OSIRIS THERAPEUTICS, INC.
Form S-1
May 12, 2006

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As filed with the Securities and Exchange Commission on May 12, 2006.

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

OSIRIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2836**	**71-0881115**
(State or other jurisdiction of incorporation or organization)	*(Primary SIC Code Number)*	*(I.R.S. Employer Identification No.)*

2001 Aliceanna St.
Baltimore, Maryland 21231
(410) 522-5005

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

C. Randal Mills, Ph.D.
President and Chief Executive Officer
2001 Aliceanna Street
Baltimore, Maryland 21231
(410) 522-5005

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Justin P. Klein, Esq.
Douglas M. Fox, Esq.
Ballard Spahr Andrews & Ingersoll, LLP
300 East Lombard Street
18th Floor
Baltimore, Maryland 21202
(410) 528-5600

Donald J. Murray, Esq.
Dewey Ballantine LLP
1301 Avenue of the Americas
New York, New York 10019
(212) 259-8000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box: / /

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. / /

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. / /

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. / /

Calculation of Registration Fee

Title of each class of securities to be registered	Proposed maximum aggregate offering price (1)	Amount of registration fee
Common Stock, $.001 par value per share	$80,000,000	$8,560

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is declared effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated May 12, 2006

Shares

Common Stock

This is the initial public offering of Osiris Therapeutics, Inc. We are offering shares of our common stock. We anticipate that the initial public offering price will be between $ and $ per share. We have applied to list our common stock on the NASDAQ National Market under the symbol "OSIR."

Investing in our common stock involves risk. See "Risk Factors" beginning on page 8.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions	$	$
Proceeds, before expenses, to Osiris Therapeutics, Inc.	$	$

We have granted the underwriters the right to purchase up to additional shares of common stock to cover over-allotments.

Deutsche Bank Securities

The date of this prospectus is , 2006.

PROSPECTUS SUMMARY

This summary highlights information appearing elsewhere in this prospectus. It may not contain all of the information that is important to you in deciding whether to invest in our common stock. You should read the entire prospectus carefully, including the "Risk Factors" section and the financial statements and related notes appearing at the end of this prospectus, before making an investment decision.

Our Business

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. We have one marketed product, Osteocel, and three biologic drug candidates in clinical development. Osteocel and our biologic drug candidates utilize human mesenchymal stem cells, or MSCs. We obtain MCSs for use in our biologic drug candidates from the adult bone marrow of volunteer donors. MSCs are progenitor cells that have strong anti-inflammatory properties, prevent scarring, and can regenerate and repair damaged tissue. We are a fully integrated company having developed stem cell capabilities in research and development, manufacturing, marketing and distribution.

We currently market and sell Osteocel for regenerating bone in orthopedic indications. It is the only commercially available product in the United States containing stem cells. Prochymal, our lead biologic drug candidate, for the treatment of inflammatory disease, is the only stem cell therapeutic entering Phase III clinical trials and is the first stem cell therapeutic to receive FDA Fast Track and Orphan Drug designations. Our pipeline of internally developed biologic drug candidates also includes Chondrogen, for regenerating cartilage in the knee, and Provacel, for repairing heart tissue following a heart attack.

Biologic Drug Candidates

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. We obtain this bone marrow from volunteer donors between the ages of 18 and 32.

Ability to Mass Produce. Through our proprietary manufacturing methods, we can grow MSCs in a controlled fashion to produce up to 5,000 treatments from a single bone marrow donation.

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. Based on our clinical experience, we believe that our biologic drug candidates are not rejected by the patient's immune system and therefore do not require matching.

Treatment on Demand. Our biologic drug candidates can be stored frozen at the point of care and, therefore, can be readily available to treat patients on demand. In contrast, other stem cell technologies under development require weeks to prepare after a patient's need is identified.

We have leveraged our MSC manufacturing, clinical and preclinical experience and proprietary know-how to advance three biologic drug candidates into the clinic.

Prochymal

We are currently entering a pivotal Phase III clinical trial for Prochymal, our biologic drug candidate for the treatment of steroid refractory Graft versus Host Disease, or 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. Due to a lack of adequate treatments, a large majority of steroid refractory GvHD patients die within six months. We are also enrolling a Phase II trial evaluating Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD.

Based on our clinical observations of the effects of Prochymal on the gastrointestinal symptoms of patients with GvHD, we are currently enrolling Crohn's Disease patients in a Phase II trial under a separate Investigational New Drug application. Crohn's Disease is a chronic condition that results in inflammation of the gastrointestinal tract.

