion of management s attention from managing our business.

Any claims relating to our making improper payments to physicians for consulting services, or other potential violations of regulations governing interactions between us and healthcare providers, could be time consuming and costly.

Our relationship with surgeons, hospitals and the marketers of our products are subject to scrutiny under various state and federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can potentially give rise to claims that the relevant law has been violated. Any violations of these laws could result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations. We cannot assure you that any of the healthcare fraud and abuse laws will not change or be interpreted in the future in a manner which restricts or adversely affects our business activities or relationships with surgeons, hospitals and marketers of our products.

Federal anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration by an individual or entity in return for, or to induce:

- the referral of an individual for a service or product for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare program; or

- purchasing, leasing, ordering or arranging for any service or product for which payment may be made by a government-sponsored healthcare program.

Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. Certain states in which we market our products have similar anti-kickback, anti-fee splitting and self-referral laws, imposing substantial penalties for violations.

We must comply with a variety of other laws, such as laws prohibiting false claims for reimbursement under Medicare and Medicaid, which can also be triggered by violations of federal anti-kickback laws; Healthcare Insurance Portability and Accountability Act of 1996, which protects the privacy of individually identifiable healthcare information; and the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections. In certain cases, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting unapproved or off-label uses of their products. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although surgeons are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. We market our products and provide promotional materials and training programs to surgeons regarding the use of our products. Although we believe our marketing, promotional materials and training programs for surgeons do not constitute promotion of unapproved uses of our products, if it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty.

The scope and enforcement of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. There can be no assurance that federal or state regulatory authorities will not challenge or investigate our current or future activities under these laws. Any such challenge or investigation could have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

We or our suppliers may be the subject of claims for non-compliance with FDA regulations in connection with the processing or distribution of allograft implants.

It is possible that allegations may be made against us or against donor recovery groups or tissue banks, including those with which we have a contractual relationship, claiming that the acquisition or processing of tissue for allograft implants does not comply with applicable FDA regulations or other relevant statutes and regulations. Allegations like these could cause regulators or other authorities to take investigative or other action against us, or could cause negative publicity for us or our industry generally. These actions or any negative publicity could cause us to incur substantial costs, divert the attention of our management from our business, harm our reputation and cause the market price of our shares to decline.

Risks Related to the Securities Markets and Ownership of Our Common Stock

We expect that the price of our common stock will fluctuate substantially, potentially adversely affecting the ability of investors to sell their shares.

The market price of our common stock is likely to be volatile and may fluctuate substantially due to many factors, including:

- volume and timing of orders for our products;
- the introduction of new products or product enhancements by us or our competitors;
- disputes or other developments with respect to intellectual property rights or other potential legal actions;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;

- quarterly variations in our or our competitor s results of operations;
- sales of large blocks of our common stock, including sales by our executive officers and directors;
- announcements of technological or medical innovations for the treatment of spine pathology;
- changes in governmental regulations or in the status of our regulatory approvals, clearances or applications;
- changes in the availability of third-party reimbursement in the United States or other countries;
- the acquisition or divestiture of businesses, products, assets or technology;
- litigation, including intellectual property litigation;
- announcements of actions by the FDA or other regulatory agencies;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

Market price fluctuations may negatively affect the ability of investors to sell our shares at consistent prices.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of the common stock;
- provide for a classified board of directors, with each director serving a staggered three-year term;
- prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent;
- prohibit our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66 2 / 3% stockholder approval; and
- require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, our bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders source of potential gain for the foreseeable future.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties.***

Our current headquarters are located in an approximately 62,000 square foot facility in San Diego, California that is leased to us until August 2012. In 2006, we purchased an approximately 100,000 square foot building in Memphis, Tennessee that we use as our primary distribution and warehouse facility. In November 2007, we entered into a 15 year lease of an approximate 140,000 square foot two-building campus style complex in San Diego, California. Relocation to the new facility is expected to be completed in phases in the second and third quarters of 2008. Under the master lease agreement, through options to acquire additional space in the project and to require the construction of an additional building on the campus, the agreement provides for facility expansion rights to an aggregate of more than 300,000 leased square feet. Subsequent to the relocation dates, we currently expect to sublease our current facility through August 2012, the date on which the related lease agreement expires, and expect lease income to approximate lease expense on the current facility.

Item 3. ***Legal Proceedings.***

We have been involved in a series of related lawsuits involving families of decedents who donated their bodies through UCLA s willed body program. We have been dismissed from these lawsuits but appeals of those dismissals are pending and the litigation is still ongoing. The complaint alleges that the head of UCLA s willed body program, Henry G. Reid, and a third party, Ernest V. Nelson, improperly sold some of the donated cadavers to the defendants (including NuVasive). Plaintiffs allege the following causes of action: (i) breach of fiduciary duty, (ii) negligence, (iii) fraud, (iv)negligent misrepresentation, (v) negligent infliction of emotional distress, (vi) intentional infliction of emotional distress, (vii) intentional interference with human remains, (viii) negligent interference with human remains, (ix) violation of California Business and Professions Code Section 17200 and (x) injunctive and declaratory relief.

Although the outcome of this lawsuit cannot be determined with certainty, we believe that we acted within the relevant law in procuring the cadavers for our clinical research and intend to vigorously defend ourselves against the claims contained in the complaint.

Item 4. ***Submission of Matters to a Vote of Security Holders.***

No matter was submitted to a vote of our security holders during the quarter ended December 31, 2007.

PART II

Item 5. ***Market for the Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Common Stock Market Price

Our common stock is traded on the NASDAQ Global Market under the symbol NUVA. The following table presents, for the periods indicated, the high and low sale prices per share of our common stock during the periods indicated, as reported on NASDAQ.

	High	Low
2006:		
First Quarter	$ 21.57	$ 17.19
Second Quarter	20.21	15.14
Third Quarter	21.38	15.21
Fourth Quarter	25.29	19.35
2007:		
First Quarter	$ 25.84	$ 21.59
Second Quarter	28.76	23.47
Third Quarter	37.74	25.93
Fourth Quarter	44.96	34.80

We had approximately 171 stockholders of record as of January 31, 2008. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in street name.

Recent Sales of Unregistered Securities

During the fiscal year ended December 31, 2007, we did not issue any securities that were not registered under the Securities Act of 1933 except as disclosed in previous filings with the Commission.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, for development of our business and do not anticipate that we will declare or pay cash dividends on our capital stock in the foreseeable future.

PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return data (through December 31, 2007) for the Company s common stock since May 13, 2004 (the date on which the Company s common stock was first registered under Section 12 of the Exchange Act) to the cumulative return over such period of (i) The NASDAQ Stock Market Composite Index, and (ii) NASDAQ Medical Equipment Index. The graph assumes that $100 was invested on the date on which the Company completed the initial public offering of its common stock, in the common stock and in each of the comparative indices. The graph further assumes that such amount was initially invested in the Common Stock of the Company at the price to which such stock was first offered to the public by the Company on the date of its initial public offering. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

COMPARISON OF CUMULATIVE TOTAL RETURN*

AMONG NUVASIVE, INC.,

THE NASDAQ STOCK MARKET (U.S.) INDEX

AND THE NASDAQ MEDICAL EQUIPMENT INDEX

* $100 invested on May 13, 2004 in stock or index including reinvestment of dividends.

Item 6. ***Selected Financial Data.***

The selected consolidated financial data set forth in the table below has been derived from our audited financial statements. The data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our audited financial statements and notes thereto appearing elsewhere in this report.

	2007	2006	2005	2004	2003
	(In thousands, except per share data)				
Statement of Operations Data:					
Total revenues	$ 154,290	$ 98,091	$ 62,606	$ 39,090	$ 23,029
Gross profit	126,908	79,063	50,214	28,862	16,238
Total operating expenses	144,160	133,289	81,708	43,502	25,473
Net loss	(11,265)	(47,910)	(30,339)	(14,210)	(10,127)
Net loss per share					
Basic and diluted	$ (0.32)	$ (1.47)	$ (1.24)	$ (0.91)	$ (6.30)
Balance Sheet Data:					
Working capital	$ 118,188	$ 136,236	$ 32,829	$ 62,656	$ 6,139
Total assets	225,687	196,184	71,490	80,752	22,371
Long-term liabilities	1,119	1,399	1,665	13	1,224
Total stockholders equity	$ 196,578	$ 176,303	$ 58,136	$ 71,397	$ 10,070

Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

Forward-Looking Statements May Prove Inaccurate

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and the notes to those statements included in this report. This discussion and analysis may contain forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, such as those set forth under heading Risk Factors, and elsewhere in this report.

Overview

We are a medical device company focused on the design, development and marketing of products for the surgical treatment of spine disorders. Our currently-marketed product portfolio is focused primarily on applications for spine fusion surgery, a market estimated to exceed $4.2 billion in the United States in 2008. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS ™ , as well as a growing offering of cervical and motion preservation products. Our currently-marketed products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. We also focus significant research and development efforts on MAS and motion preservation products in the areas of (i) fusion procedures in the lumbar and thoracic spine, (ii) cervical fixation products, and (iii) motion preservation initiatives such as total disc replacement and nucleus-like cervical disc replacement. We dedicate significant resources to our sales and marketing efforts, including training spine surgeons on our unique technology and products.

Our MAS platform combines three categories of our product offerings:

- NeuroVision® a proprietary software-driven nerve avoidance system;
- MaXcess® a unique split-blade design retraction system providing enhanced surgical access to the spine; and
- Specialized implants including our SpheRx® pedicle screw system and CoRoent® suite of implants.

We also offer a suite of traditional spine surgery products, including certain CoRoent® suite of implants, a titanium surgical mesh system, a line of precision-machined cervical and lumbar allograft implants, and related instrumentation. Our Triad ® and Extensure lines of bone allograft, in our patented saline packaging, is human bone that has been processed and precision shaped for transplant. We also offer fusion fixation products that offer unique technological benefits such as our Gradient Plus ™ Cervical Plate and SpheRx pedicle screw system.

We have an active product development pipeline focused on expanding our current fusion product platform as well as products designed to preserve spinal motion. In particular, we have a pivotal clinical study underway with respect to our NeoDisc ® cervical disc replacement device and are actively seeking to initiate clinical trials with other potential products.

Since inception, we have been unprofitable. As of December 31, 2007, we had an accumulated deficit of $168.0 million.

Revenues. From inception to December 31, 2007, we have recognized $392.0 million in revenue from sales of our products. The majority of our revenues are derived from the sale of disposables and implants and we expect this trend to continue in the near term. We loan our surgical instrument sets at no cost to surgeons and hospitals that purchase disposables and implants for use in individual procedures; there are no minimum purchase requirements of disposables and implants related to these loaned surgical instruments. In addition, we place NeuroVision, MaXcess and other MAS surgical instrument sets with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of disposables and implants. These extended loan transactions represent approximately 20% of our total stock of loaner surgical assets. Our implants and disposables are currently sold and shipped from our San Diego and Memphis facilities or from limited disposable inventories stored at our independent sales agents sites. We recognize revenue for disposables or implants used upon receiving a purchase order from the hospital indicating product use or implantation. Additionally, we sell a small number of MAS instrument sets, MaXcess devices, and NeuroVision systems. To date, we have derived less than 5% of our total revenues from these sales.

Sales and Marketing. Through 2007, substantially all of our operations are located in the United States and substantially all of our sales to date have been generated in the United States. We distribute our products through a sales force comprised of independent exclusive sales agents and our own directly employed sales professionals. Our sales force provides a delivery and consultative service to our surgeon and hospital customers and is compensated based on sales and product placements in their territories. Sales force commissions are reflected in our statement of operations in the sales, marketing and administrative expense line. We expect to continue to expand our distribution channel. In the second quarter of 2006, we completed our efforts to transition our sales force to one that is exclusive to us with respect to the sale of spine products. Late in 2007 and continuing in 2008, we commenced international sales efforts with the initial focus on European markets. We expect our international sales force to be made up of a combination of distributors and direct sales personnel.

Acquisition of Radius Medical LLC. On January 23, 2007, NuVasive and Radius Medical, LLC (Radius), along with certain members and managers of Radius, entered into an Asset Purchase Agreement (the Purchase Agreement) providing for the acquisition by us of substantially all of Radius right, title and interest in and to the assets used by Radius in connection with the design, development, marketing and distribution of collagen-based medical biomaterials, together with the intellectual property rights, contractual rights, inventories, and certain liabilities related thereto. The transaction allows us to sell and market a biologic product, FormaGraft ® , a synthetic bone void filler designed to aid in bone growth with fusion procedures, and a platform for future development. FormaGraft received 510(k) clearance from the Food and Drug Administration (FDA) in May 2005. The acquisition is consistent with our objective of developing or acquiring innovative technologies.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon our audited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to bad debts, inventories, long-term assets, income taxes, and stock

compensation. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates.

We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition. We follow the provisions of the Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* , which sets forth guidelines for the timing of revenue recognition based upon factors such as passage of title, installation, payment and customer acceptance. We recognize revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectibility is reasonably assured. Specifically, revenue from the sale of implants and disposables is recognized upon receipt of a purchase order from the hospital indicating product use or implantation or upon shipment to third party customers who immediately accept title. Revenue from the sale of our instrument sets is recognized upon receipt of a purchase order and the subsequent shipment to customers who immediately accept title.

Allowance for Doubtful Accounts. We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. The allowance for doubtful accounts is reviewed quarterly and is estimated based on the aging of account balances, collection history and known trends with current customers. As a result of this review, the allowance is adjusted on a specific identification basis. Increases to the allowance for doubtful accounts result in a corresponding charge to the sales, marketing and administrative expense line. We maintain a relatively large customer base that mitigates the risk of concentration with one customer. However, if the overall condition of the healthcare industry were to deteriorate, or if the historical data used to calculate the allowance provided for doubtful accounts does not accurately reflect our customer s future failure to pay outstanding receivables, significant additional allowances could be required.

Excess and Obsolete Inventory and Instruments. We calculate an inventory reserve for estimated obsolescence and excess inventory based upon historical turnover and assumptions about future demand for our products and market conditions. Our allograft implants have a four-year shelf life and are subject to demand fluctuations based on the availability and demand for alternative implant products. Our inventory, which consists primarily of disposables and specialized implants, is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimates and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. Increases in the reserve for excess and obsolete inventory result in a corresponding charge to cost of goods sold.

A stated goal of our business is to focus on continual product innovation and to obsolete our own products. While we believe this provides a competitive edge, it also results in the risk that our products and related capital instruments will become obsolete prior to sale or to the end of their anticipated useful lives. If we introduce new products or next-generation products, we may be required to dispose of existing inventory and related capital instruments prior to the end of their estimated useful life and/or write off the value or accelerate the depreciation of the these assets.

Long Term Assets. Property and equipment is carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method based on the estimated useful lives of three to seven years for machinery and equipment and three years for loaner instruments. We own land and a building in Memphis, Tennessee that we use as a warehouse and distribution facility. The building is being depreciated over a period of 20 years. Maintenance and repairs are expensed as incurred. Intangible assets, consisting of purchased and licensed technology and a supply agreement, are amortized on a straight-line basis over their estimated useful lives of 14 to 20 years.

We evaluate our long-term assets for indications of impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If this evaluation indicates that the value of the long-term asset may be impaired, we make an assessment of the recoverability of the net carrying value of the asset over its

remaining useful life. If this assessment indicates that the long-term asset is not recoverable, we reduce the net carrying value of the related asset to fair value and may adjust the remaining depreciation or amortization period. We have not recognized any impairment losses on long-term intangible assets through December 31, 2007.

Accounting for Income Taxes. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a full valuation allowance on our net deferred tax assets as of December 31, 2007 due to uncertainties related to our ability to utilize our deferred tax assets in the foreseeable future.

Valuation of Stock-Based Compensation. On January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which establishes accounting for share-based awards exchanged for employee and non-employee director services and requires us to expense the estimated fair value of these awards over the requisite service period. In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) 107, which provided supplemental implementation guidance for SFAS 123(R). We have applied the provisions of SAB 107 in our adoption of SFAS 123(R). Prior to January 1, 2006, we accounted for our share-based employee compensation plans using the intrinsic value method under the recognition and measurement provisions of Accounting Principles Board Opinion (APB) 25, *Accounting for Stock Issued to Employees* , and related guidance. Option awards issued to non-employees are recorded at their fair value as determined in accordance with Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services,* and are periodically revalued as the options vest and are recognized as expense over the related service period.

For purposes of calculating the stock-based compensation, we estimate the fair value of stock options and shares issued under the Employee Stock Purchase Plan using a Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of short lived exchange traded options that have no vesting restrictions and are fully transferable. In addition, the Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. Stock-based compensation related to stock options is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans* (FIN 28). If there is a difference between the assumptions used in determining stock-based compensation cost and the actual factors which become known over time, we may change the input factors used in determining stock-based compensation costs or future grants. These changes, if any, may materially impact our results of operations in the period such changes are made.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our consolidated financial statements and notes thereto included in this report, which contain accounting policies and other disclosures required by GAAP.

Results of Operations

Revenue

Year Ended December 31,			2006 to 2007		2005 to 2006	
2007	2006	2005	$ Change	% Change	$ Change	% Change

Revenue	$	154,290	$	98,091	$	62,606	$	56,199	57%	$ 35,485	57%

Revenues have increased over time due primarily to continued market acceptance of our products within our MAS ® platform, including NeuroVision ® , MaXcess ® disposables, and our specialized implants such as our XLP lateral plate, SpheRx ® pedicle screw system and CoRoent ® suite of products. The execution of our strategy of expanding our product offering for the lumbar region and addressing broader indications further up the spine in the thoracic and cervical regions through product introductions in 2006 and 2007 have significantly contributed to revenue growth. Additionally, the completion of our transition to an exclusive sales force in mid-2006 has increased the effort focused on selling our products as well as the overall market penetration.

Cost of Goods Sold

	Year Ended December 31,			2006 to 2007		2005 to 2006	
	2007	2006	2005	$ Change	% Change	$ Change	% Change
Cost of Goods Sold	$ 27,382	$ 19,028	$ 12,392	$ 8,354	44%	$ 6,636	54%
% of total revenue	18%	19%	20%				

Cost of goods sold consists of purchased goods and depreciation expense for instruments.