Chondrogen

We recently completed enrollment in a Phase I/II clinical trial for Chondrogen, our biologic drug candidate for the regeneration of meniscus, a type of cartilage that cushions the knee joint. In the United States each year, approximately 800,000 people have surgery to remove damaged or torn meniscus. Patients who have had this procedure are 10 to 15 times more likely to develop osteoarthritis, a highly debilitating orthopedic condition. In several preclinical studies, Chondrogen regenerated meniscal tissue and prevented osteoarthritis. Currently, there are no FDA approved products to regenerate meniscal tissue.

Provacel

We recently completed enrollment in a Phase I clinical trial for Provacel, our biologic drug candidate for the repair of heart muscle in patients who have suffered a heart attack. In the United States approximately 700,000 individuals each year experience their first heart attack. Despite the utilization of current treatments, many of these patients become disabled with heart failure within six years. In preclinical studies in animal models, Provacel targeted the damaged area of the heart following a single treatment. These studies also indicate that Provacel prevents scar formation that typically occurs after a heart attack and significantly improves cardiac function eight to ten weeks after its administration.

Osteocel

We launched Osteocel in July 2005. To date, it has been used in over 1,100 surgical procedures. Osteocel consists of a matrix of cancellous bone containing mesenchymal stem cells and is used in spinal fusion and other orthopedic surgical procedures. As Osteocel does not require an additional surgery, it overcomes the disadvantages of autograft, principally post-operative pain. Autograft is a procedure to harvest bone from another site within the same patient and is the current standard of care for the regeneration of bone. Osteocel is currently distributed exclusively by us for orthopedic indications and jointly with Blackstone Medical for spinal procedures.

The Mesenchymal Stem Cell

We believe mesenchymal stem cells, or MSCs, found in adult bone marrow will be a more promising therapeutic option than other stem cell types, including the most basic stem cell type, embryonic stem cells, or ESCs. ESCs give rise to all cell types found within the human body, but difficulties in expanding and ethical controversies surrounding the sourcing of ESCs have limited their therapeutic development. MSCs are one of two populations of stem

cells that exist in adult bone marrow. The other population of stem cells found in adult bone marrow, hematopoietic stem cells, or HSCs, give rise to most types of blood cells. However, the therapeutic potential of HSCs has been limited to hematological disorders because of their ability to only differentiate into blood cells.

In contrast, 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 where they interact with local cells to reduce inflammation and scarring. In our preclinical and clinical studies, this ability has demonstrated potential therapeutic benefits in a broad range of inflammatory, orthopedic and cardiovascular diseases and disorders. MSCs also have low immunogenicity because they do not express certain cell surface molecules essential for the activation of immune cells. This allows MSCs to be utilized as a potential therapeutic treatment in patients without donor matching.

Our Business Strategy

We are striving to be the first company to receive FDA marketing approval and to commercialize a stem cell therapy. Our goal is to be the leading stem cell therapy company through the development and commercialization of stem cell therapies to address disease areas with significant unmet medical need and commercial potential. To achieve this goal, we are pursuing the following strategies:

Successfully commercialize our lead stem cell therapy, Prochymal.

Leverage Osteocel's orthopedic sales infrastructure for Chondrogen.

Expand our pipeline of biologic drug candidates where our stem cell technology has a therapeutic potential.

Exploit our MSC technology, manufacturing ability and proprietary know-how to advance our pipeline.

Internally develop and commercialize future biologic drug candidates.

Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. We may be unable, for many reasons, including those that are beyond our control, to implement our current business strategy. Those reasons could include delays in obtaining, or a failure to obtain, regulatory approval for our biologic drug candidates which are based on novel technology; our failure to maintain and to protect our intellectual property assets; and our failure to obtain additional capital as needed, among others. We have a limited operating history as a stem cell therapeutic company, and as of December 31, 2005 we had an accumulated deficit of $142.5 million. We expect losses to continue for at least the next several years. Our net loss for the fiscal year ended December 31, 2005 was $20.0 million. We are unable to predict the extent of any future losses or when we will become profitable, if at all. We do not anticipate generating significant revenues from sales of our biologic drug candidates, if approved for marketing, for at least several years, if at all. All of our biologic drug candidates are in development and none have been approved by the FDA for commercial sale. Even if we succeed in developing and commercializing one or more of our biologic drug candidates, we may never generate sufficient sales revenue to achieve and then sustain profitability. Before this offering, our Chairman of the Board of Directors, Peter Friedli, beneficially owned greater than 50% of our outstanding common stock. After this offering, Mr. Friedli will continue to have a significant influence over corporate actions requiring stockholder approval through his significant beneficial ownership.

Our Corporate Information

We were incorporated in Delaware in April 2002. Our predecessor company was organized in 1992. Our principal executive offices are located at 2001 Aliceanna St., Baltimore, Maryland 21231, and our telephone number is (410) 522-5005. We maintain an Internet website at www.OsirisTx.com. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

As used in this prospectus, references to "we," "our," "us" and "Osiris" refer to Osiris Therapeutics, Inc. and its subsidiaries, unless the context requires otherwise.

Osiris®, Osteocel®, Prochymal , Chondrogen , and Provacel are trademarks of Osiris Therapeutics, Inc. Other trademarks and service marks appearing in this prospectus are the property of their respective owners.

The Offering

Common stock offered by Osiris	shares
Common stock to be outstanding after this offering	shares
Use of proceeds	To fund the growth of our business, including additional clinical trials and preclinical research and development activities; to repay principal and interest on our $20.6 million promissory note; and for general corporate purposes, including working capital needs. See "Use of Proceeds."
NASDAQ National Market symbol	"OSIR"

The number of shares of our common stock outstanding after this offering is based on 36,651,884 shares outstanding as of April 19, 2006. Unless otherwise indicated, all information in this prospectus reflects the following:

a -for- reverse split of our common stock to be completed before the closing of this offering;

the conversion of all outstanding shares of our preferred stock into shares of our common stock, as adjusted for the stock split, upon the closing of this offering; and

the conversion of $ of our convertible notes into shares of our common stock (assuming a public offering price of $ per share), as adjusted for the stock split, upon the closing of this offering.

The number of shares of our common stock to be outstanding immediately after this offering excludes:

2,265,916 shares of our common stock issuable upon exercise of options outstanding as of December 31, 2005, at a weighted average exercise price of $0.10 per share, of which, as of that date;

options to purchase 714,549 shares were exercisable; and

management-owned options to purchase 930,000 shares were outstanding and will be exercisable upon the closing of this offering; and

8,500,000 shares of our common stock issuable upon exercise of warrants outstanding as of December 31, 2005, at a weighted average exercise price of $0.10 per share, all of which warrants were exercisable as of that date, and of which 5,000,000 have subsequently been cancelled; and

3,400,000 shares of our common stock available for future grant under our 2006 Omnibus Plan as of April 17, 2006.

Unless we specifically state otherwise, the information in this prospectus assumes that the underwriters do not exercise their option to purchase up to shares of our common stock to cover over-allotments, if any.

Summary Financial Data

The following tables summarize our financial data. This information is only a summary and should be read together with our financial statements and the related notes included in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information included in this prospectus.

The pro forma net loss attributable to common stockholders per share information is computed using the weighted average number of common shares outstanding, after giving pro forma effect to the conversion of all outstanding shares of our convertible preferred stock into shares of common stock, the conversion of all our mandatorily redeemable convertible preferred stock into shares of common stock, and the conversion of certain convertible notes into shares of common stock, all concurrently with the completion of this offering, as if the conversion had occurred at the dates of the original issuances.

	Year Ended December 31,		
	2003	2004	2005
	(in thousands, except per share data)		
Statement of Operations Data:			
Product sales	$	$	$ 957
Cost of goods sold			444
Gross profit			513
Revenue from collaborative research licenses and grants	3,981	3,911	3,013
Operating expenses:			
Research and development	18,639	11,888	16,927
General and administrative	4,467	1,704	2,294
Total operating expenses	23,106	13,592	19,221
Loss from operations	(19,125)	(9,681)	(15,695)
Interest expense, net	(605)	(847)	(4,300)
Net loss	$ (19,730)	$ (10,528)	$ (19,995)
Basic and diluted net loss per share	$ (0.90)	$ (0.30)	$ (0.56)
Weighted average shares of common stock used in computing basic and diluted net loss per share	21,901	35,255	35,837
Pro forma basic and diluted net loss per share applicable to common stockholders (unaudited)			$
Shares used to compute pro forma basic and diluted net loss per share			

The following table presents a summary of our balance sheet as of December 31, 2005:

- on an actual basis;
- on a pro forma basis to give effect to the conversion of all outstanding shares of our preferred stock into shares of common stock, and the conversion of $ of our convertible notes into shares of common stock (assuming a public offering price of $ per share), each of which will become effective upon the closing of this offering; and
- on a pro forma as adjusted basis to give effect to:
  - the sale of the shares of common stock by us in this offering at an assumed initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us; and
  - repayment of our outstanding promissory note, consisting of $20.6 million in principal and an aggregate of $ million in interest payments, assuming eight months of accrued interest since the issuance of the note on November 29, 2005.