Cost of goods sold as a percentage of revenue has decreased over time due to (i) a higher portion of our sales coming from products with higher margins and (ii) efficiencies gained with growth and volume. The year-over-year increase in cost of goods sold in total dollars in 2007 compared to 2006 and in 2006 compared to 2005 resulted primarily from (i) increased material costs of $6.2 million and $4.2 million, respectively, associated with the higher revenue in each year; and (ii) increased depreciation expense of $2.8 million and $2.9 million, respectively, due to higher capital levels of surgical instrument sets used in surgeries. We expect cost of goods sold, as a percentage of revenue, to remain relatively consistent for the foreseeable future.

Consistent with our philosophy of obsoleting our own products, we launched several new products and enhancements in 2006 and 2007. In connection with the product launches, certain instruments were rendered obsolete as of the launch date. As a result, we reduced the useful life of such instruments to end on the respective launch dates and incurred additional depreciation expense of $61,000 and $646,000 in 2007 and 2006, respectively. This depreciation expense is included in cost of goods sold in the accompanying statement of operations for the respective years.

Operating Expenses

Sales, Marketing and Administrative

	Year Ended December 31,			2006 to 2007		2005 to 2006	
	2007	2006	2005	$ Change	% Change	$ Change	% Change
Sales, Marketing and Administrative	$ 119,579	$ 94,632	$ 56,515	$ 24,947	26%	38,117	67%
% of total revenue	78%	96%	90%				

Sales, marketing and administrative expenses consist primarily of compensation, commission and training costs for personnel engaged in sales, marketing and customer support functions; independent sales agents commissions; surgeon training costs; shareowner (employee) related expenses for our administrative functions; third party professional service fees; and facilities and insurance expenses. In addition, we classify the amortization expense related to purchased technology in this expense category.

In the second quarter of 2006, we completed our efforts to transition our sales force to one that is exclusive to us with respect to the sale of spine products. Our exclusive sales force consists of independent sales agents and directly-employed sales personnel.

The increases in sales, marketing and administrative expense principally result from growth in our product sales and the overall growth in the Company, including headcount increases in 2006 and 2007.

Increases in costs based on additional product sales, such as sales force compensation and other direct costs related to the sales force, royalty expense, and shipping costs were $11.7 million and $20.2 million in 2007 and 2006, respectively, compared to the prior years. The significant increase in total dollars in these aggregated categories in 2006 compared to 2005 relates primarily to the transition to an exclusive sales force. Total costs related to our sales force, as a percent of revenue, were 33.4%, 47.2%, and 43.6% in 2007, 2006 and 2005, respectively. The year-over year fluctuations are the result of the costs associated with our transition to an exclusive sales force; increasing in 2006 compared to 2005 and decreasing in 2007 compared to 2006 as a result of completing the transition in mid-2006. Going forward, we expect the total costs related to the sales force as a percent of revenue will decrease.

We also experienced increased costs as a result of overall company growth and headcount additions in our marketing and administrative support functions. Marketing and administrative compensation and personnel costs increased $4.3 million and $5.8 million in 2007 and 2006, respectively, compared to the prior years. Stock-based compensation increased $0.8 million and $8.9 million in 2007 and 2006, respectively, compared to the prior years. The increase in 2006 is due primarily to the recognition of compensation expense related to stock options required under SFAS 123R (adopted on January 1, 2006). Facility, equipment and computer expenses increased by $1.5 million and $1.4 million in 2007 and 2006 respectively, compared to the prior years. Amortization expense related to acquired intangible assets increased by $1.0 million and $0.2 million in 2007 and 2006 respectively, compared to the prior years, as a result of acquisition activity in 2007.

On a long-term basis, as a percentage of revenue, we expect total sales, marketing and administrative costs to continue to decrease over time as we begin to see the synergies of investments we have made (such as our sales force exclusivity transition). However, we have other significant expenses planned that are designed to increase the scalability of our business. For example, we purchased and began the implementation of a new enterprise resource planning software system, or ERP system, in 2007. We will capitalize the majority of the aggregate $7.2 million anticipated cost of the ERP project and amortize them over a 7 year period. We have incurred $4.8 million related to the ERP project through December 31, 2007. These costs have been capitalized and amortization will commence when the system is placed in service (which is expected to occur in the second half of 2008). In addition, we entered into a lease of a two-building campus-style headquarters complex in November 2007 to accommodate our Company growth. Relocation to the new facility is expected to be in phases in the second and third quarters of 2008, and as a result, we will incur increased facility costs beginning on the relocation dates. In addition, the lease term for our current facility continues through August 2012, which requires us to either find a new tenant for our current headquarters or otherwise exit the lease. If we have difficulty finding a new tenant or exiting the lease, we could be required to continue paying rent and related costs on this facility through August 2012.

Research and Development

	Year Ended December 31,			2006 to 2007		2005 to 2006	
	2007	2006	2005	$ Change	% Change	$ Change	% Change
Research & Development	$ 24,581	$ 18,541	12,296	$ 6,040	33%	$ 6,245	51%
% of total revenue	16%	19%	20%				

Research and development expense consists primarily of product research and development, regulatory and clinical functions, and shareowner (employee) related expenses. During 2007, 2006 and 2005, we launched a number of products and product enhancements, including in 2007, the SpheRx II and DBR II Pedicle Screw Systems, the XLP Lateral Plate, Gradient Plus cervical plate and an expanded line of CoRoent implants. In 2006, we launched our next generation instrument sets for spine fusion procedures, the MaXcess ® III retractor system, and CoRoent ® implant line extensions, and in 2005 we launched, NeuroVision updates, SpheRx ® DBR and CoRoent line extensions. In the third quarter of 2006, we commenced patient enrollment in our NeoDisc ® clinical trial, resulting in increased research and development costs subsequent to this date.

The year-over-year increases in research and development costs in 2007 compared to 2006 and in 2006 compared to 2005 are primarily due to (i) increases in compensation and other shareowner related expenses of $4.4 million and $1.8 million in 2007 and 2006, respectively, primarily due to increased headcount to support our product development and enhancement efforts; (ii) increased NeoDisc ® trial cost of $3.1 million and $1.7 million in 2007 and 2006 respectively; and (iii) a decrease in stock-based compensation expense of $0.5 million in 2007 compared to 2006 and an increase in stock-based compensation expense of $1.4 million in 2006 compared to 2005. The increase in 2006 is due primarily to the recognition of compensation expense related to stock options required under SFAS 123R (adopted on January 1, 2006).

We expect research and development costs to continue to increase in absolute dollars for the foreseeable future in support of our ongoing development activities and planned clinical trial activities; however, as a percentage of revenue, these costs are expected to decrease moderately over time.

Interest and Other Income, Net

	Year Ended December 31,			2006 to 2007		2005 to 2006	
	2007	2006	2005	$ Change	% Change	$ Change	% Change
Interest and Other Income , net	$ 5,987	$ 6,316	$ 1,155	$ (329)	(5)%	$ 5,161	447%
% of total revenue	4%	6%	2%				

Interest and other income, net consists primarily of interest income. The decrease in net interest income in 2007 compared to 2006 is due to lower investment balances in 2007 compared to 2006 as a result of cash used to operate our business and to lower yields available in the market for our investment portfolio. The increase in net interest income in 2006 compared to 2005 is due primarily to interest earned on the investment of proceeds of $142.0 million received from our secondary public offering completed in February 2006.

Stock-Based Compensation

The compensation cost that has been included in the statement of operations for all share-based compensation arrangements was as follows:

	Year Ended December 31,			2006 to 2007		2005 to 2006	
	2007	2006	2005	$ Change	% Change	$ Change	% Change
Stock-Based Compensation							
Sales, Marketing & Administrative	$ 11,404	$ 10,581	$ 1,635	$ 823	8%	$ 8,946	547%
Research & Development	2,217	2,764	1,405	$ (547)	(20)%	1,359	97%
Total Stock-Based Compensation	$ 13,621	$ 13,345	$ 3,040	$ 276	2%	$ 10,305	339%
% of total revenue	9%	14%	5%				

On January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R), which establishes accounting for share-based awards exchanged for shareowner (employee) and non-employee director services and requires us to expense the estimated fair value of these awards over the requisite service period. In March 2005, the SEC issued Staff Accounting Bulletin (SAB) 107, which provided supplemental implementation guidance for SFAS 123(R). We have applied the provisions of SAB 107 in our adoption of SFAS 123(R). Prior to January 1, 2006, we accounted for our share-based awards to shareowners and directors using the intrinsic value method under the recognition and measurement provisions of APB 25.

Through December 31, 2005, we recorded total deferred stock-based compensation for certain options granted during 2003 and 2004, of $8.6 million for the incremental difference at the grant date between the fair value per share determined by the board of directors and the deemed fair value per share determined solely for financial reporting purposes in conjunction with our initial public offering. Amortization of deferred stock-based compensation through December 31, 2005, net of terminations, was $7.2 million. Upon adoption of SFAS 123(R), the unamortized

balance of deferred compensation of $1.2 million at December 31, 2005 was reclassified to additional paid in capital in our consolidated balance sheet. Future compensation expense calculated using the fair value provisions of SFAS 123 related to these options has been included as a component of stock-based compensation in our statements of operations.

We elected to adopt the modified prospective transition method permitted by SFAS 123(R) and accordingly prior periods have not been restated to reflect the impact of SFAS 123(R). The modified prospective transition method requires that stock-based compensation expense be recorded for (i) any share-based awards granted to shareowners and non-employee directors through, but not yet vested as of December 31, 2005, based on the grant-date fair value estimated in accordance with the pro forma provisions of SFAS 123, *Accounting for Stock-Based Compensation* (SFAS 123), and (ii) any share-based awards granted to shareowners and non-employee directors subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

Stock-based compensation related to stock options is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation*

Rights and Other Variable Stock Option Award Plans (FIN 28). As of December 31, 2007, there was $10.6 million of unrecognized compensation expense for stock options which is expected to be recognized over a weighted-average period of approximately 1.1 years. In addition, as of December 31, 2007, there was $0.9 million of unrecognized compensation expense for shares expected to be issued under the Employee Stock Purchase Plan that will be recognized through April 2008.

Business Combinations and Asset Acquisitions

Radius Medical LLC. On January 23, 2007, we acquired assets used by Radius Medical LLC, or Radius, in connection with the design, development, marketing and distribution of collagen-based medical biomaterials, together with the intellectual property rights, contractual rights, inventories, and certain liabilities related thereto. In connection with the transaction, we made net cash payments totaling $5.0 million and issued 451,677 unregistered shares of our common stock, which were subsequently registered. We also funded at closing $2.0 million in cash into an escrow account for the benefit of Radius, which will be maintained for a period of 18 months. As part of the acquisition, we also acquired certain rights and obligations under a supply agreement with Maxigen Biotech, Inc. (MBI) with respect to product manufacture and distributor rights. MBI is a Taiwanese company who manufactures FormaGraft and owns a portion of the core technology.

In connection with the acquisition of Radius, we made a separate $2.0 million equity investment in MBI. On May 1, 2007, the equity investment in MBI was completed resulting in NuVasive ownership of approximately 9% of MBI. We account for this investment at cost and included in other assets on the consolidated balance sheet.

RiverBend Design LLC. On August 12, 2005, we acquired assets and intellectual property from RiverBend Design LLC, or RiverBend, pursuant to the terms of an Intellectual Property Purchase Agreement. The acquired intellectual property includes a patent application and related technology and know-how for use in developing dynamic stabilization products. We made a closing payment to RiverBend of 51,308 unregistered shares of common stock valued at $1.0 million for accounting purposes. In addition, we will make royalty payments to RiverBend based on sales of products based on the acquired technology. The purchase price of $1.0 million has been allocated to purchased technology and is being amortized over a useful life of 17 years.

Pearsalls Limited. On August 4, 2005, we acquired technology and assets from Pearsalls Limited, or Pearsalls, a privately-owned company based in the United Kingdom (Pearsalls). The acquired assets include an investigational nucleus-like cervical disc replacement device called NeoDisc ™ . Also acquired was all of Pearsall s intellectual property related to embroidery technology for use in surgical implants. We made a closing payment of $12.0 million, consisting of $5.0 million in cash and $7.0 million in common stock. In addition, the original transaction provided for us to make additional milestone payments totaling up to $31.5 million as progress is made towards FDA approval for marketing of the NeoDisc investigational device and to pay a royalty of 5% on NeoDisc product sales. In the second quarter of 2006, we recorded a payment obligation by us of $10.5 million related to an achieved milestone. In September 2006, we entered into an agreement with Pearsalls Limited,, resulting in a total payment of $20.0 million in settlement of (i) the $10.5 million liability recorded in the second quarter of 2006; (ii) future contingent milestone payments of up to $21.0 million; and (iii) all future contingent royalty payments to Pearsalls; all of which relate to NeoDisc and related technology. The terms of the agreement also render the manufacturing relationship for NeoDisc non-exclusive, giving us control over the manufacturing of NeoDisc, and effects the full transfer of intellectual property rights to NuVasive. The $20 million payment consisted of $12 million in cash and $8 million in additional common stock. The total charge recorded in 2006 was $20.1 million, including transaction costs.

RSB Spine LLC. On June 3, 2005, we acquired intellectual property and related assets for cervical plate technology from RSB Spine LLC, or RSB,. We made a closing payment of $7.3 million, consisting of $3.8 million in cash and $3.5 million in common stock. In addition, the acquisition agreement provides for additional payments of $1.2 million over a period of four years and contingent payments over a period of 12 years based upon the sale of the products derived from the cervical plate technology. We re-launched the cervical plate under our own

product name (the SmartPlate ® Gradient CLP ™) in July 2005.

These transactions and their impact to our consolidated statement of position and results of operations are fully described in Notes 2 and 3 to the consolidated financial statements included in this report.

In-Process Research and Development

In 2005, we recorded an in-process research and development (IPRD) charge of $12.9 million related to our acquisition of the technology assets of Pearsalls Limited in the third quarter of 2005. At the date of the acquisition, the projects associated with the IPRD efforts had not yet reached technological feasibility and the research and development in process had no alternative future uses. Accordingly, the amounts were charged to expense on the acquisition date.

Valuation of IPRD. The value assigned to acquired in-process technology is determined by identifying products under research in areas for which technological feasibility had not been established. The value of the in-process technology was determined using a discounted cash flow model similar to the income approach, focusing on the income producing capabilities of the in-process technologies. Under this approach, the value is determined by estimating the revenue contribution generated by each of the identified technologies. Revenue estimates were based on (i) individual product revenues, (ii) anticipated growth rates, (iii) anticipated product development and introduction schedules, (iv) product sales cycles, and (v) the estimated life of a product s underlying technology. From the revenue estimates, operating expense estimates, including costs of sales, general and administrative, selling and marketing, and income taxes, were deducted to arrive at operating income. Revenue growth rates were estimated by management for the product and gave consideration to relevant market sizes and growth factors, expected industry trends, the anticipated nature and timing of new product introductions by us and our competitors, individual product sales cycles and the estimated life of the product s underlying technology. Operating expense estimates reflect NuVasive s historical expense ratios. Additionally, these projects will require continued research and development after they have reached a state of technological and commercial feasibility. The resulting operating income stream was discounted to reflect its present value at the date of acquisition.

The rate used to discount the net cash flows from purchased in-process technology is our weighted-average cost of capital (WACC), taking into account our required rates of return from investments in various areas of the enterprise and reflecting the inherent uncertainties in future revenue estimates from technology investments including the uncertainty surrounding the successful development of the acquired in-process technology, the useful life of such technology, the profitability levels of such technology, if any, and the uncertainty of technological advances, all of which are unknown at this time.

Liquidity and Capital Resources

Since our inception in 1997, we have incurred significant losses and as of December 31, 2007, we had an accumulated deficit of approximately $168.0 million. We have not yet achieved profitability, but do expect to be marginally profitable in 2008. To date, our operations have been funded primarily with proceeds from the sale of our equity securities which total $284.5 million since inception, including $210.1 million sold in the public markets.

Cash, cash equivalents and marketable securities was $89.7 million at December 31, 2007 and $117.4 million at December 31, 2006. The decrease was due primarily to the cash used to fund our operations, to acquire capital assets and surgical instrument sets to support products launched in 2007, for the acquisition of Radius Medical LLC and for our $2.0 million investment in MBI.

Net cash used in operating activities was $0.9 million in 2007 compared to $25.6 million in 2006. The decrease of net cash used in operating activities of $24.7 million was primarily due to our improved operating results in the period.

Net cash provided by investing activities was $14.3 million in 2007 compared to net cash used by investing activities of $89.8 million in 2006. In 2006, we received and invested the proceeds of our secondary offering of $142.0 million, offset by cash used to acquire property and equipment and to support the business operations. In 2007, investing activity decreased significantly as cash was used to (i) acquire Radius Medical LLC, (ii) invest in MBI and (iii) support the business operations.

Net cash provided by financing activities was $7.0 million in 2007 compared to $144.4 million in 2006. In 2006, we completed an offering of our common stock in the public markets, resulting in proceeds of $142.0 million. In 2007, the proceeds from the sale of common stock under our equity plans increased by $4.7 million.

We believe our current cash and cash equivalents together with our short-term marketable securities and the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements for at least the next 12 months.

Contractual Obligations and Commitments

We are committed under operating leases and other contractual obligations. Our operating lease commitments are related to both our current and future corporate headquarters leases and two automobiles. Our corporate headquarters leases continue through August 2012 and June 2023, respectively. The rent expense related to our corporate headquarters leases will be recorded on a straight-line basis in accordance with GAAP. We are in the process of soliciting bids for sublet of our current corporate headquarters facility.