	As of December 31, 2005		
	Actual	Pro forma	Pro forma as adjusted
		(in thousands)	
Balance Sheet Data:			
Cash and short-term investments	$ 43,371	$	$
Working capital	38,103		
Total assets	51,014		
Long-term debt, less current portion	47,411		
Mandatorily redeemable convertible preferred stock	64,267		
Convertible preferred stock	32,746		
Accumulated deficit	(142,544)		
Total stockholders' equity (deficit)	(73,662)		

RISK FACTORS

Before you invest in our common stock, you should understand the high degree of risk involved. You should consider carefully the description of those risks set forth below as well as the other information in this prospectus, including the historical financial statements and related notes, before you decide to purchase shares of our common stock. If any of the following risks actually occurs, our business, financial condition and operating results could be adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.

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, 2005, we had an accumulated deficit of $142.5 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 II and III clinical trials for Prochymal;
- 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 Provacel and, if supported by the Phase I clinical trial, initiate Phase II clinical trials;
- 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;
- relocate some or all of our business operations to a newly 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

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market value of our common stock will decline and you could lose part or all of your investment.

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 trial 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 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 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. Although not our current focus, 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.

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. 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, this pathway 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 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. The graveness of their underlying disease and dire prognosis, even if successfully treated for GvHD, could 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 Chondrogen and Provacel 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 likely have to demonstrate, among other things, that our biologic drug candidate is as safe and is more efficacious than those treatments by a statistically significant difference. 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 differentiate our biologic drug candidates from stem cell drug candidates of other companies derived from human embryonic or fetal tissue, which have given rise to significant ethical controversies;
- 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, Chondrogen and Provacel 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, 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 12 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 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 limits 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 32. 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 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 inadvertently or unwittingly 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 have only limited experience manufacturing Osteocel and our biologic drug candidates. 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. We have not built commercial-scale manufacturing facilities, and we have limited manufacturing experience with Osteocel and our biologic drug candidates. These difficulties 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 Boston Scientific Corporation for cardiovascular applications of our MSC technology; and
- we have a collaboration with JCR Pharmaceuticals Co., Ltd. granting to JCR an exclusive right to Prochymal for the treatment of GvHD in Japan.

Although we have no current intention to do so, 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 which 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 have used 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 recently delivered a notice of termination to the contract manufacturer that we had been using to manufacture our biologic drug candidates under development. As a result, this contract terminates in September 2006. We anticipate either renegotiating our contract with this contract manufacturer or negotiating a new agreement with another contract manufacturer. The transition to a replacement contract manufacturer has additional risks, including those risks associated with the development by the replacement contract manufacturer of sufficient levels of expertise in the manufacturing process. If we are unable to renegotiate this agreement or enter into a replacement agreement with another contract manufacturer on reasonable terms and in a timely manner, or if any replacement contract manufacturer is unable to develop sufficient manufacturing expertise in a timely manner, we

could experience shortages of clinical trial materials, which would negatively impact our ability to complete our clinical trials and obtain marketing approval for the commercial sale of our biologic drug candidates.

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 stem cells for our clinical trials and 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 clinical trials and distribution of Osteocel due to a lack of available product. In addition, we have subleased a portion of our facility which requires approval under our lease. We are seeking approval from our landlord for this sublease.

Currently, we maintain insurance coverage totaling $12.3 million against damage to our property and equipment, an additional $4.0 million to cover business interruption and extra expenses, $5.6 million to cover R&D restoration expenses, and $50,000 to cover restoration of valuable papers. If we have underestimated our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies.

We have experienced significant management turnover.

Our current Chief Executive Officer, C. Randal Mills, joined us in July 2004. All of our executive officers have joined us since then. Since 1999, we have experienced significant management turnover. Including interim appointees, we have had six chief executive officers since 1999. The departure of two of these resulted in litigation against us. This lack of management continuity, and the resulting lack of long-term history with our company, could result in operational and administrative inefficiencies and added costs. If we were to experience additional turnover at the executive level, these risks would be exacerbated.