The following summarizes our long-term contractual obligations and commitments as of December 31, 2007 *(in thousands)* :

			Payments Due by Period		
	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	After 5 Years
Operating leases	$ 122,011	$ 4,244	$ 24,912	$ 15,328	$ 77,527
Deferred consideration payments under acquisition agreements	650	300	350		
Royalty obligations	12,262	1,829	4,631	2,630	3,172
Total	$ 134,923	$ 6,373	$ 29,893	$ 17,958	$ 80,699

In connection with the acquisition of RSB Spine LLC, we are contingently obligated to make additional consideration payments over a period of 12 years based upon sales of the products derived from Smart Plate ® Gradient CLP ™ and related technology.

In addition, as a result of our acquisition of Radius Medical LLC in January 2007, we are obligated to purchase, on an annual basis, a minimum number of units of FormaGraft ® from Maxigen Biotech, Inc. at an annual cost of approximately $900,000.

The expected timing of payments of the obligations discussed above is estimated based on current information. Timing of payment and actual amounts paid may be different depending on the time of receipt of services or changes to agreed-upon amounts for some obligations. Amounts disclosed as contingent or milestone-based obligations depend on the achievement of the milestones or the occurrence of the contingent events and can vary significantly.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk.***

Our exposure to interest rate risk at December 31, 2007 is related to our investment portfolio which consists largely of debt instruments of high quality corporate issuers and the U.S. government and its agencies. Due to the short-term nature of these investments, we have assessed that there is no material exposure to interest rate risk arising from our investments. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. At December 31, 2007, we do not hold any material asset-backed investment securities and in 2007, we did not realize any losses related to asset-backed investment securities.

We have operated mainly in the United States of America, and the majority of our sales since inception have been made in U.S. dollars. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

Interest Rate Risk. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The primary objective of our investment activities is to preserve the principal while at the same time maximizing yields without significantly increasing the risk. To achieve this objective, we maintain our portfolio of cash equivalents and investments in instruments that meet high credit quality standards, as specified in our investment policy. None of our investments are held for trading purposes. Our policy also limits the amount of credit exposure to any one issue, issuer and type of instrument.

The following table presents the carrying value and related weighted-average rate of return for our investment portfolio as of December 31, 2007:

		Carrying Value (In thousands)	Weighted Average Rate of Return
Classified as Current Assets:			
Money Market Funds	$	52,469	4.43%
Commercial Paper with initial maturities of 90 days or less		9,251	4.80%
Corporate Notes with initial maturities of greater than 90 days		9,996	5.27%
		71,716	
Less cash equivalents		(52,469)	
Short-term marketable securities		19,247	
Classified as Non-Current Assets:			
Debt securities issued by the U.S. Treasury and other U.S. government agencies		7,035	4.83%
Corporate Notes		1,501	4.60%
		8,536	
Total interest bearing instruments	$	27,783	

As of December 31, 2007, the stated maturities of our investments are $71.7 million within one year and $8.5 million within one to three years. These investments are recorded on the balance sheet at fair market value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income.

Item 8. ***Financial Statements and Supplementary Data.***

The consolidated financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.***

None

Item 9A. ***Controls and Procedures***

Disclosure Controls and Procedures. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (Exchange Act) is recorded, processed, summarized and reported within the timelines specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the Company s disclosure controls and procedures (as such term is defined in SEC Rules 13a 15(e) and 15d 15(e)) as of December 31, 2007. Based on such evaluation, our management has concluded as of December 31, 2007, the Company s disclosure controls and procedures are effective.

Management s Report on Internal Control over Financial Reporting. Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial

Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States.

Management has used the framework set forth in the report entitled *Internal Control Integrated Framework* published by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission to evaluate the effectiveness of the Company s internal control over financial reporting. Management has concluded that the Company s internal control over financial reporting was effective as of December 31, 2007. Ernst & Young LLP, the Company s independent registered public accounting firm, has issued an attestation report on the Company s internal control over financial reporting which is included herein.

Changes in Internal Control over Financial Reporting. There has been no change to our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

NuVasive, Inc.

We have audited NuVasive, Inc. s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). NuVasive, Inc. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the effectiveness of the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, NuVasive, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of NuVasive, Inc. as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2007 of NuVasive, Inc. and our report dated February 25, 2008

expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

February 25, 2008

San Diego, California

Item 9B. ***Other Information.***

None

PART III

Certain information required by Part III is omitted from this report because the Company will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A (the Proxy Statement) for its annual meeting of stockholders to be held on May 22, 2008, and certain information included in the Proxy Statement is incorporated herein by reference.

Item 10. ***Directors and Executive Officers of the Registrant.***

We have adopted a Code of Conduct and Ethics for all officers, directors and shareowners. The Code of Conduct and Ethics is available on our website, *www.nuvasive.com,* and in our filings with the Securities and Exchange Commission. We intend to disclose future amendments to, or waivers from, provisions of our Code of Conduct and Ethics that apply to our Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer, or controller, or persons performing similar functions, within four business days of such amendment or waiver.

The other information required by this Item 10 will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 11. ***Executive Compensation.***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 13. ***Certain Relationships and Related Transactions.***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14. ***Principal Accountant Fees and Services.***

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules.***

(a) The following documents are filed as a part of this report:

(1) Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2007 and 2006

Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005

Consolidated Statements of Stockholders Equity for the years ended December 31, 2007, 2006 and 2005

Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules: Schedule II Valuation Accounts

All other financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits. See subsection (b) below.

(b) Exhibits. The following exhibits are filed as part of this report:

Exhibit Number	Description
2.1(1)	Asset Purchase Agreement, dated as of June 3, 2005, by and between NuVasive, Inc. and RSB Spine LLC
2.2(2)	Agreement, dated as of January 3, 2007, by and between NuVasive, Inc. and RSB Spine LLC
2.3(3)	Asset Purchase Agreement, dated as of August 4, 2005, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.
2.4(4)	Amendment No. 1 to Asset Purchase Agreement, dated as of September 26, 2006, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.
2.5(5)	Intellectual Property Purchase Agreement, dated as of August 12, 2005, by and between NuVasive, Inc. and RiverBend Design LLC
2.6(6)	Asset Purchase Agreement, dated as of January 23, 2007, by and among NuVasive, Inc. and Radius Medical, LLC, Biologic, LLC, Antone Family Partners, Russel Cook and Duraid Antone
3.1(7)	Restated Certificate of Incorporation
3.2(7)	Restated Bylaws
4.1(8)	Second Amended and Restated Investors Rights Agreement, dated July 11, 2002, by and among NuVasive, Inc. and the other parties named therein
4.2(8)	Amendment No. 1 to Second Amended and Restated Investors Rights Agreement, dated June 19, 2003, by and among NuVasive, Inc. and the other parties named therein
4.3(8)	Amendment No. 2 to Second Amended and Restated Investors Rights Agreement, dated February 5, 2004, by and among NuVasive, Inc. and the other parties named therein
4.4(3)	Registration Rights Agreement, dated as of August 4, 2005, between NuVasive, Inc. and Pearsalls Limited
4.5(4)	Registration Rights Agreement Termination Agreement, dated as of September 26, 2006, between NuVasive, Inc. and Pearsalls Limited
4.6(17)	Specimen Common Stock Certificate
10.1(8)#	1998 Stock Option/ Stock Issuance Plan
10.2(8)#	Form of Notice of Grant of Stock Option under our 1998 Stock Option/ Stock Issuance Plan
10.3(8)#	Form of Stock Option Agreement under our 1998 Stock Option/ Stock Issuance Plan, and form of addendum thereto
10.4(8)#	Form of Stock Purchase Agreement under our 1998 Stock Option/ Stock Issuance Plan
10.5(9)#	Form of Stock Issuance Agreement under our 1998 Stock Option/ Stock Issuance Plan
10.6(9)#	Form of Stock Issuance Agreement under our 1998 Stock Option/ Stock Issuance Plan, dated April 21, 2004, and May 4, 2004
10.7(10)#	2004 Equity Incentive Plan
10.8(10)#	Form of Stock Option Award Notice under our 2004 Equity Incentive Plan
10.9(10)#	Form of Option Exercise and Stock Purchase Agreement under our 2004 Equity Incentive Plan
10.10(10)#	Forms of Restricted Stock Grant Notice and Restricted Stock Agreement under our 2004 Equity Incentive Plan

10.11(10)#	Form of Restricted Stock Unit Award Agreement under our 2004 Equity Incentive Plan
10.12(10)#	2004 Employee Stock Purchase Plan

Exhibit Number	Description
10.13(11)#	Employment Letter Agreement, dated July 12, 1999, as amended on January 20, 2004 and May 23, 2006, between NuVasive, Inc. and Alexis V. Lukianov
10.14(8)#	Bonus Agreement, dated February 25, 2000, between NuVasive, Inc. and Alexis V. Lukianov
10.15(8)#	Employment Agreement, dated December 20, 2002, as amended on January 20, 2004, between NuVasive, Inc. and Kevin C. O Boyle
10.16(11)#	Employment Agreement, dated January 20, 2004, as amended on May 23, 2006, between NuVasive, Inc. and Keith Valentine
10.17(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and Patrick Miles
10.18(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and James J. Skinner
10.19(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and G. Bryan Cornwall
10.20(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and Jonathan D. Spangler
10.21(12)#	Employment Agreement, dated December 5, 2005, between NuVasive, Inc. and Jeffrey P. Rydin
10.22(12)#	Employment Agreement, dated December 5, 2005, between NuVasive, Inc. and Jason M. Hannon
10.23(8)#	Form of Indemnification Agreement between NuVasive, Inc. and each of our directors and officers
10.24(8)	Intellectual Property Purchase Agreement, dated October 10, 2002, between NuVasive, Inc. and Spine Partners, LLC
10.25(5)	Intellectual Property Purchase Agreement Addendum, dated as of August 12, 2005, by and between NuVasive, Inc. and Spine Partners, LLC
10.26(13)	Sublease, dated October 12, 2004, by and between NuVasive, Inc. and Gateway, Inc.
10.27(11)	Earnest Money Contract and Agreement, dated May 26, 2006, between NuVasive, Inc. and New York Life Insurance Company
10.28(14)#	Description of 2006 performance bonus arrangements for our executive officers
10.29(15)#	Description of 2007 annual salaries for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.30(16)#	Summary of the 2007 bonus payments to our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.31(18)	Customer Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.32(18)	IBM Global Services Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.33(19)	Lease Agreement for Sorrento Summit, entered into as of November 6, 2007, between the Company and HCPI/Sorrento, LLC.
10.34(20)#	Description of 2008 annual salaries and annual stock grant for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
21.1	List of subsidiaries of NuVasive, Inc.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350

(1) Incorporated by reference to our Current Report on Form 8-K filed with the Securities and Exchange Commission (the Commission) on June 9, 2005.

(2) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 9, 2007.

(3) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 10, 2005.

(4) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on September 29, 2006.

(5) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 17, 2005.

(6) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 25, 2006.

(7) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 13, 2004.

(8) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004.

(9) Incorporated by reference to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on May 11, 2004.

(10) Incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004.

(11) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 30, 2006.

(12) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on December 7, 2005.

(13) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 15, 2004.

(14) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 13, 2006.

(15) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 22, 2007.

(16) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on February 23, 2007.

(17) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006.

(18) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on August 8, 2007.

(19) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on November 8, 2007.

(20) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 11, 2008.

The Commission has granted confidential treatment to us with respect to certain omitted portions of this exhibit (indicated by asterisks). We have filed separately with the Commission an unredacted copy of the exhibit.

# Indicates management contract or compensatory plan.

SUPPLEMENTAL INFORMATION

Copies of the Registrant s Proxy Statement for the Annual Meeting of Stockholders to be held on May 22, 2008, and copies of the form of proxy to be used for such Annual Meeting, will be furnished to the SEC prior to the time they are distributed to the Registrant s Stockholders.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NUVASIVE, INC.

By: /s/ Alexis V. Lukianov

Alexis V. Lukianov

Chairman and Chief Executive Officer

(Principal Executive Officer)

Date: February 29, 2008

By: /s/ Kevin C. O Boyle

Kevin C. O Boyle

Executive Vice President and

Chief Financial Officer

(Principal Financial Officer)

Date: February 29, 2008

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alexis V. Lukianov and Kevin C. O Boyle, jointly and severally, his or her attorneys-in -fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in -fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature		Title		Date
/s/ Alexis V. Lukianov Alexis V. Lukianov		Chairman and Chief Executive Officer (Principal Executive Officer)		February 29, 2008
/s/ Kevin C. O Boyle Kevin C. O Boyle		Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)		February 29, 2008
/s/ Jack R. Blair Jack R. Blair		Director		February 29, 2008
/s/ Peter C. Farrell Peter C. Farrell		Director		February 29, 2008

Signature		Title		Date
/s/ Robert J. Hunt Robert J. Hunt		Director		February 29, 2008
/s/ Lesley H. Howe Lesley H. Howe		Director		February 29, 2008
/s/ Hansen Yuan Hansen Yuan		Director		February 29, 2008
/s/ Eileen M. More Eileen M. More		Director		February 29, 2008

NUVASIVE, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

NuVasive, Inc.

We have audited the accompanying consolidated balance sheets of NuVasive, Inc. as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2007. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of NuVasive, Inc. at December 31, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, NuVasive, Inc. changed its method of accounting for Share-Based Payments in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004) on January 1, 2006.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of NuVasive, Inc. s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 25, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

February 25, 2008

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NUVASIVE, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2007	2006
	(In thousands, except par value)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,915	$ 41,476
Short-term marketable securities	19,247	73,930
Accounts receivable, net of allowance of $926 and $737, respectively	27,496	18,960
Inventory, net	36,280	18,636
Prepaid expenses and other current assets	1,240	1,716
Total current assets	146,178	154,718
Property and equipment, net of accumulated depreciation	43,538	30,573
Long-term marketable securities	8,536	1,996
Intangible assets, net of accumulated amortization	24,496	8,441
Other assets	2,939	456
Total assets	$ 225,687	$ 196,184
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 13,839	$ 8,938
Royalties payable	2,076	1,068
Accrued payroll and related expenses	12,075	8,476
Total current liabilities	27,990	18,482
Long-term liabilities	1,119	1,399
Commitments and contingencies		
Stockholders equity:		
Preferred Stock, $.001 par value; 5,000 shares authorized, no shares issued and outstanding at December 31, 2007 and 2006		
Common Stock, $.001 par value; 70,000 shares authorized 35,330 and 33,929 issued and outstanding at December 31, 2007 and 2006, respectively	35	34
Additional paid-in capital	364,469	333,009
Accumulated other comprehensive income (loss)	54	(25)
Accumulated deficit	(167,980)	(156,715)
Total stockholders equity	196,578	176,303
Total liabilities and stockholders equity	$ 225,687	$ 196,184

See accompanying notes to consolidated financial statements.

NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2007	**2006**	**2005**
	(In thousands, except per share amounts		
Revenue	$ 154,290	$ 98,091	$ 62,606
Cost of goods sold	27,382	19,028	12,392
Gross profit	126,908	79,063	50,214
Operating expenses:			
Sales, marketing and administrative	119,579	94,632	56,515
Research and development	24,581	18,541	12,296
In-process research and development			12,897
NeoDisc technology costs		20,116	
Total operating expenses	144,160	133,289	81,708
Interest and other income (expense), net	5,987	6,316	1,155
Net loss	$ (11,265)	$ (47,910)	$ (30,339)
Net loss per share:			
Basic and diluted	$ (0.32)	$ (1.47)	$ (1.24)
Weighted-average shares basic and diluted	34,782	32,501	24,473

See accompanying notes to consolidated financial statements.

NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common stock Shares	Amount	Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
				(In thousands)			
Balance at December 31, 2004	23,951	$ 24	$ 153,323	$ (3,441)	$ (43)	$ (78,466)	$ 71,397
Issuance of common stock under employee and director stock option and purchase plans	485		1,757				1,757
Issuance of common stock for acquisitions	670	1	12,269				12,270
Compensation expense related to issuance of stock options to non-employees			988				988
Amortization of stock-based compensation			(194)	2,246			2,052
Unrealized loss on marketable securities and foreign currency translation					11		11
Net loss						(30,339)	(30,339)
Balance at December 31, 2005	25,106	25	168,143	(1,195)	(32)	(108,805)	58,136
Issuance of common stock under employee and director stock option and purchase plans	592	1	2,618				2,619
Issuance of common stock for NeoDisc technology costs	402		8,060				8,060
Issuance of common stock in secondary offering	7,829	8	142,038				142,046
Elimination of unamortized deferred compensation balance			(1,195)	1,195			
Stock based compensation expense			13,345				13,345
Unrealized loss on marketable securities and foreign currency translation					7		7
Net loss						(47,910)	(47,910)
Balance at December 31, 2006	33,929	34	333,009		(25)	(156,715)	176,303
Issuance of common stock under employee and director stock option and purchase plans	949	1	7,338				7,339

Issuance of common stock for acquisitions	452		10,501					10,501
Stock-based compensation expense			13,621					13,621
Unrealized loss on marketable securities and foreign currency translation					79			79
Net loss						(11,265)		(11,265)
Balance at December 31, 2007	35,330	$ 35	$ 364,469	$	$ 54	$ (167,980)	$	196,578

See accompanying notes to consolidated financial statements.

NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2007	2006	2005
		(In thousands)	
Operating activities:			
Net loss	$ (11,265)	$ (47,910)	$ (30,339)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	12,952	8,350	4,359
In-process research and development			12,897
Stock-based compensation	13,621	13,345	3,040
NeoDisc technology costs		8,060	
Reserve recorded for obsolete inventory in connection with planned 2006 product introductions and enhancements		343	
Allowance for doubtful accounts	882	124	443
Allowance for excess and obsolete inventory	827	1,769	535
Other	187	53	539
Changes in operating assets and liabilities:			
Accounts receivable	(9,418)	(7,422)	(5,219)
Inventory	(18,339)	(8,878)	(6,864)
Prepaid expenses and other current assets	349	(220)	(370)
Accounts payable and accrued liabilities	5,719	3,987	(1,303)
Accrued payroll and related expenses	3,598	2,794	2,427
Net cash used in operating activities	(887)	(25,605)	(19,855)
Investing activities:			
Cash paid for acquisition	(6,970)		(8,800)
Purchases of property and equipment	(24,403)	(20,396)	(12,675)
Purchases of short-term marketable securities	(75,135)	(130,510)	(44,918)
Sales of short-term marketable securities	129,818	63,525	88,566
Purchases of long-term marketable securities	(23,540)	(1,996)	
Sales of long-term marketable securities	17,000		
Other assets	(2,483)	(452)	(75)
Net cash provided by (used in) investing activities	14,287	(89,829)	22,098
Financing activities:			
Payments of long-term liabilities	(300)	(300)	(18)
Issuance of common stock	7,339	144,665	1,760
Net cash provided by financing activities	7,039	144,365	1,742
Increase in cash and cash equivalents	20,439	28,931	3,985
Cash and cash equivalents at beginning of year	41,476	12,545	8,560
Cash and cash equivalents at end of year	$ 61,915	$ 41,476	$ 12,545
Supplemental disclosure of non-cash transactions:			
Issuance of common stock for NeoDisc technology costs	$	$ 8,060	$
Issuance of common stock in connection with acquisitions	$ 10,501	$	$ 12,270

See accompanying notes to consolidated financial statements.

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Significant Accounting Policies

Description of Business. NuVasive, Inc. (the Company or NuVasive) was incorporated in Delaware on July 21, 1997. The Company designs, develops and markets products for the surgical treatment of spine disorders and operates in one business segment. The Company began commercializing its products in 2001. Its current product portfolio is focused primarily on applications for spine fusion surgery. Its principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS ™ , as well as a growing offering of cervical and motion preservation initiatives. Currently-marketed products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. The Company also focuses significant research and development efforts on MAS and motion preservation products in the areas of (i) fusion procedures in the lumbar and thoracic spine, (ii) cervical fixation products, and (iii) motion preservation initiatives such as total disc replacement and nucleus-like cervical disc replacement. The Company dedicates significant resources to sales and marketing efforts, including training spine surgeons on its unique technology and products.

The Company loans its MAS systems to surgeons and hospitals who purchase disposables and implants for use in individual procedures. In addition, NeuroVision, MaXcess and surgical instrument sets are placed with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of disposables and implants. The Company also sells a small quantity of MAS instrument sets, and MaXcess and NeuroVision systems to hospitals. The Company also offers a range of bone allograft in patented saline packaging and spine implants such as rods, plates and screws. Implants and disposables are shipped from the Company s facilities or from limited disposable inventories stored at independent sales agents sites.

In 2006, the Company began its first clinical trial in the United States for the NeoDisc cervical disc replacement device.

Basis of Presentation and Principles of Consolidation. The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, NuVasive Europe GmbH and NuVasive UK Limited. All significant intercompany balances and transactions have been eliminated in consolidation. There has been no material activity by the Company s subsidiaries during the years presented.

Use of Estimates. To prepare financial statements in conformity with generally accepted accounting principles accepted in the United States of America, management must make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Reclassification. Certain reclassifications to prior period information have been made for consistent presentation. Specifically, in 2006 and 2005 the Company classified all bonus expense in sales, marketing and administrative expense in the statement of operations. Beginning in 2007, such expense is classified according to employee function. Expense of $0.8 million and $0.5 million in 2006 and 2005, respectively, has been reclassified from sales, marketing and administrative expense to research and development expense to conform to this presentation change.

Cash, Cash Equivalents and Short-term Marketable Securities. The Company classifies investments with original maturities of 90 days or less when acquired as cash equivalents. All of the Company s short-term marketable securities are classified as available-for-sale and are reported at fair value, with unrealized gains and losses included in stockholders equity as a component of accumulated other comprehensive loss. Any unrealized gains or losses deemed other than temporary will be reflected in interest and other income (expense), net. The cost of securities sold is based on the specific identification method and realized gains and losses are included in interest and other income (expense), net. The Company has cash equivalents and investments with various high quality institutions and, by policy, limits the amount of credit exposure to any one institution.

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accounts Receivable and Related Valuation Account. Accounts receivable in the accompanying consolidated balance sheets are presented net of allowance for doubtful accounts.

The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for specific receivables if and when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices as well as a review of the overall quality and age of those invoices not specifically reviewed. In determining the provision for invoices not specifically reviewed, the Company analyzes historical collection experience and current economic trends. If the historical data used to calculate the allowance provided for doubtful accounts does not reflect the Company s future ability to collect outstanding receivables or if the financial condition of customers were to deteriorate, resulting in impairment of their ability to make payments, an increase in the provision for doubtful accounts may be required.

Fair Value of Financial Instruments. The carrying value of cash and cash equivalents, accounts receivable, and accounts payable and accrued expenses are considered to be representative of their respective fair values because of the short-term nature of those instruments.

Concentration of Credit Risk and Significant Customers. Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and cash equivalents, short-term marketable securities and accounts receivable. The Company limits its exposure to credit loss by placing its cash and investments with high credit quality financial institutions. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity. No single customer represented greater than 10 percent of sales for any of the years presented.

Inventory. Inventory is stated at the lower of cost or market and is recorded in cost of goods sold based on a method that approximates specific identification. The Company reviews the components of its inventory on a periodic basis for excess, obsolete and impaired inventory, and records a reserve for the identified items. At December 31, 2007 and 2006, the balance of the allowance for excess and obsolete inventory is $3.6 million and $2.9 million, respectively.

Long-Term Assets. Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets (ranging from two to seven years). Leasehold improvements are amortized using the straight-line method over the estimated useful life of the asset or the lease term, whichever is shorter. Building and improvements are depreciated over a period of 20 years. Intangible assets, consisting of purchased and licensed technology and a supply agreement, are amortized on a straight-line basis over their estimated useful lives of 14 to 20 years. The Company evaluates its long-term assets for

indications of impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If this evaluation indicates that the value of the long-term asset may be impaired, the Company makes an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the long-term asset is not recoverable, the Company reduces the net carrying value of the related asset to fair value and may adjust the remaining depreciation or amortization period. If indicators of impairment are present, the initial evaluation of intangible assets is based on the estimated undiscounted future cash flows of the technology over the remaining amortization period.

In the third quarter of 2006, the Company launched several new products and/or product enhancements, including the MaXcess III retractor system, next generation instrument sets for spine fusion procedures and three new radiolucent CoRoent ® implants. In connection with these launches, certain instruments were rendered obsolete as of the launch date. As a result, the Company reduced the useful life of such instruments to end on the respective launch dates and incurred additional depreciation expense of $61,000 and $646,000 in 2007 and 2006, respectively. This depreciation expense is included in cost of goods sold in the accompanying statement of operations.

The Company has not recognized any other impairment losses on its long-term assets through December 31, 2007.

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue Recognition. The Company follows the provisions of the Securities and Exchange Commission s Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition,* which sets forth guidelines for the timing of revenue recognition based upon factors such as passage of title, installation, payment and customer acceptance. The Company recognizes revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectibility is reasonably assured. Specifically, revenue from the sale of implants and disposables is recognized upon receipt of a purchase order from the hospital indicating product use or implantation or upon shipment to third party customers who immediately accept title. Revenue from the sale of instrument sets is recognized upon receipt of a purchase order and the subsequent shipment to customers who immediately accept title.

Research and Development. Research and development costs are expensed as incurred.

Product Shipment Costs. Product shipment costs are included in sales, marketing and administrative expense in the accompanying consolidated statements of operations.

Income Taxes. In accordance with SFAS No. 109, *Accounting for Income Taxes,* a deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities as measured by the enacted tax rates which will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

Net Loss Per Share. The Company computes net loss per share using the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period. Due to the net loss reported in all periods, the effect of stock options is anti-dilutive and is therefore excluded. Although these options are currently not included in the net loss per share calculation, they could be dilutive when, and if, the Company reports future earnings.

	Years Ended December 31,		
	2007	2006	2005
	(In thousands, except per share data)		
Numerator:			

Reported net loss	$ (11,265)	$ (47,910)	$ (30,339)
Denominator for basic and diluted net loss per share:			
Weighted-average common shares	34,782	32,501	24,473
Basic and diluted net loss per share	$ (0.32)	$ (1.47)	$ (1.24)

In 2007, 2006, and 2005, potential common stock equivalents, as of the end of the year, excluded from historical diluted loss per share because of their anti-dilutive effect totaled 4.4 million, 3.9 million and 3.3 million shares, respectively.

Stock-Based Compensation. On January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which establishes accounting for share-based awards exchanged for employee and non-employee director services and requires the Company to expense the estimated fair value of these awards over the requisite service period. The Company has no awards with market or performance conditions. In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) 107, which provided supplemental implementation guidance for SFAS 123(R). The Company has applied the provisions of SAB 107 in the adoption of SFAS 123(R). Prior to January 1, 2006, the Company accounted for its share-based awards to employees and directors using the

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

intrinsic value method under the recognition and measurement provisions of Accounting Principles Board Opinion (APB) 25, *Accounting for Stock Issued to Employees,* and related guidance.

The Company elected to adopt the modified prospective transition method permitted by SFAS 123(R) and accordingly prior periods have not been restated to reflect the impact of SFAS 123(R). The modified prospective transition method requires that stock-based compensation expense be recorded for (i) any share-based awards granted to employees and non-employee directors through, but not yet vested as of December 31, 2005 based on the grant-date fair value estimated in accordance with the pro forma provisions of SFAS 123, *Accounting for Stock-Based Compensation* (SFAS 123), and (ii) any share-based awards granted to employees and non-employee directors subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

Comprehensive Income (Loss). SFAS No. 130, *Reporting Comprehensive Income,* requires that all components of comprehensive income, including net income, be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss which includes the unrealized gain (loss) on short-term marketable securities and foreign currency translation adjustments for the years ended December 31, 2007, 2006 and 2005, did not differ significantly from the reported net loss.

2. Business Combinations

Radius Acquisition. On January 23, 2007, NuVasive and Radius Medical, LLC (Radius), along with certain members and managers of Radius, entered into an Asset Purchase Agreement (the Purchase Agreement) providing for the acquisition by NuVasive of substantially all of Radius right, title and interest in and to the assets used by Radius in connection with the design, development, marketing and distribution of collagen-based medical biomaterials, together with the intellectual property rights, contractual rights, inventories, and certain liabilities related thereto. The Company has included the results of the acquired Radius operations in its statement of operations from the date of the acquisition. The Company does not consider the Radius acquisition material to its results of operations or financial position, and therefore is not presenting pro forma information.

Reasons for the Radius Acquisition. The transaction provides NuVasive with a biologic product, FormaGraft ® , a synthetic bone void filler designed to aid in bone growth with fusion procedures, and a platform for future development. FormaGraft received 510(k) clearance from the Food and Drug Administration (FDA) in May 2005. The acquisition is consistent with the Company s objectives of developing or acquiring innovative technologies.

In connection with the transaction, Radius received net cash payments of approximately $5.0 million and 451,677 unregistered shares of NuVasive common stock, which were subsequently registered. NuVasive also funded at closing $2 million in cash into an escrow account, which will be maintained for a period of eighteen months from the acquisition date to secure the indemnification obligations of Radius and its members under the Purchase Agreement. At the end of this eighteen month period, the funds held in escrow that are not subject to pending indemnification claims will be disbursed to Radius.

As part of the acquisition, NuVasive also acquired, as of January 23, 2007, all of Radius right, title and interest in and to that certain Supply Agreement dated November 4, 2004, by and between Maxigen Biotech, Inc. (MBI) and Radius, as amended to date (the MBI Supply Agreement). MBI is a Taiwanese company that manufactures FormaGraft and owns a portion of the core technology underlying FormGraft. Under the MBI Supply Agreement and following NuVasive s succession to Radius interest therein, MBI has agreed to exclusively sell to NuVasive (and NuVasive has agreed to exclusively purchase from MBI) such quantities as NuVasive may order of all current and future products manufactured by MBI for use as synthetic bone graft substitutes consisting of certain collagens or ceramics, and grants exclusive distributor rights to NuVasive for North America, EU countries, South American and Central American countries, Australia, New Zealand and their respective territories (with additional territories

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

on a non-exclusive basis). NuVasive is required to purchase a minimum of $0.9 million of product from MBI per calendar year. In 2007, NuVasive purchased a total of $1.9 million of product from MBI. MBI has also granted to NuVasive an exclusive, perpetual, royalty-free license to use all such MBI products, and all related proprietary rights and proprietary information relating thereto, including without limitation, rights to conduct research and development, develop modifications, improvements or additional products and to use and sell such improvements and additional products. Radius was required to pay MBI a one-time license fee in consideration for the above described license, which obligation was satisfied by Radius.

Purchase Price. The total purchase consideration consisted of (*in thousands, except share and per share data*):

Net cash paid to Radius	$	4,970
NuVasive common stock issued on the closing date (451,667 shares at $23.25 per share)		10,501
Cash deposited in escrow		2,000
Acquisition-related costs, consisting primarily of professional fees		306
Total purchase price	$	17,777

The Company has allocated the total purchase consideration to the assets acquired based on their respective fair values at the acquisition date. The following table summarizes the preliminary allocation of the purchase price (*in thousands*).

MBI Supply Agreement	$	9,400
Licensed technology		7,145
Inventory		132
Goodwill		1,100
Total purchase price	$	17,777

In connection with the acquisition of Radius, NuVasive made a separate $2.0 million equity investment in MBI. On May 1, 2007, the equity investment in MBI was completed resulting in NuVasive ownership of approximately 9% of MBI. The Company accounts for this investment at cost and includes it in other assets on the consolidated balance sheet.

RSB Acquisition. On June 3, 2005, the Company acquired the intellectual property and related assets for cervical plate technology from RSB Spine LLC (RSB), a privately owned company focused on spine technology (the RSB Acquisition), in a purchase business combination transaction. The Company has included the results of the acquired RSB operations in its statement of operations from the date of the acquisition. The Company does not consider the RSB Acquisition material to its results of operations or financial position, and therefore is not presenting pro forma information.

The total purchase consideration of $8.5 million consisted of cash paid of $4.0 million, including professional fees, common stock issued valued at $3.5 million for accounting purposes and deferred consideration payable of $1.1 million.

The allocation of the purchase consideration to the assets and liabilities acquired resulted in an excess of the fair value of net tangible and intangible assets acquired over the total purchase price of approximately $874,000 which has been recorded as a long-term liability in accordance with Statement of Financial Accounting Standards No. 141, *Business Combinations.*

Under the acquisition agreement, RSB will receive four annual non-contingent deferred purchase consideration payments of $300,000 through June 2009. In addition, RSB will receive annual payments over a period of 12 years based upon sales of the products derived from the cervical plate technology. Any amounts paid under this

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

arrangement will first be applied to reduce the long-term liability and then will be recorded as goodwill when incurred. The recorded values of the long-term liability and the shares issued have been reduced to reflect this adjustment.

In exchange for contingent cash payments totaling $500,000 through June 2009, the purchase agreement granted NuVasive the right of first refusal on all additional existing technologies and any future technology that may be developed by RSB in the five years following the closing date. Through December 31, 2007, a total of $200,000 has been paid under this term of the agreement. In January 2007, an additional agreement was entered into with RSB under which the Company relinquished its right of first refusal to certain technologies that may be developed by RSB and eliminated its contingent obligation to make the additional $300,000 in cash payments and agreed to make one additional non-contingent cash payment of $50,000 in June 2009.

In connection with the original transaction with RSB, NuVasive has written off assets, consisting primarily of inventory, totaling approximately $497,000 for the initial alpha/beta testing of the Company s own cervical plate under development. The charge is recorded in cost of goods sold in the accompanying consolidated statement of operations for the year ended December 31, 2005.

3. Asset Acquisitions

On August 4, 2005, NuVasive acquired technology and assets from Pearsalls Limited, a privately-owned company based in the United Kingdom (Pearsalls). The acquired assets include an investigational nucleus-like cervical disc replacement device called NeoDisc ® . Also acquired was all of Pearsall s intellectual property related to embroidery technology for use in surgical implants. NuVasive made a closing payment of $12.0 million, consisting of $5.0 million in cash and $7.0 million in unregistered common stock which has subsequently been registered. In addition, the transaction provided for NuVasive to make additional payments totaling up to $31.5 million as progress is made towards FDA approval for marketing of the NeoDisc product. Finally, the agreement called for Pearsalls to receive a royalty of 5% on NeoDisc product sales. No royalties will be due on other products based on the acquired technology, except for a limited royalty on products for non-spine applications.

The total purchase consideration of $13.0 million consisted of cash paid of $5.3 million, including professional fees, and common stock issued valued at $7.7 million for accounting purposes.

The purchase price has been allocated to the fair value of the assets acquired at the date of the acquisition consisting of fixed assets of $113,500. The remaining purchase price of $12.9 million has been allocated to in-process research and development (IPRD) because the projects associated with the IPRD efforts had not yet reached technological feasibility and the research and development in process had no alternative future uses. Accordingly, the $12.9 million was charged to expense on the acquisition date.

In June 2006, the Company received conditional FDA approval of the Investigational Device Exemption to begin clinical trial enrollment for our NeoDisc cervical disc replacement device. This FDA approval was a development milestone under the Pearsall s agreement, and resulted in a payment obligation by us of $10.5 million which accrued in the second quarter of 2006. In September 2006, the Company entered into an additional agreement with Pearsalls, resulting in a total payment of $20.0 million in settlement of (i) the $10.5 million liability recorded in the second quarter of 2006; (ii) future contingent milestone payments of up to $21.0 million; and (iii) certain future contingent royalty payments; all of which relate to NeoDisc and related technology. The terms of the additional agreement also render the manufacturing relationship for NeoDisc non-exclusive, giving NuVasive control over the manufacturing of NeoDisc, and effects the transfer of intellectual property rights to NuVasive. The $20 million total payment consisted of $12 million in cash and $8 million in NuVasive stock and is recorded as technology development costs in the consolidated statement of operations. The total charge recorded in 2006 was $20.1 million, including transaction costs, and has been charged to expense in 2006 because the projects associated with the IPRD efforts, as of the date of the 2006 transaction, had still not yet reached technological feasibility and the continuing research and development in process had no alternative future uses.