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, and Cary J. Claiborne. 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. 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 also rely from time-to-time on outside advisors who assist us in formulating our research and development and clinical strategy. We may not be able to attract and retain

these individuals on acceptable terms which could have a material adverse effect on our business, financial condition and results of operations.

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 Centocor, the manufacturer of Remicade, 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 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 filed a patent application covering the composition of matter and methods of manufacture of our commercially available product, Osteocel. This patent has not yet issued and there can be no assurances that it 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 we do not have a granted patent specifically directed to Osteocel, and 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 that is not covered by a granted patent, 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.

For example, we are aware of patents owned by third parties that are directed toward mesenchymal stem cells and the use thereof. Our preliminary research suggests that our biologic drug candidates, upon commercialization, would not infringe a valid claim of these patents. However, our review of these patents is still at an early stage, and our views are subject to change.

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. A hearing date for the opposition has not been set, and the losing party has the right to appeal the initial decision. If we do not prevail in the opposition proceedings, we will not have broad patent protection with respect to mesenchymal stem cells in Europe. The outcome of the proceedings is uncertain at this time. 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.

Finally, 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 four 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, three of which have been determined to be possibly related to MSCs. 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), 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 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 trial. 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 prevented, any of which would adversely affect our ability to generate operating revenues.

Any of the following factors may serve to delay, limit or prevent final marketing approval for our biologic drug candidates;

- 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.

We may experience such delays in the future.

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 determined that it met 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 Europe and the United States, may designate drugs for relatively small patient populations as orphan drugs. Although the FDA has 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 FDA will not approve another application to market the same drug for the same indication, except in limited circumstances, for a period of seven years in the United States. 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, 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 treatment of steroid refractory GvHD.

Risks Related to this Offering

There has been no prior market for our common stock, and it may trade at prices below the initial public offering price.

Prior to this offering, there has been no public market for our common stock. We cannot predict the extent to which a trading market for our common stock will develop or be sustained after this offering. The initial public offering price will be determined by negotiations between us and the representative of the underwriters based on factors that may not be indicative of future performance, and may not bear any relationship to the price at which our common stock will trade upon completion of this offering. You may be unable to sell your shares of common stock at or above the initial public offering price.

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be 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 initial public offering price. 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.

Purchasers in this offering will suffer immediate dilution and may experience additional dilution in the future.

If you purchase common stock in this offering, you will pay more for your shares than the amounts paid by existing stockholders for their shares. In addition, the net tangible book value of your shares based upon our actual book value will immediately be less than the offering price you paid. For more information, see the discussion under the caption "Dilution."

The future sale of our common stock could negatively affect our stock price.

If our existing stockholders sell a large number of shares of common stock, or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. These stockholders may sell their shares of our common stock starting at various times following this offering. We have agreed, under certain circumstances, to register the resale of shares held by our existing stockholders. In addition, we intend to register approximately 6.9 million shares of common stock that are reserved for issuance under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to lock-up agreements and restrictions on our affiliates. For more information, see the discussion under the caption "Shares Eligible for Future Sale."

Contract rights may exist that grant third parties preemptive or registration rights.

Prior to the appointment of our current management, we engaged in numerous financing transactions. In the course of these transactions, we are aware that we have granted to third parties contract rights to, among other things, cause us to sell to them additional equity or other securities or cause us to register the sale of shares previously sold to them. We may have granted similar rights to additional parties that we are not aware of. No one has made any claim against us in this regard, and we do not believe that any such rights are outstanding except to the extent contained in contracts we have filed as exhibits to this registration statement. Nevertheless, if there are other rights that can be proven by third parties to exist, our share capital could be diluted and we could incur additional expenses, and the market for our stock could be more volatile or depressed because of sales of stock pursuant to these rights.

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.

Upon completion of this offering, our executive officers, directors and beneficial owners of 5% or more of our common stock and their affiliates will, in aggregate, beneficially own approximately % of our outstanding common stock, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock and the conversion of $ of our convertible notes into shares of our common stock (assuming a public offering price of $ per share), but assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options or warrants. 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. For more information, see the discussion under the caption "Principal Stockholders."