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On August 12, 2005, NuVasive acquired assets and intellectual property from RiverBend Design LLC (RiverBend), pursuant to the terms of an Intellectual Property Purchase Agreement. The acquired intellectual property includes a patent application and related technology and know-how for use in developing dynamic stabilization products. NuVasive made a closing payment to RiverBend of 51,308 unregistered shares of common stock which have subsequently been registered. In addition, NuVasive will make royalty payments to RiverBend based on sales of products based on the acquired technology. The purchase price of $1.0 million has been allocated to purchased technology and is being amortized on a straight-line basis over the estimated useful life of 17 years.

At the same time as the transaction with RiverBend, NuVasive executed an Intellectual Property Purchase Agreement Addendum (the Addendum) with Spine Partners LLC (Spine Partners), a company affiliated with RiverBend. The Addendum amended the terms of the Intellectual Property Purchase Agreement dated October 10, 2002, between NuVasive and Spine Partners. The Addendum adjusts the royalty payments due to Spine Partners for the NuVasive SpheRx multi-axial pedicle screws. The Addendum also effects the transfer to NuVasive of multiple patent applications and related technology and know-how relating to pedicle-based dynamic stabilization systems.

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Balance Sheet Details

Cash Equivalents and Marketable Securities. Short-term marketable securities include auction rate securities, commercial paper, government securities and corporate bonds that are classified as available-for-sale as follows:

	Cost	Estimated Fair Value
	(In thousands)	
December 31, 2007		
Classified as current assets		
Money market funds	$ 52,469	$ 52,469
Commercial paper	9,261	9,251
Corporate notes	9,987	9,996
	71,717	71,716
Less cash equivalents	(52,469)	(52,469)
Short-term marketable securities	19,248	19,247
Classified as non-current assets		
Corporate notes	1,501	1,501
Debt securities issued by the U.S. Treasury and other U.S. government agencies	7,022	7,035
Total marketable securities at December 31, 2007	$ 27,771	$ 27,783
December 31, 2006		
Classified as current assets		
Money market funds	$ 8,910	$ 8,910
Commercial paper	66,733	66,708
Auction rate securities	26,600	26,600
	102,243	102,218
Less cash equivalents	(28,288)	(28,288)
Short-term marketable securities	73,955	73,930
Classified as non-current assets Debt securities issued by the U.S. Treasury and other U.S. government agencies	2,000	1,996
Total marketable securities at December 31, 2006	$ 75,955	$ 75,926

As of December 31, 2007, the stated maturities of our investments are $71.7 million within one year and 8.5 million within one to three years. These investments are recorded on the balance sheet at fair market value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income. There are no material unrealized gains or losses at December 31, 2007.

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property and Equipment. Property and equipment consisted of the following (*in thousands*)*:*

	December 31, 2007	2006
Loaner equipment	$ 42,292	$ 28,725
Machinery and equipment	7,879	6,267
Computer equipment and software	8,128	2,232
Leasehold improvements	3,861	2,884
Furniture and fixtures	1,422	1,239
Land, building and improvements	4,896	4,840
	68,478	46,187
Less: accumulated depreciation and amortization	(24,940)	(15,614)
	$ 43,538	$ 30,573

Goodwill and Intangible Assets. Goodwill and intangible assets were acquired in connection with the business combination and asset acquisitions discussed in Notes 2 and 3. Goodwill represents the excess of the aggregate purchase price over the fair value of the tangible and identifiable intangible assets acquired by the Company. The goodwill recorded as a result of the business combinations in the years presented is not deductible for tax purposes. Goodwill is not amortized, but rather is tested for impairment at least annually in accordance with Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). The Company has determined that it is a single reporting unit for the purpose of goodwill impairment tests under SFAS 142. During the year ended December 31, 2007 there was no impairment to goodwill. As of December 31, 2007, the carrying amount of goodwill was $1.1 million.

Goodwill and intangible assets as of December 31, 2007 consisted of the following *(in thousands)*:

	Weighted Average Amortization Period in Years	Gross Assets	Accumulated Amortization	Net Assets
Goodwill		$ 1,100	$	$ 1,100
Purchased Technology	17	9,200	1,388	7,812
Licensed Technology	14	7,145	334	6,811
Supply Agreement	20	9,400	627	8,773
Total		$ 26,845	$ 2,349	$ 24,496

Intangible assets as of December 31, 2006 consisted of the following *(in thousands)*:

	Gross Assets	Accumulated Amortization	Net Assets
Other	$ 100	$ 12	$ 88
Purchased Technology	9,200	847	8,353
Total	$ 9,300	$ 859	$ 8,441

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Total amortization expense related to intangible assets is set forth in the table below *(in thousands)*:

	Year Ended December 31,		
	2007	**2006**	**2005**
Purchased Technology	$ 541	$ 541	$ 306
Supply Agreement	334		
Licensed Technology	627		
Other	15	12	
Total	$ 1,517	$ 553	$ 306

The estimated future amortization of intangible assets on an annual basis is $1.5 million per year for each of the next five years, with the balance of $15.8 million to be expensed through 2027.

Accounts Payable and Accrued Liabilities. Accounts payable and accrued liabilities consisted of the following (*in thousands*) *:*

	December 31,	
	2007	**2006**
Accounts payable	$ 1,680	$ 3,543
Accrued expense	6,085	3,566
Other	6,074	1,829
	$ 13,839	$ 8,938

5. Commitments and Contingencies

The Company leases its corporate headquarters under an operating lease, which expires on August 31, 2012. The minimum annual rent on the Company s facility is subject to increases based on stated rental adjustment terms of certain leases, taxes, insurance and operating costs. For financial reporting purposes, rent expense is recognized on a straight-line basis over the term of the lease. Accordingly, rent expense recognized in excess of rent paid is reflected as deferred rent and is included in accounts payable and accrued liabilities in the accompanying consolidated balance sheets.

On November 6, 2007, the Company entered into a 15-year operating lease agreement for the purpose of relocating its corporate headquarters to an approximately 140,000 square feet two-building campus style complex. Rental payments will consist of base rent of $2.43 per square foot per month, escalating at an annual rate of three percent over the 15-year period of the lease, plus related operating expenses. The lease provides an allowance of $6.0 million for tenant improvements and certain rent abatements through November 2008. Relocation to the new facility is expected to be completed in phases in the second and third quarters of 2008. In addition, through options to acquire additional space in the

project and to require the construction of an additional building on the campus, the agreement provides for facility expansion rights to an aggregate of more than 300,000 leased square feet. In connection with the lease, the Company has issued a $3.1 million irrevocable transferrable letter of credit secured by a cash investment.

Subsequent to the relocation date, the Company expects to sublease the current facility through August 2012, the date on which the related lease agreement expires, and expects lease income to approximate lease expense on the current facility.

In 2007, NuVasive entered into various contracts for improvements and furnishings related to the lease of a larger corporate headquarters facility as discussed above. Total tenant improvements and related purchases to be paid by NuVasive are estimated to be $8.4 million. NuVasive has entered into contractual agreements related to

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

these tenant improvements and related purchases of which $5.8 million remains committed as of December 31, 2007.

During 2007, NuVasive entered into contracts relative to installation, modification and maintenance of an enterprise reporting system. Total remaining commitments total $1.3 million at December 31, 2007.

The Company s future minimum annual lease payments, including payments for costs directly associated with the facility leases, and long-term contractual obligations for years ending after December 31, 2007 are as follows *(in thousands):*

	Operating Leases	Other Contractual Obligations
2008	$ 4,244	$ 2,129
2009	7,995	2,015
2010	8,327	1,566
2011	8,590	1,370
2012	8,218	1,400
Thereafter	84,637	4,432
Total minimum payments	$ 122,011	$ 12,912

Other contractual obligations consist of certain intellectual property purchase and consulting agreements for which the Company is required to make annual payments.

In connection with the acquisition of RSB described in Note 2, the Company is contingently obligated to make additional annual payments over a period of 12 years based upon sales of the products derived from the cervical plate technology. Through December 31, 2007, these amounts have not been significant.

As a result of the acquisition of Radius Medical LLC in January 2007, the Company is obligated to purchase, on an annual basis, a minimum number of units of FormaGraft from Maxigen Biotech, Inc. at an annual cost of approximately $900,000.

The expected timing of payments of the obligations discussed above is estimated based on current information. Timing of payment and actual amounts paid may be different depending on the time of receipt of goods or services or changes to agreed-upon amounts for some obligations. Amounts disclosed as contingent or milestone-based obligations depend on the achievement of the milestones or the occurrence of the contingent events and can vary significantly.

Rent expense, including expenses directly associated with the facility leases, was approximately $1.8 million for each of the years ended December 31, 2007, 2006 and 2005.

The Company is party to certain claims and legal actions arising in the normal course of business. The Company does not expect any such claims and legal actions to have a material adverse effect on its business, results of operations or financial condition.

6. Stockholders Equity

There are 5,000,000 shares of preferred stock authorized and none issued or outstanding at December 31, 2007 and 2006.

Stock Options. In October 1998, the Company adopted the 1998 Stock Incentive Plan (the 1998 Plan) to grant options to purchase common stock to eligible employees, non-employee members of the board of directors, consultants and other independent advisors who provide services to the Company. Under the 1998 Plan, 3,922,800 shares of common stock, as amended, were reserved for issuance upon exercise of options granted

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

by the Company. The board of directors determines the terms of the stock option agreements, including vesting requirements. Options under the 1998 Plan have a 10-year term and generally vest over a period not to exceed four years from the date of grant. All options granted under the 1998 Plan allow for early exercise prior to the option becoming fully vested. Unvested common shares obtained upon early exercise of options are subject to repurchase by the Company at the original issue price.

In April 2004, the board of directors replaced the 1998 Plan with the 2004 Equity Incentive Plan (the 2004 Plan) under which 800,000 shares (plus the remaining shares available for grant under the 1998 Plan) of the Company s common stock are authorized for future issuance, and reserved for purchase upon exercise of options granted. In addition, the 2004 Plan provides for automatic annual increases in the number of shares reserved for issuance thereunder equal to the lesser of (i) 4% of the Company s outstanding shares on the last business day in December of the calendar year immediately preceding; (ii) 4,000,000 shares; or (iii) a number of shares determined by the board of directors.

The 2004 Plan provides for the grant of incentive and nonstatutory stock options and rights to purchase stock to employees, directors and consultants of the Company. The 2004 Plan provides that incentive stock options will be granted only to employees and are subject to certain limitations as to fair value during a calendar year. Under the 2004 Plan, the exercise price of incentive stock options must equal at least the fair value on the date of grant and the exercise price of non-statutory stock options and the issuance price of common stock under the stock issuance program may be no less than 85% of the fair value on the date of grant or issuance. The options are exercisable for a period of up to ten years after the date of grant and generally vest 25% one year from date of grant and ratably each month thereafter for a period of 36 months. In addition, the board of directors has provided for the acceleration of 50% of the unvested options of all employees upon a change in control and the vesting of the remaining unvested options for those employees that are involuntarily terminated within a year of the change in control.

Also in April 2004, the board of directors approved the Employee Stock Purchase Plan (ESPP). The ESPP initially allowed for the issuance of up to 100,000 shares of NuVasive common stock, increasing annually on December 31 by the lesser of (i) 600,000 shares; (ii) 1% of the outstanding shares of NuVasive common stock; or (iii) a lesser amount determined by the board of directors. Under the terms of the ESPP, employees can elect to have up to 15% of their annual compensation, up to a maximum of $25,000 per year withheld to purchase shares of NuVasive common stock. The purchase price of the common stock is equal to 85% of the lower of the fair market value per share of the common stock on the commencement date of the two-year offering period or the end of each semi-annual purchase period. In 2007, 2006, and 2005, 113,494, 106,258, and 57,276 shares, respectively, were purchased under the ESPP and 626,227 remain available for issuance under the ESPP as of December 31, 2007.

In November 2003, the Company amended the 1998 Plan to provide for the acceleration of 50% of the unvested options of all employees upon a change in control and the vesting of the remaining unvested options for those employees that are involuntarily terminated within a year of the change in control. As of December 31, 2007, substantially all of the options affected by the modification are vested.

Through December 31, 2005, the Company had recorded total deferred stock-based compensation for certain options granted during 2003 and 2004 of 8.6 million for the incremental difference at the grant date between the fair value per share determined by the board of directors and the deemed fair value per share determined solely for financial reporting purposes in conjunction with the Company s initial public offering. Deferred stock-based compensation was recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans* (FIN 28), over the

vesting period of the related options, generally four years. Amortization of deferred stock-based compensation through December 31, 2005, net of terminations, was $7.2 million. Upon adoption of SFAS 123(R), the unamortized balance of deferred compensation of $1.2 million at December 31, 2005 was reclassified to additional paid in capital in the Company s consolidated balance sheet. Compensation expense in 2006 and subsequent years, calculated in accordance with SFAS 123(R), related to these options is included as a component of the related expense category within operating expenses.

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock-Based Compensation. On January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which establishes accounting for share-based awards exchanged for employee and non-employee director services and requires the Company to expense the estimated fair value of these awards over the requisite employee service period. The Company has no awards with market or performance conditions. In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) 107, which provided supplemental implementation guidance for SFAS 123(R). The Company has applied the provisions of SAB 107 in the adoption of SFAS 123(R). Prior to January 1, 2006, the Company accounted for its share-based awards to employees and directors using the intrinsic value method under the recognition and measurement provisions of Accounting Principles Board Opinion (APB) 25, *Accounting for Stock Issued to Employees,* and related guidance.

Option or stock awards issued to non-employees are recorded at their fair value as determined in accordance with SFAS 123, *Accounting for Stock-Based Compensation,* and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services,* and are periodically revalued as the options vest and are recognized as expense over the related service period.

For purposes of calculating the stock-based compensation under SFAS 123(R), the Company estimates the fair value of stock options and shares issued under the Employee Stock Purchase Plan using a Black-Scholes option-pricing model which is consistent with the model used for pro forma disclosures under SFAS 123 prior to the adoption of SFAS 123(R). The Black-Scholes option-pricing model was developed for use in estimating the fair value of short lived exchange traded options that have no vesting restrictions and are fully transferable. In addition, the Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. The expected volatility is based on the historical volatility of the Company s common stock over the most recent period commensurate with the estimated expected term of the Company s stock options. The expected term of the Company s stock options is based on historical experience. In addition, in accordance with SFAS 123(R) share-based compensation expense recognized in the statement of operations in 2006 for award grants after January 1, 2006 is based on awards ultimately expected to vest and is reduced for estimated forfeitures. In the Company s pro forma information required under SFAS 123 for the periods prior to 2006, the Company accounted for forfeitures as they occurred.

The assumptions used to estimate the fair value of stock options granted and stock purchase rights under the Employee Stock Purchase Plan (ESPP) are as follows:

	Year Ended December 31,		
	2007 Actual	2006 Actual	2005 Pro Forma
Stock Options			
Volatility	50%	65%	60%
Expected term (years)	2.5 to 4.5	2.5 to 4.5	5.0

Risk free interest rate	3.4% to 4.9%	4.4% to 5.1%	4.1%
Expected dividend yield	0.0%	0.0%	0.0%
ESPP(1)			
Volatility	50%	65%	N/A
Expected term (years)	0.5	0.5	
Risk free interest rate	4.4% to 4.9%	4.4% to 5.0%	
Expected dividend yield	0.0%	0.0%	

(1) Shares issued under the ESPP were insignificant in periods prior to 2006.

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The compensation cost that has been included in the statement of operations for all share-based compensation arrangements was as follows for the three years ended December 31, 2007, 2006 and 2005:

	Years Ended December 31,		
	2007	2006	2005
	(In thousands, except per share amounts)		
Sales, marketing and administrative expense	$ 11,404	$ 10,581	$ 1,635
Research and development expense	2,217	2,764	1,405
Stock based compensation expense	$ 13,621	$ 13,345	$ 3,040
Effect on basic and diluted net loss per share	$ (0.39)	$ (0.41)	$ (0.12)

Stock-based compensation related to stock options is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans* (FIN 28). As of December 31, 2007, there was $10.6 million of unrecognized compensation expense for stock options which is expected to be recognized over a weighted-average period of approximately 1.1 years. In addition, as of December 31, 2007, there was $0.9 million of unrecognized compensation expense for shares expected to be issued under the Employee Stock Purchase Plan which is expected to be recognized through April 2008. The total intrinsic value of options exercised was $20.2 million, $8.0 million and $5.4 million, respectively, the years ended December 31, 2007, 2006 and 2005.

The following table illustrates the effect on net losses as if the Company had applied the fair value recognition provisions of SFAS 123 to determine stock-based compensation in 2005:

	Year Ended December 31, 2005
	(In thousands, except per share amounts)
Net loss as reported	$ (30,339)
Add: Stock-based compensation included in net loss	2,052
Deduct: Stock-based employee and director compensation expense determined under fair value method for all awards	(5,209)
Pro forma net loss	$ (33,496)
Basic and diluted net loss per share as reported	$ (1.24)
Basic and diluted pro forma net loss per share	$ (1.37)

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Following is a summary of stock option activity through December 31, 2007 under all stock option plans:

	Underlying Shares	Weighted Avg. Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value as of December 31, 2007
		(In thousands, except per share data)		
Outstanding at December 31, 2004	2,970	$ 5.02		
Granted	1,043	$ 15.70		
Exercised	(427)	$ 3.02		
Cancelled	(316)	$ 9.37		
Outstanding at December 31, 2005	3,270	$ 8.27		
Granted	1,331	$ 18.41		
Exercised	(485)	$ 2.99		
Cancelled	(205)	$ 13.70		
Outstanding at December 31, 2006	3,911	$ 12.07		
Granted	1,394	$ 24.61		
Exercised	(830)	$ 6.45		
Cancelled	(113)	$ 17.85		
Outstanding at December 31, 2007	4,362	$ 16.97	7.74	$ 98,480
Exercisable at December 31, 2007	2,101	$ 12.11	6.93	$ 57,578
Vested or Expected to Vest at December 31, 2007	4,234	$ 17.99	7.87	$ 96,355

The weighted-average fair value of options granted in the years ended December 31, 2007, 2006 and 2005, was $10.81, $9.68 and $8.64 per share, respectively. The aggregate intrinsic value of options at December 31, 2007 is based on the Company s closing stock price on December 31, 2007 of $39.52. The Company received $5.4 million, $1.5 million and $1.3 million in proceeds from the exercise of stock options during the years ended December 31, 2007, 2006 and 2005, respectively.

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes information about stock options outstanding and exercisable at December 31, 2007 *:*

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	**Number of Shares**	**Weighted Average Remaining Contractual Life (Years)**	**Weighted Average Exercise Price (Shares in thousands)**	**Number of Shares**	**Weighted Average Exercise Price**
$0.25 to $3.75	444	5.52	$ 2.93	443	$ 2.93
$9.41 to $9.50	536	6.82	$ 9.50	490	$ 9.50
$9.86 to $1 6.62	566	7.10	$ 13.04	418	$ 12.76
$16.63 to $19.27	1,310	7.74	$ 18.21	642	$ 18.23
$19.28 to $43.20	1,240	8.91	$ 22.87	63	$ 19.72
$24.59 to $35.85	213	9.12	$ 27.61	40	$ 25.57
$36.11 to $43.20	53	9.87	$ 41.15	5	$ 36.64
$0.25 to $43.20	4,362	7.74	$ 16.97	2,101	$ 12.11

Common Stock Reserved for Future Issuance. The following table summarizes common shares reserved for issuance at December 31, 2007 on exercise or conversion of *(in thousands)* :

Common stock options:	
Issued and outstanding	4,362
Available for future grant	387
Available for issuance under the Employee Stock Purchase Plan	626
Total shares reserved for future issuance	5,375

The Company recorded expense of $476,000, $785,000 and $988,000 and in 2007, 2006, and 2005, respectively, related to the vesting of stock options granted to non-employees under consulting agreements, in accordance with EITF 96-18.

7. Income Taxes

On July 13, 2006, the FASB issued FIN 48. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted the provisions of FIN 48 on January 1, 2007. There were no unrecognized tax benefits as of the date

of adoption. As a result of the implementation of FIN 48, the Company did not recognize an increase in the liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company s policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company s balance sheets at December 31, 2007 and 2006, and has not recognized interest and/or penalties in the statement of operations for the year ended December 31, 2007.

The Company is subject to taxation in the United States and various state jurisdictions. All of the Company s tax years are subject to examination by the United States and California tax authorities due to the carry forward of unutilized net operating losses and R&D credits.

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The adoption of FIN 48 did not impact the Company s financial condition, results of operations or cash flows. At December 31, 2007, the Company had net deferred tax assets of $55.2 million. Due to uncertainties surrounding the Company s ability to generate future taxable income to realize these assets, a full valuation has been established to offset the net deferred tax asset. Additionally, the future utilization of the Company s net operating loss and research and development credit carry forwards to offset future taxable income may be subject to an annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that may have occurred previously or that could occur in the future. Although the Company determined that an ownership change had not occurred through December 31, 2006, it is possible that an ownership change occurred subsequent to that date.

The Company is analyzing its research and development costs and has not yet completed the analysis. Until this analysis is completed, the Company has removed the deferred tax assets for research and development credits of $6.4 million generated through 2007 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits under FIN 48. Due to the existence of the valuation allowance, future changes in the Company s unrecognized tax benefits will not impact the Company s effective tax rate.

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company s deferred tax assets and liabilities at December 31, 2007 and 2006 are as follows:

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carryforwards	$ 35,446	$ 35,556
Income tax credit carryforwards		4,720
Capitalized assets and other	12,384	11,398
Other	7,407	6,965
	55,237	58,639
Valuation allowance	(55,237)	(58,639)
Total deferred tax assets, net of valuation allowance	$	$

8. Impact of Recently Issued Accounting Standards.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards required (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is currently evaluating the effect that the adoption of SFAS 157 will have on its consolidated results of operations and financial condition and is not yet in a position to determine such effects.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, such as debt issuance costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS 159, changes in fair value are recognized in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and is required to be adopted by the Company in the first quarter of fiscal 2008. The Company is currently determining whether fair value accounting is appropriate for any of the eligible items and cannot estimate the impact, if any, that SFAS 159 will have on the Company s consolidated results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141R). SFAS 141R requires the use of full fair value to record all the identifiable assets, liabilities, noncontrolling interests and goodwill acquired in a business combination. SFAS 141R is effective for fiscal years beginning on or after December 15, 2008.

9. Quarterly Data (unaudited)

The following quarterly financial data, in the opinion of management, reflects all adjustments, consisting of normal recurring adjustments necessary, for a fair presentation of results for the periods presented *(in thousands except per share data):*

	Year Ended December 31, 2007			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenues	$ 33,220	$ 35,618	$ 38,522	$ 46,930
Gross profit	27,513	28,908	31,597	38,890
Total operating expenses	33,792	33,952	35,182	41,234
Net loss	$ (4,420)	$ (3,416)	$ (2,283)	$ (1,146)
Basic and diluted net loss per common share	$ (0.13)	$ (0.10)	$ (0.07)	$ (0.03)

	Year Ended December 31, 2006			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenues	$ 19,685	$ 22,724	$ 25,194	$ 30,488
Gross profit	15,805	17,637	20,289	25,332
Total operating expenses	25,009	37,944	40,809	29,527
Net loss	$ (8,106)	$ (18,470)	$ (18,651)	$ (2,683)
Basic and diluted net loss per common share	$ (0.27)	$ (0.56)	$ (0.56)	$ (0.08)

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Schedule II: Valuation Accounts

	Balance at Beginning of Period	Additions(1)	Deductions(2)	Balance at End of Period
		(In thousands)		
Accounts Receivable Reserve				
Year ended December 31, 2007	$ 737	$ 991	$ 802	$ 926
Year ended December 31, 2006	$ 613	$ 495	$ 371	$ 737
Year ended December 31, 2005	$ 255	$ 443	$ 85	$ 613

	Balance at Beginning of Period	Additions(3)	Deductions(4)	Balance at End of Period
Inventory Reserve				
Year ended December 31, 2007	$ 3,100	$ 3,551	$ 3,037	$ 3,614
Year ended December 31, 2006	$ 1,332	$ 2,685	$ 917	$ 3,100
Year ended December 31, 2005	$ 844	$ 1,019	$ 531	$ 1,332

(1) Amount represents customer balances deemed uncollectible.

(2) Uncollectible accounts written-off, net of recoveries.

(3) Amount represents excess and obsolete reserve recorded to cost of sales. In 2006, this amount includes a reserve of approximately $343,000 recorded in connection with planned 2006 product introductions and enhancements. In 2005, this amount includes an approximately $484,000 write-off of cervical plate inventory in connection with the acquisition of RSB Spine LLC.

(4) Excess and obsolete inventory written-off against reserve.

Index to Exhibits

Exhibit Number	Description
2 .1(1)	Asset Purchase Agreement, dated as of June 3, 2005, by and between NuVasive, Inc. and RSB Spine LLC
2 .2(2)	Agreement, dated as of January 3, 2007, by and between NuVasive, Inc. and RSB Spine LLC
2 .3(3)	Asset Purchase Agreement, dated as of August 4, 2005, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.
2 .4(4)	Amendment No. 1 to Asset Purchase Agreement, dated as of September 26, 2006, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.
2 .5(5)	Intellectual Property Purchase Agreement, dated as of August 12, 2005, by and betweenNuVasive, Inc. and RiverBend Design LLC
2 .6(6)	Asset Purchase Agreement, dated as of January 23, 2007, by and among NuVasive, Inc. and Radius Medical, LLC, Biologic, LLC, Antone Family Partners, Russel Cook and Duraid Antone
3 .1(7)	Restated Certificate of Incorporation
3 .2(7)	Restated Bylaws
4 .1(8)	Second Amended and Restated Investors Rights Agreement, dated July 11, 2002, by and among NuVasive, Inc. and the other parties named therein
4 .2(8)	Amendment No. 1 to Second Amended and Restated Investors Rights Agreement, dated June 19, 2003, by and among NuVasive, Inc. and the other parties named therein
4 .3(8)	Amendment No. 2 to Second Amended and Restated Investors Rights Agreement, dated February 5, 2004, by and among NuVasive, Inc. and the other parties named therein
4 .4(3)	Registration Rights Agreement, dated as of August 4, 2005, between NuVasive, Inc. and Pearsalls Limited
4 .5(4)	Registration Rights Agreement Termination Agreement, dated as of September 26, 2006, between NuVasive, Inc. and Pearsalls Limited
4 .6(17)	Specimen Common Stock Certificate
10 .1(8)#	1998 Stock Option/ Stock Issuance Plan
10 .2(8)#	Form of Notice of Grant of Stock Option under our 1998 Stock Option/ Stock Issuance Plan
10 .3(8)#	Form of Stock Option Agreement under our 1998 Stock Option/ Stock Issuance Plan, and form of addendum thereto
10 .4(8)#	Form of Stock Purchase Agreement under our 1998 Stock Option/ Stock Issuance Plan
10 .5(9)#	Form of Stock Issuance Agreement under our 1998 Stock Option/ Stock Issuance Plan
10 .6(9)#	Form of Stock Issuance Agreement under our 1998 Stock Option/ Stock Issuance Plan, dated April 21, 2004, and May 4, 2004
10 .7(10)#	2004 Equity Incentive Plan
10 .8(10)#	Form of Stock Option Award Notice under our 2004 Equity Incentive Plan
10 .9(10)#	Form of Option Exercise and Stock Purchase Agreement under our 2004 Equity Incentive Plan
10 .10(10)#	Forms of Restricted Stock Grant Notice and Restricted Stock Agreement under our 2004 Equity Incentive Plan
10 .11(10)#	Form of Restricted Stock Unit Award Agreement under our 2004 Equity Incentive Plan
10 .12(10)#	2004 Employee Stock Purchase Plan
10 .13(11)#	Employment Letter Agreement, dated July 12, 1999, as amended on January 20, 2004 and May 23, 2006, between NuVasive, Inc. and Alexis V. Lukianov
10 .14(8)#	Bonus Agreement, dated February 25, 2000, between NuVasive, Inc. and Alexis V. Lukianov
10 .15(8)#	Employment Agreement, dated December 20, 2002, as amended on January 20, 2004, between NuVasive, Inc. and Kevin C. O Boyle
10 .16(11)#	Employment Agreement, dated January 20, 2004, as amended on May 23, 2006, between NuVasive, Inc. and Keith Valentine
10 .17(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and Patrick Miles
10 .18(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and James J. Skinner
10 .19(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and G. Bryan Cornwall
10 .20(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and Jonathan D. Spangler

Exhibit Number	Description
10 .21(12)#	Employment Agreement, dated December 5, 2005, between NuVasive, Inc. and Jeffrey P. Rydin
10 .22(12)#	Employment Agreement, dated December 5, 2005, between NuVasive, Inc. and Jason M. Hannon
10 .23(8)#	Form of Indemnification Agreement between NuVasive, Inc. and each of our directors and officers
10 .24(8)	Intellectual Property Purchase Agreement, dated October 10, 2002, between NuVasive, Inc. and Spine Partners, LLC
10 .25(5)	Intellectual Property Purchase Agreement Addendum, dated as of August 12, 2005, by and between NuVasive, Inc. and Spine Partners, LLC
10 .26(13)	Sublease, dated October 12, 2004, by and between NuVasive, Inc. and Gateway, Inc.
10 .27(11)	Earnest Money Contract and Agreement, dated May 26, 2006, between NuVasive, Inc. and New York Life Insurance Company
10 .28(14)#	Description of 2006 performance bonus arrangements for our executive officers
10 .29(15)#	Description of 2007 annual salaries for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10 .30(16)#	Summary of the 2007 bonus payments to our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10 .31(18)	Customer Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10 .32(18)	IBM Global Services Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10 .33(19)	Lease Agreement for Sorrento Summit, entered into as of November 6, 2007, between the Company and HCPI/Sorrento, LLC.
10 .34(20)#	Description of 2008 annual salaries and annual stock grant for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
21 .1	List of subsidiaries of NuVasive, Inc.
23 .1	Consent of Independent Registered Public Accounting Firm
31 .1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31 .2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
32 .1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350
32 .2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350

(1) Incorporated by reference to our Current Report on Form 8-K filed with the Securities and Exchange Commission (the Commission) on June 9, 2005.

(2) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 9, 2007.

(3) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 10, 2005.

(4) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on September 29, 2006.

(5) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 17, 2005.

(6) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 25, 2006.

(7) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 13, 2004.

(8) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004.

(9) Incorporated by reference to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on May 11, 2004.

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(10) Incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004.

(11) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 30, 2006.

(12) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on December 7, 2005.

(13) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 15, 2004.

(14) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 13, 2006.

(15) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 22, 2007.

(16) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on February 23, 2007.

(17) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006.

(18) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on August 8, 2007.

(19) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on November 8, 2007.

(20) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 11, 2008.

The Commission has granted confidential treatment to us with respect to certain omitted portions of this exhibit (indicated by asterisks). We have filed separately with the Commission an unredacted copy of the exhibit.

# Indicates management contract or compensatory plan.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2008

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 000-50744

NUVASIVE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0768598**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4545 Towne Centre Court

San Diego, CA 92121

(Address of principal executive offices, including zip code)

(858) 909-1800

(Registrant s telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No. x

As of April 30, 2008 there were 35,566,298 shares of the registrant s common stock outstanding.

NUVASIVE, INC.

QUARTERLY REPORT ON FORM 10-Q

March 31, 2008

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EXHIBIT 31.2

EXHIBIT 32

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NUVASIVE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited and in thousands)

	March 31, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 258,529	$ 61,915
Short-term marketable securities	4,952	19,247
Accounts receivable, net	30,335	27,496
Inventory, net	45,684	36,280
Prepaid expenses and other current assets	2,280	1,240
Total current assets	341,780	146,178
Property and equipment, net of accumulated depreciation	54,287	43,538
Intangible assets, net of accumulated amortization	26,159	24,496
Long-term marketable securities	15,118	8,536
Other assets	9,691	2,939
Total assets	$ 447,035	$ 225,687
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 22,096	$ 13,839
Accrued payroll and related expenses	10,347	12,075
Royalties payable	1,853	2,076
Total current liabilities	34,296	27,990
Senior convertible notes	230,000	
Long-term liabilities	989	1,119
Commitments and contingencies		
Stockholders equity:		
Common stock, 70,000 shares authorized; and 35,513 and 35,330 issued and outstanding at March 31, 2008 and December 31, 2007, respectively	35	35
Additional paid-in capital	357,226	364,469
Accumulated other comprehensive income loss	123	54
Accumulated deficit	(175,634)	(167,980)
Total stockholders equity	181,750	196,578
Total liabilities and stockholders equity	$ 447,035	$ 225,687

See accompanying notes to unaudited condensed consolidated financial statements.

NUVASIVE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited and in thousands, except per share data)

	Three Months Ended March 31,	
	2008	**2007**
Revenues	$ 51,184	$ 33,220
Cost of goods sold	9,095	5,707
Gross Profit	42,089	27,513
Operating expenses:		
Sales, marketing and administrative	39,317	28,449
Research and development	6,976	5,343
In-process research and development	4,176	
Total operating expenses	50,469	33,792
Interest and other income, net	726	1,859
Net loss	$ (7,654)	$ (4,420)
Net loss per share:		
Basic and diluted	$ (0.22)	$ (0.13)
Weighted average shares basic and diluted	35,411	34,314

See accompanying notes to unaudited condensed consolidated financial statements.

NUVASIVE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited and in thousands)

	Three Months Ended March 31,	
	2008	**2007**
Operating activities:		
Net loss	$ (7,654)	$ (4,420)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,883	2,854
Stock-based compensation	5,150	3,144
Acquired in-process research and development	4,176	
Other non-cash adjustments	(47)	523
Changes in operating assets and liabilities:		
Accounts receivable	(2,929)	(2,552)
Inventory	(9,306)	(3,362)
Prepaid expenses and other current assets	(1,040)	376
Accounts payable and accrued liabilities	5,260	1,410
Accrued payroll and related expenses	(1,728)	(1,034)
Net cash used in operating activities	(4,235)	(3,061)
Investing activities:		
Cash paid for pedicle screw technology	(6,256)	
Cash paid for acquisition of Radius Medical, LLC		(6,970)
Purchases of property and equipment	(11,369)	(1,698)
Sales of short-term marketable securities	17,300	45,350
Purchases of short-term marketable securities	(3,005)	(30,435)
Sales of long-term marketable securities	2,000	2,000
Purchases of long-term marketable securities	(8,582)	(10,467)
Other assets	740	31
Net cash used in investing activities	(9,172)	(2,189)
Financing activities:		
Issuance of senior convertible notes, net of issuance costs	222,414	
Purchase of convertible note hedges	(45,758)	
Sale of warrants	31,786	
Issuance of common stock	1,579	1,175
Net cash provided by financing activities	210,021	1,175
Increase (decrease) in cash and cash equivalents	196,614	(4,075)
Cash and cash equivalents at beginning of period	61,915	41,476
Cash and cash equivalents at end of period	$ 258,529	$ 37,401
Supplemental disclosure of non-cash transaction:		
Issuance of common stock in connection with acquisition of Radius Medical LLC	$	$ 10,501
Leasehold improvements paid by lessor	$ 2,848	$

See accompanying notes to unaudited condensed consolidated financial statements.

NuVasive, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

1. Description of Business

NuVasive, Inc. (the Company or NuVasive) was incorporated in Delaware on July 21, 1997. The Company designs, develops and markets products for the surgical treatment of spine disorders and operates in one business segment. The Company began commercializing its products in 2001. Its current product portfolio is focused on applications for lumbar, thoracic and cervical spine fusion. The principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS ®, as well as a growing offering of cervical and lumbar motion preservation products. The Company s products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. MAS combines NeuroVision ®, a nerve avoidance system, MaXcess ®, a minimally disruptive surgical system, and specialized implants, including fixation products for fusion and CoRoent® suite of implants. Fusion fixation products include the SpheRx® pedicle screw systems, XLP ™ lateral fixation plate, Halo ™ Anterior fixation plate, NuVasive Helix ACP ™ cervical plate and Gradient Plus ™ cervical plate. The Company also offers our Triad® and Extensure ™ lines of bone allograft, in patented saline packaging, and a synthetic bone void filler, FormaGraft ®, designed to aid in bone growth with fusion procedures.

The Company loans its NeuroVision systems to surgeons and hospitals who purchase disposables and implants for use in individual procedures. In addition, NeuroVision, MaXcess and surgical instrument sets are placed with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of disposables and implants. The Company sells a small quantity of surgical instrument sets and NeuroVision systems to hospitals. The Company offers a range of bone allograft in patented saline packaging and spine implants such as rods, plates and screws. Implants and disposables are shipped from the Company s facilities or from limited disposable inventories stored at sales agents sites.

NuVasive focuses significant research and development efforts on both MAS and motion preservation products in the areas of (i) fusion procedures in the lumbar and thoracic spine, (ii) cervical fixation products, and (iii) motion preservation products such as total disc replacement and nucleus-like cervical disc replacement. The Company dedicates significant resources to its sales and marketing efforts, including training spine surgeons on its unique technology and products.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Pursuant to these rules and regulations, the Company has condensed or omitted certain information and footnote disclosures it normally includes in its annual consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States (GAAP). In management s opinion, the financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company s financial position and of the results of operations and cash flows for the periods presented.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2007 included in NuVasive s Annual Report on Form 10-K filed with the Securities and Exchange Commission. Operating results for the three months ended March 31, 2008 and 2007 are not necessarily indicative of the results that may be expected for any other

interim period or for the full year. The balance sheet at December 31, 2007 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements. Certain 2007 balances have been reclassified to conform with 2008 financial statement classification.

3. Convertible Senior Notes

In March 2008, the Company issued $230.0 million principal amount of 2.25% Convertible Senior Notes due 2013 (the Notes), which included the subsequent exercise of the option to purchase an additional $30.0 million aggregate principal amount of Notes. The net proceeds from the offering, after deducting the initial purchasers discount and costs directly related to the offering were approximately $208.4 million. The Company will pay 2.25% interest per annum on the principal amount of the Notes, payable semi-annually in arrears in cash on March 15 and September 15 of each year. The Notes mature on March 15, 2013.

The Notes will be convertible into shares of the Company s common stock, $0.01 par value per share, based on an initial conversion rate, subject to adjustment, of 22.3515 shares per $1,000 principal amount of Notes (which represents an initial conversion price of approximately $44.74 per share). Holders may convert their notes at their option on any day up to and including the second scheduled trading day immediately preceding the maturity date. If a fundamental change to the Company s business occurs, as defined in the Notes, holders of the Notes have the right to require that the Company repurchase the Notes, or a portion thereof, at the principal amount thereof plus accrued and unpaid interest.

In connection with the offering of the Notes, the Company entered into convertible note hedge transactions (the hedge) with the initial purchasers and/or their affiliates (the counterparties) entitling the Company to purchase up to 5.1 million shares of the Company s common stock, subject to adjustment, at an initial stock price of $44.74 per share, subject to adjustment. In addition, the Company sold to these counterparties warrants to acquire up to 5.1 million shares of the Company s common stock (the warrants), subject to adjustment, at an initial strike price of $49.13 per share, subject to adjustment. The cost of the hedge that was not covered by the proceeds from the sale of the warrants was approximately $14.0 million and is reflected as a reduction of additional paid-in capital as of March 31, 2008. The impact of the hedge is to raise the effective conversion price of the notes to approximately $49.13 per share (or approximately 20.3542 shares per $1,000 principal amount of the Notes). The hedge is expected to reduce the potential equity dilution upon conversion of the notes if the daily volume-weighted average price per share of the Company s common stock exceeds the strike price of the hedge. The warrants could have a dilutive effect on the Company s earnings per share to the extent that the price of the Company s common stock during a given measurement period exceeds the strike price of the warrants.

4. Acquisition of Pedicle Screw Technology

The Company completed a buy-out of royalty obligations on SpheRx® pedicle screw and related technology products and acquired new pedicle screw intellectual property totaling $6.3 million. Of the total purchase price, $2.1 million, representing the present value of the expected future cash flows associated with the terminated royalty obligations, was allocated to intangible assets to be amortized on a straight-line basis over a seven year period. The remaining $4.2 million was allocated to in-process research and development because the associated projects had not yet reached technological feasibility and had no alternative future use.

5. Balance Sheet Reserves

The balances of the reserves for accounts receivable and inventory are as follows:

(in thousands)	March 31, 2008	December 31, 2007
Reserves for accounts receivable	$ 927	$ 926
Reserves for inventory	$ 3,514	$ 3,614

6. Net Loss Per Share

NuVasive computes net loss per share using the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period. Due to the net loss reported in all periods, the effect of stock options and warrants is anti-dilutive and therefore excluded. Although these options are currently not included in the net loss per share calculation, they could be dilutive when, and if, the Company reports future earnings.

(in thousands, except per share amounts)	Three Months Ended March 31, 2008	2007
Numerator:		
Net loss	$ (7,654)	$ (4,420)
Denominator for basic and diluted net loss per share:		
Weighted average common shares outstanding	35,411	34,314
Basic and diluted net loss per share	$ (0.22)	$ (0.13)

7. Comprehensive Income

Comprehensive income which includes the unrealized gain (loss) on short-term investments and foreign currency translation adjustments for the three month periods ended March 31, 2008 and 2007 did not differ significantly from the reported net loss.

8. Stock Based Compensation

For purposes of calculating the stock-based compensation under SFAS 123(R), the Company estimates the fair value of stock options and shares issued under the Employee Stock Purchase Plan, or ESPP, using a Black-Scholes option-pricing model. No shares were issued under the ESPP in the three month periods ended March 31, 2008 and 2007. The assumptions used to estimate the fair value of stock options granted in the three month periods ended March 31, 2008 and 2007 are as follows:

	Three Months Ended March 31, 2008	**Three Months Ended March 31, 2007**
Volatility	42%	50%
Expected term (years)	2.5 to 4.5	2.5 to 4.5
Risk free interest rate	2.5% to 2.8%	4.5% to 4.8%
Expected dividend yield	0.0%	0.0%

The compensation cost that has been included in the statement of operations for all share-based compensation arrangements was as follows:

	Three Months Ended March 31,	
(in thousands, except per share amounts)	**2008**	**2007**
Sales, marketing and administrative expense	$ 4,504	$ 2,628
Research and development expense	646	516
Stock-based compensation expense	$ 5,150	$ 3,144
Effect on basic and diluted net loss per share	$ (0.15)	$ (0.09)

Stock-based compensation for stock options is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans* (FIN 28). As of March 31, 2008, there was $10.3 million of unrecognized stock-based compensation expense. This cost is expected to be recognized over a weighted-average period of approximately 1.6 years.

9. New Building Lease

On November 6, 2007, the Company entered into a 15-year lease agreement for the purpose of relocating our corporate headquarters to an approximately 140,000 square feet two-building campus style complex. Rental payments consist of base rent of $2.43 per square foot per month, escalating at an annual rate of three percent over the 15-year period of the lease, plus related operating expenses. In addition, through options to acquire additional space in the project and to require the construction of an additional building on the campus, the agreement provides for

facility expansion rights to an aggregate of more than 300,000 leased square feet. In connection with the lease, the Company issued a $3.1 million irrevocable transferrable letter of credit. Relocation to the new facility began in March 2008 and is expected to continue through the third quarter of 2008. Subsequent to the relocation date, the Company expects to sublease the current facility through August 2012, the date on which the related lease agreement expires, and expects lease income to approximate lease expense on the current facility.

The table below provides the minimum cash payments required under the new building lease for rent and related operating expenses.

Year		(in thousands)
2008	$	1,548
2009		5,151
2010		5,801
2011		6,003
2012		6,214
2013 and thereafter		82,339
	$	107,056

10. Impact of Recently Issued Accounting Standards

Effective January 1, 2008, the Company adopted FASB Statement No. 157 (SFAS 157), *Fair Value Measurements* which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. On February 6, 2008, the FASB deferred the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. These nonfinancial items include assets and liabilities such as reporting units measured at fair value in a goodwill impairment test and nonfinancial assets acquired and liabilities assumed in a business combination. The Company measures certain assets at fair value and thus there was no impact on the Company s consolidated financial statement at the adoption of SFAS 157. SFAS 157 requires disclosure that establishes a framework for measuring fair value and expands disclosure about fair value measurements. The statement requires fair value measurement be classified and disclosed in one of the following three categories: Level 1 quoted prices in active markets for identical assets and liabilities; Level 2 quoted prices for identical or similar assets and liabilities in markets that are not active, or observable inputs other than quoted prices in active markets for identical assets and liabilities; and Level 3 unobservable inputs. All of the Company s assets measured at fair value on a recurring basis subject to the disclosure requirements of SFAS 157 as of March 31, 2008 are categorized as Level 1.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits entities to choose to measure certain financial instruments and other eligible items at fair value when the items are not otherwise currently required to be measured at fair value. We adopted SFAS 159 effective January 1, 2008. Upon adoption, we did not elect the fair value option for any items within the scope of SFAS 159 and, therefore, the adoption of SFAS 159 did not have an impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141R). SFAS 141R requires the use of full fair value to record all the identifiable assets, liabilities, noncontrolling interests and goodwill acquired in a business combination. SFAS 141R is effective for fiscal years beginning on or after December 15, 2008.

11. Subsequent Event Agreement to Acquire Osteocel Biologics Business

On May 8, 2008, NuVasive signed a definitive agreement to acquire the Osteocel biologics business from Osiris Therapeutics, Inc. (Osiris). The Osteocel business includes a proprietary adult stem cell bone graft product with the beneficial properties of autograft and a processing facility with significant supply stream capacity. Under the terms of the agreement, NuVasive will acquire the Osteocel biologics business from Osiris for $35 million in cash at closing, plus additional milestone-based contingent payments not to exceed $50 million in either cash or a

combination of cash and stock, at the Company s election. The purchase price will be funded out of available cash and the transaction is not subject to financing conditions. The Company presently anticipates that the closing will occur in the third quarter of 2008, subject to Osiris shareholder approval and customary regulatory approvals.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements May Prove Inaccurate

You should read the following discussion of our financial condition and results of operations in conjunction with the unaudited consolidated financial statements and the notes to those statements included in this report. This discussion may contain forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, such as those set forth under heading Risk Factors, and elsewhere in this report, and in our Annual Report on Form 10-K for the year ending December 31, 2007. We do not intend to update these forward looking statements to reflect future events or circumstances.

Overview

We are a medical device company focused on the design, development and marketing of products for the surgical treatment of spine disorders. Our currently-marketed product portfolio is focused on applications for spine fusion surgery, a market estimated to exceed $4.2 billion in the United States in 2008. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS ® , as well as a growing offering of cervical and motion preservation products. Our currently-marketed products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. We also focus significant research and development efforts on both MAS and motion preservation products in the areas of (i) fusion procedures in the lumbar and thoracic spine, (ii) cervical fixation products, and (iii) motion preservation products such as total disc replacement and nucleus-like cervical disc replacement. We dedicate significant resources to our sales and marketing efforts, including training spine surgeons on our unique technology and products.

Our MAS platform combines three categories of our product offerings:

- NeuroVision® a proprietary software-driven nerve avoidance system;
- MaXcess® a unique split-blade design retraction system providing enhanced surgical access to the spine; and
- Specialized implants, including our fixation products for fusions and CoRoent® suite of implants.

Our fusion fixation products include our SpheRx® pedicle screw systems, XLPTM lateral fixation plate, HaloTM Anterior Fixation plate, NuVasive Helix ACP ™ cervical plate and Gradient Plus ™ cervical plate. We also offer our Triad® and Extensure ™ lines of bone allograft, in our patented saline packaging, and a synthetic bone void filler, FormaGraft ® , designed to aid in bone growth with fusion procedures.

We have an active product development pipeline focused on expanding our current fusion product platform as well as products designed to preserve spinal motion. In particular, we have an ongoing pivotal clinical study, which began in the third quarter of 2006, with respect to our investigational cervical disc replacement device.

Since inception, we have been unprofitable. As of March 31, 2008, we had an accumulated deficit of $175.6 million.

Revenues. The majority of our revenues are derived from the sale of implants and disposables and we expect this trend to continue in the near term. We loan our surgical instrument sets at no cost to surgeons and hospitals that purchase disposables and implants for use in individual procedures; there are no minimum purchase requirements of disposables and implants related to these loaned surgical instruments. In addition, we place NeuroVision, MaXcess and other MAS or cervical surgical instrument sets with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of disposables and implants. These extended loan transactions represent less than 20% of our total stock of loaner surgical assets. Our implants and disposables are currently sold and shipped from our San Diego and Memphis facilities or from limited disposable inventories stored at our sales agents sites. We recognize revenue for disposables or implants used upon receiving a purchase order from the hospital indicating product use or implantation. In addition, we sell a small number of MAS instrument sets, MaXcess devices, and NeuroVision systems. To date, we have derived less than 5% of our total revenues from these sales.

Sales and Marketing. Through March 31, 2008, substantially all of our operations are located in the United States and substantially all of our sales to date have been generated in the United States. We distribute our products through a sales force comprised of independent exclusive sales agents and our own directly employed sales professionals. Our sales force provides a delivery and consultative service to our surgeon and hospital customers and is compensated based on sales and product placements in their territories. Sales force commissions are reflected in our statement of operations in the sales, marketing and administrative expense line. We expect to continue to expand our distribution channel. In the second quarter of 2006, we completed our efforts to transition our sales force to one that is exclusive to us with respect to the sale of spine products. Late in 2007, we began an expansion in international markets focusing initially on European markets. We expect our international sales force to be made up of a combination of distributors and direct sales personnel.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to bad debts, inventories, long-term assets, income taxes, and stock compensation. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates.

We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition. We follow the provisions of the Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition,* which sets forth guidelines for the timing of revenue recognition based upon factors such as passage of title, installation, payment and customer acceptance. We recognize revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Specifically, revenue from the sale of implants and disposables is recognized upon receipt of a purchase order from the hospital indicating product use or implantation or upon shipment to third party customers who immediately accept title. Revenue from the sale of our instrument sets is recognized upon receipt of a purchase order and the subsequent shipment to customers who immediately accept title.

Allowance for Doubtful Accounts. We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. The allowance for doubtful accounts is reviewed quarterly and is estimated based on the aging of account balances, collection history and known trends with current customers. As a result of this review, the allowance is adjusted on a specific identification basis. Increases to the allowance for doubtful accounts result in a corresponding sales, marketing and administrative expense. We maintain a relatively large customer base that mitigates the risk of concentration with one customer. However, if the overall condition of the healthcare industry were to deteriorate, or if the historical data used to calculate the allowance provided for doubtful accounts does not reflect our customer s future ability to pay outstanding receivables, significant additional allowances could be required.

Excess and Obsolete Inventory and Instruments. We calculate an inventory reserve for estimated obsolescence and excess inventory based upon historical turnover and assumptions about future demand for our products and market conditions. Our allograft implants have a four-year shelf life and are subject to demand fluctuations based on the availability and demand for alternative implant products. Our MAS inventory, which consists primarily of disposables and specialized implants, is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimates and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The

estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. Increases in the reserve for excess and obsolete inventory result in a corresponding expense to cost of goods sold.

A stated goal of our business is to focus on continual product innovation and to obsolete our own products. While we believe this provides a competitive edge, it also results in the risk that our products and related capital instruments will become obsolete prior to the end of their anticipated useful lives. If we introduce new products or next-generation products prior to the end of the useful life of a prior generation, we may be required to dispose of existing inventory and related capital instruments and/or write off the value or accelerate the depreciation of these assets.

Long Term Assets. Property and equipment is carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method based on the estimated useful lives of three to seven years for machinery and equipment and three years for loaner instruments. We own land and a building in Memphis, Tennessee that we use as a warehouse and distribution facility. The building is depreciated over a period of 20 years. Maintenance and repairs are expensed as incurred. Intangible assets consist of purchased and licensed technology and a supply agreement are amortized on a straight-line basis over their estimated useful lives ranging from 14 to 20 years.

We evaluate our long-term assets for indications of impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If this evaluation indicates that the value of the long-term asset may be impaired, we make an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the long-term asset is not recoverable, we reduce the net carrying value of the related asset to fair value and may adjust the remaining depreciation or amortization period. We have not recognized any material impairment losses on long-term intangible assets through March 31, 2008.

Accounting for Income Taxes. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a full valuation allowance on our net deferred tax assets as of March 31, 2008 due to uncertainties related to our ability to utilize our deferred tax assets in the foreseeable future.

Valuation of Stock-Based Compensation. On January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which establishes accounting for share-based awards exchanged for employee and non-employee director services and requires us to expense the estimated fair value of these awards over the requisite service period. Option awards issued to non-employees are recorded at their fair value as determined in accordance with Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services,* and are periodically revalued as the options vest and are recognized as expense over the related service period.

For purposes of calculating the stock-based compensation, we estimate the fair value of stock options and shares issued under the Employee Stock Purchase Plan using a Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of short lived exchange traded options that have no vesting restrictions and are fully transferable. In addition, the Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. Stock-based compensation related to stock options is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans* (FIN 28). If there is a difference between the assumptions used in determining stock-based compensation cost and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining stock-based compensation costs. These changes, if any, may materially impact our results of operations in the period such changes are made.

In Process Research and Development. In 2008, we recorded an in-process research and development (IPRD) charge of $4.2 million related to the acquisition of pedicle screw technology in the first quarter of 2008. At the date of the acquisition, the projects associated with the IPRD efforts had not yet reached technological feasibility and the research and development in process had no alternative future uses. Accordingly, the amounts were charged to expense on the acquisition date.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States (GAAP). See our unaudited consolidated financial statements and notes thereto included in this report, and our audited consolidated financial statements and notes thereto for the year ended December 31, 2007 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, which contain accounting policies and other disclosures required by GAAP.

Results of Operations

Revenue

	Three Months Ended March 31,			
(dollars in thousands)	**2008**	**2007**	**$ Change**	**% Change**
Revenue	$ 51,184	$ 33,220	$ 17,964	54.1%

Revenues have increased over time due primarily to continued market acceptance of our products within our MAS platform, including NeuroVision, MaXcess disposables, and our specialized implants such as our XLP lateral plate, SpheRx® pedicle screw systems, and CoRoent® suite of products. The execution of our strategy of expanding our product offering for the lumbar region and addressing broader indications further up the spine in the thoracic and cervical regions through a variety of new product introductions in 2008 and 2007 have contributed to revenue growth in both years. Additionally, the completion of our transition to an exclusive sales force in mid-2006 has increased the effort focused on selling our products, as well as the overall market penetration, resulting in higher sales.

Cost of Goods Sold

	Three Months Ended March 31,			
(dollars in thousands)	**2008**	**2007**	**$ Change**	**% Change**
Cost of goods sold	$ 9,095	$ 5,707	$ 3,388	59.4%
% of revenue	17.8%	17.2%		

Cost of goods sold consists of purchased goods and overhead costs, including depreciation expense for instruments.

The increase in cost of goods sold in total dollars in the three month period ended March 31, 2008 compared to the same period in 2007 resulted primarily from (i) increased direct costs of $2.3 million primarily to support revenue growth; and (ii) increased depreciation expense of $0.5 million incurred on the increased amount of surgical instrument sets we hold for use in surgeries. We expect cost of goods sold, as a percentage of revenue, to remain relatively consistent for the foreseeable future.

Operating Expenses

Sales, Marketing and Administrative.

(dollars in thousands)	Three Months Ended March 31, 2008	2007	$ Change	% Change
Sales, marketing and administrative	$ 39,317	$ 28,449	$ 10,868	38.2%
% of revenue	76.8%	85.6%		

Sales, marketing and administrative expenses consist primarily of compensation, commission and training costs for personnel engaged in sales, marketing and customer support functions, distributor commissions, surgeon training costs, shareowner (employee) related expenses for our administrative functions, third party professional service fees, amortization of acquired intangible assets, and facilities and insurance expenses.

The increases in sales, marketing and administrative expenses principally result from growth in our revenue and the overall growth in the Company, including expenses that fluctuate with sales and expenses associated with investments in our infrastructure and headcount growth. Increases in costs based on revenue, such as sales force compensation, royalty expense, and shipping costs were $5.9 million, $.7 million and $0.6 million, respectively, for the three month period ended March 31, 2008 compared to the same period in 2007. Total costs related to our sales force, as a percent of revenue, decreased to 30% from 33% for the three months ended March 31, 2008 compared to the same period in 2007. The decrease in costs as a percentage of revenue were primarily attributable to the increased revenues and to certain costs associated with our transition to sales force exclusivity that were incurred in the 2007 period but not incurred in the 2008 period. Increases in costs as a result of overall company growth and administrative support were $2.2 million for compensation and other shareowner related costs for the three month period ended March 31, 2008, compared to the same period in 2007, and an increase in equipment and facility costs of $0.6 million for the three month period ended March 31, 2008, compared to the same period in 2007.

In the second quarter of 2006, we completed our efforts to transition our sales force to one that is exclusive to us in the field of spine products. Our exclusive sales force consists of independent sales agents and directly-employed sales personnel. On a long-term basis, as a percentage of revenue, we expect sales, marketing and administrative costs to continue to decrease over time as we begin to see the synergies of investments we have made (such as our sales force exclusivity transition). However, we have other significant expenses planned that are designed to increase the scalability of our business. For example, we purchased and began the implementation of a new enterprise resource planning, or ERP, software system, in 2007. We will capitalize the majority of the aggregate $8.6 million anticipated cost of the ERP project and amortize it over a 7 year period. In addition, we entered into a lease of a two-building campus-style headquarters complex in November 2007 to accommodate our Company s growth. Relocation to the new facility began in March 2008 and is expected to be completed in the third quarter of 2008, and as a result, we will incur increased facility costs beginning on the relocation dates. Specifically, we expect to incur approximately $3.1 million in incremental facility costs in 2008.

See Note 9 to the unaudited condensed consolidated financial statements included in this filing for additional information regarding this lease and the expected additional costs related thereto. Subsequent to completion of our relocation to the new facility, we expect to sublease the current 62,000 square foot facility through August 2012, the date on which the related lease agreement expires. We expect to realize sublease income sufficient to cover our expenses on this facility over the term of the sublease; however, we have not yet entered into a sublease agreement and cannot be assured that such a sublease, if any, will provide the anticipated sublease income. Lease expense on the current facility, before any anticipated sublease income, is expected to be $1.3 million in 2008.

Research and Development.

	Three Months Ended March 31,			
(dollars in thousands)	**2008**	**2007**	**$ Change**	**% Change**
Research and development	$ 6,976	$ 5,343	$ 1,633	30.6%
% of revenue	13.6%	16.1%		

Research and development expense consists primarily of product research and development, clinical trial costs, regulatory and clinical functions, and shareowner-related expenses.

The increase in research and development costs in the periods presented are primarily due to increases in (i) compensation and other shareowner related expenses of $0.9 million for the three month period ended March 31, 2008, compared to the same period in 2007, primarily due to increased headcount to support our product development and enhancement efforts; and (ii) increased supply costs of $0.5 million for the three month period ended March 31, 2008, compared to the same period in 2007, related to product development activities. We expect research and development costs to continue to increase in absolute dollars for the foreseeable future in support of our ongoing development activities and planned clinical trial activities; however, as a percentage of revenue these costs are expected to decrease moderately over time.

In-Process Research and Development.

(dollars in thousands)	Three Months Ended March 31, 2008	2007	$ Change	% Change
In-process research and development	$ 4,176	$	$ 4,176	100%
% of revenue	8.2%	0.0%		

The Company completed a buy-out of royalty obligations on SpheRx® pedicle screw and related technology products and acquired new pedicle screw intellectual property for an aggregate purchase price of $6.3 million. The total purchase price was allocated as $2.1 million to intangible assets to be amortized on a straight-line basis over a seven year period and $4.2 million to in-process research and development.

Interest and Other Income, Net

(dollars in thousands)	Three Months Ended March 31, 2008	2007	$ Change	% Change
Interest and other income, net	$ 726	$ 1,859	$ (1,133)	(60.9)%
% of revenue	1.4%	5.6%		

Interest and other income, net consists primarily of interest income earned offset by interest expense incurred. This category also includes, in the first quarter of 2007, other income of $0.4 million related to our relinquishment of a right of first refusal to certain technology associated with the 2005 acquisition of RSB Spine LLC. Excluding this item, interest and other income, net decreased in the period presented due to (i) lower investment balances and interest rates for 2008 period resulting in a decrease of $0.3 million and (ii) interest expense related to the convertible senior notes of $0.4 million in 2008.

Stock-Based Compensation

(in thousands, except per share amounts)	Three Months Ended March 31, 2008	2007
Sales, marketing and administrative expense	$ 4,504	$ 2,628
Research and development expense	646	516
Total stock-based compensation expense	$ 5,150	$ 3,144

We granted approximately 1,487,000 and 1,117,000 options in the first three months of 2008 and 2007, respectively, with a per option grant date weighted average fair value of $14.14 and $10.26, respectively. We recognize stock-based compensation expense on a accelerated basis in accordance with FIN 28, which effectively results in the recognition of approximately 60% of the total compensation expense for a particular option within 12 months of its grant date. The increase in stock-based compensation expense in the three months ended March 31, 2008 compared to the same period in 2007 is due primarily to additional options granted in the 2008 period and the increased weighted average fair value per option in 2008.

Liquidity and Capital Resources

Since our inception in 1997, we have incurred significant losses and as of March 31, 2008, we had an accumulated deficit of approximately $175.6 million. We have not yet achieved profitability, and do not expect to be profitable in 2008 after considering the in-process research and development charge. We expect our sales, marketing and administrative expense and research and development expense will continue to grow and, as a result, we will need to generate significant net sales to achieve profitability. To date, our operations have been funded primarily with proceeds from the sale of our equity securities.

In March 2008, we issued $230.0 million principal amount of 2.25% Convertible Senior Notes due 2013 (the Notes). The net proceeds from the offering, after deducting the initial purchasers discount and costs directly related to the offering, were approximately $208.4 million. We will pay 2.25% interest per annum on the principal amount of the Notes, payable semi-annually in arrears in cash on March 15 and September 15 of each year. The Notes mature on March 15, 2013.

Cash, cash equivalents and short-term and long-term marketable securities, was $278.6 million at March 31, 2008 and $89.7 million at December 31, 2007. The increase was due primarily to the net proceeds from our convertible debt financing transaction in March of 2008.

Net cash used in operating activities was $4.2 million in the first quarter of 2008 compared to $3.1 million in the same period in 2007. The increase in net cash used in operating activities of $1.1 million was primarily due to the improved results for the quarter excluding the charge for in process research and development.

Net cash used by investing activities was $9.2 million in the first quarter of 2008 compared to $2.2 million in the same period in 2007. The increase in net cash used by investing activities of $7.0 million is primarily due to our $9.7 million increase in capital asset purchases and $6.3 million purchases of pedicle screw technology and intangible assets in 2008, offset by cash paid for the acquisition of Radius Medical, LLC of $7.0 million in 2007.

Net cash provided by financing activities was $210.0 million in the first quarter of 2008 compared to $1.2 million in the same period in 2007. The change in net cash provided by financing activities of $208.8 million is primarily due to the receipt of net proceeds of $208.4 million from the issuance of convertible debt in March 2008.

We expect that cash provided by operating activities may fluctuate in future periods as a result of a number of factors, including fluctuations in our working capital requirements and of our capital expenditures for additional loaner assets, our operating results, and cash used in any future acquisitions. In addition, we expect to incur additional capital expenditures for leasehold improvements for the new headquarters facility and for the ERP software implementation in 2008. We have sufficient cash and investments on hand to finance our operations for the foreseeable future.

Commitments

As described in our Annual Report on Form 10-K for the year ended December 31, 2007, we entered into agreements for the acquisition and integration of a new enterprise resource planning software, or ERP, system. These agreements include a software license agreement with SAP America, Inc., pursuant to which we acquired software rights for the ERP software platform. The acquisition cost of the software platform is not material to our business. Pursuant to this agreement, SAP agreed to provide ERP software to us, provide ongoing support during the software implementation process, and to provide longer term technical and professional support. In addition, we executed a customer agreement with International Business Machines Corporation (IBM), pursuant to which we engaged IBM to act as the primary implementer of our ERP software. IBM will provide implementation, consulting, and software customization services during the course of our ERP implementation and beyond. The remaining commitments as of March 31, 2008 under these contracts are approximately $2.1 million through mid-2008. We will capitalize the majority of these costs as long-term assets and amortize them over a 7-year period concurrent with the estimated useful life of the related software.

On November 6, 2007, the Company entered into a 15-year lease agreement for the purpose of relocating our corporate headquarters to an approximately 140,000 square feet two-building campus style complex. Rental payments consist of base rent of $2.43 per square foot, escalating at an annual rate of three percent over the 15-year period of the lease, plus related operating expenses. Relocation to the new facility began in the first quarter of 2008 and is expected to continue through the third quarter of 2008. In addition, through options to acquire additional space in the project and to require the construction of an additional building on the campus, the agreement provides for facility expansion rights to an aggregate of more than 300,000 leased square feet. Under the terms of this lease, NuVasive is required to make minimum lease payments, including operating expenses as follows: $1.5 million in 2008, $5.2 million in 2009, $5.8 million in 2010, $6.0 million in 2011, $6.2 million in 2012, and $82.3 million thereafter for a total of $107.1 million over the 15-year period. In connection with the lease, the Company issued a

$3.1 million irrevocable transferrable letter of credit. Subsequent to the relocation dates, the Company expects to sublease the current facility through August 2012, the date on which the related lease agreement expires, and expects lease income to approximate the lease expense on the current facility.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our exposure to interest rate risk at March 31, 2008 is related to our investment portfolio which consists largely of debt instruments of high quality corporate issuers and the U.S. government and its agencies. Due to the short-term nature of these investments, we have assessed that there is no material exposure to interest rate risk arising from our investments. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. At March 31, 2008, we do not hold any material asset-backed investment securities and in 2007 and 2008, we did not realize any losses related to asset-backed investment securities.

We have operated mainly in the United States of America, and the majority of our sales since inception have been made in U.S. dollars. Further, the majority of our sales to international markets have been to independent distributors in transactions conducted in U.S. dollars. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

Interest Rate Risk. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The fair market value of fixed rate securities may be adversely impacted by fluctuations in interest rates while income earned on floating rate securities may decline as a result of decreases in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities. We have historically maintained a relatively short average maturity for our investment portfolio, and we believe a hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (Exchange Act), is recorded, processed, summarized and reported within the timelines specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the Company s disclosure controls and procedures (as such term is defined in Exchange Act Rules 13a 15(e) and 15d 15(e)) as of March 31, 2008. Based on such evaluation, our management has concluded as of March 31, 2008, the Company s disclosure controls and procedures are effective.

Changes in Internal Control over Financial Reporting. There has been no change to our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

An investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described under Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2007 together with all other information contained or incorporated by reference in this report before you decide to invest in our common stock. If any of the risks described in this report or in our annual report actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment.

Item 5. Other Information

The condensed consolidated statement of cash flows included in our Form 8-K filed with the Securities and Exchange Commission on April 22, 2008 contained a typographical error; specifically, it omitted brackets on the in process research and development charge included under Investing Activities for the three months ended March 31, 2008. The Condensed Consolidated Statement of Cash Flows included in this Form 10-Q corrects this error.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No	Description
3.1 (1)	Restated Certificate of Incorporation
3.2 (1)	Restated Bylaws
4.1	Indenture, dated March 7, 2008, between the NuVasive Inc. and U.S. Bank National Association, as Trustee.
4.2	Form of 2.25% Convertible Senior Note due 2013.
4.3	Registration Rights Agreement, dated March 7, 2007, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013.
10.1	Purchase Agreement, dated March 3, 2008, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013.
10.2	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013.
10.3	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013.
10.4	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013.
10.5	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013.
10.6	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013.
10.7	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013.
10.8	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013.
10.9	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32 *	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 2004.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of NuVasive, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NUVASIVE, INC.

Date: May 9, 2008

By: /s/ ALEXIS V. LUKIANOV
Alexis V. Lukianov
Chairman and Chief Executive Officer

Date: May 9, 2008

By: /s/ KEVIN C. O BOYLE
Kevin C. O Boyle
Executive Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit No	Description
3.1 (1)	Restated Certificate of Incorporation
3.2 (1)	Restated Bylaws
4.1	Indenture, dated March 7, 2008, between the NuVasive Inc. and U.S. Bank National Association, as Trustee.
4.2	Form of 2.25% Convertible Senior Note due 2013.
4.3	Registration Rights Agreement, dated March 7, 2007, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013.
10.1	Purchase Agreement, dated March 3, 2008, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013.
10.2	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013.
10.3	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013.
10.4	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013.
10.5	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013.
10.6	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013.
10.7	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013.
10.8	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013.
10.9	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32 *	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 2004.

*

These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of NuVasive, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

OSIRIS THERAPEUTICS, INC.

THIS PROXY IS BEING SOLICITED BY THE BOARD OF DIRECTORS
OF
OSIRIS THERAPEUTICS, INC.

The undersigned, revoking any previous proxies relating to these shares, hereby acknowledges receipt of the Notice and Proxy Statement dated , 2008 in connection with the Special Meeting of Stockholders of Osiris Therapeutics, Inc. to be held at 2:00 p.m., EDT, on , , 2008 at the offices of Osiris Therapeutics, Inc., 7015 Albert Einstein Drive, Columbia, Maryland 21046, and hereby appoints C. Randal Mills and Philip R. Jacoby, Jr., and each of them (with full power to act alone), the attorneys and proxies of the undersigned, with power of substitution to each, to vote all shares of the Common Stock of OSIRIS THERAPEUTICS, INC. registered in the name provided herein which the undersigned is entitled to vote at the Special Meeting of Stockholders, and at any postponements or adjournments thereof, with all the powers the undersigned would have if personally present. Without limiting the general authorization hereby given, said proxies are, and each of them is, instructed to vote or act as indicated on the reverse side hereof on the proposals set forth in said Proxy.

SEE REVERSE SIDE FOR ALL PROPOSALS. If you wish to vote in accordance with the Board of Directors recommendations, just sign on the reverse side. You need not mark any boxes. Please mark, date and return this card promptly, using the enclosed envelope. No postage is required if mailed in the United States.

(SEE REVERSE SIDE)

Please Detach and Mail in the Envelope Provided

x Please mark votes as in this example.

The Board of Directors recommends a vote FOR Proposal 1.

1. Proposal to approve the Asset Purchase Agreement dated May 8, 2008, by and between Osiris and NuVasive, Inc. and the transactions contemplated thereby, including the sale by Osiris of its Osteocel product line, including Osteocel® and Osteocel® XO, and related business assets.

FOR	AGAINST	ABSTAIN
o	o	o

In their discretion, the proxies are authorized to vote upon such other matters as may properly come before the meeting or any adjournments or postponements thereof.

This Proxy when executed will be voted in the manner directed herein. If no direction is made this proxy will be voted FOR Proposal No. 1.

PLEASE MARK, SIGN, DATE AND RETURN PROMPTLY IN THE ENCLOSED ENVELOPE.

Signature: Date:

Signature: Date:

NOTE: Please insert date and sign exactly as name(s) appears hereon. Joint owners should each sign. When signing as attorney, executor, administrator, trustee, guardian, or officer or other authorized person on behalf of a corporation or other entity, or in another representative capacity, please give full title as such under signature(s).