In addition, Peter Friedli, our Chairman of the Board of Directors, beneficially owned approximately 53% of our outstanding common stock as of May 10, 2006. Accordingly, Mr. Friedli currently has, and will continue to have, a significant influence over the outcome of all corporate actions requiring stockholder approval. For example, since our certificate of incorporation does not provide our stockholders with cumulative voting rights, Mr. Friedli, acting with his affiliates, will be able to elect all of our directors. This power to elect directors could be used in ways that benefit Mr. Friedli and his affiliates to the detriment of other stockholders.

Certain provisions of Delaware law and of our charter documents 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
- advance notice procedures our stockholders must comply with 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.

Our management has broad discretion over the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return.

Our management will have broad discretion over the use of proceeds from this offering. You may not agree with management's decisions, and our use of the proceeds may not yield any return on your investment in us. The failure of our management to apply the net

proceeds of this offering effectively could have a material adverse effect on our business, financial condition and results of operations.

We do not expect to pay cash dividends on our common stock in the foreseeable future. As a result, you must rely on stock appreciation for any return on your investment.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend upon our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our Board of Directors. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Furthermore, we may become subject to contractual restrictions or prohibitions on the payment of dividends.

The requirements of being a public company may strain our resources and distract management.

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the related regulations of the SEC, as well as the rules of The NASDAQ National Market. We have not previously been subject to these requirements, and they may place a strain on our systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight will be required. In addition, we will be required to have our independent public accounting firm attest to and report on management's assessment of the effectiveness of our internal controls over financial reporting. This may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. Also, we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and we cannot assure you that we will be able to do so in a timely fashion. If we are unable to conclude that we have effective internal controls over financial reporting or, if our independent auditors are unable to provide us with an attestation and an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, and the market price for our common stock could be significantly harmed.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. Forward-looking statements include statements about our expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as "anticipate," "believe," "continue," "ongoing," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project" or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. 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;
- status of the regulatory process for our biologic drug candidates;
- implementation of our corporate strategy;
- our financial performance, including expectations for revenue growth from Osteocel and our biologic drug candidates;
- our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for MSCs and biologic drug candidates;
- our use of the proceeds from this offering;
- our cash needs;
- patents and proprietary rights;
- expected market sizes and growth;
- ability of our potential products to treat disease;
- our plans for sales and marketing; and
- types of regulatory frameworks we expect will be applicable to our potential products.

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. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including the factors described in the section entitled "Risk Factors" in this prospectus. Accordingly, you should not unduly rely on these forward-looking statements, which speak only as of the date of this prospectus. We undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this prospectus or to reflect the occurrence of unanticipated events. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $ million, or $ million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of $ per share and after deducting underwriting discounts and commissions and the estimated offering expenses payable by us.

We intend to use the net proceeds to us from this offering to pay:

- approximately $ million for conducting a Phase III clinical trial for Prochymal;
- approximately $ million for conducting a Phase III clinical trial for Chondrogen, assuming successful completion of the Phase I/II clinical trial for Chondrogen currently underway;
- approximately $ million for preclinical and other clinical research and development activities relating to our biologic drug candidates; and
- approximately $ million for early repayment of principal and interest on a promissory note.

We intend to use the balance of the proceeds for general corporate purposes, including working capital needs and potential acquisitions of technologies or businesses.

The above-referenced promissory note matures on November 28, 2008 and is prepayable by us without penalty. The full $20.6 million of principal currently remains outstanding, and since its issuance on November 28, 2005, the note has accrued interest at a rate of 6% per annum. The note also has a redemption premium of 9%, which increases over time to 27% by maturity.

We are not obligated to use the net proceeds from this offering for any particular purpose, and the amounts and timing of our actual use of proceeds will depend upon numerous factors, including cash flows from operations, the growth of our business and other factors described under "Risk Factors." Also, although we periodically evaluate acquisition and licensing opportunities, we currently have no commitments or agreements with respect to any specific acquisition or additional license. As a result, we cannot specify with certainty the amounts that we may allocate to the particular uses of the net proceeds of this offering. Our management will have significant flexibility and discretion in applying the net proceeds of this offering. Pending any use, we will invest the net proceeds of this offering generally in short-term, investment grade, interest bearing securities but cannot predict that these investments will yield a favorable return.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the growth and development of our business. We do not intend to pay cash dividends on our common stock in the foreseeable future.

CAPITALIZATION

The following table presents our capitalization as of December 31, 2005:

- on an actual basis;
- on a pro forma basis to give effect to the conversion of all outstanding shares of our preferred stock into shares of common stock, and the conversion of $ of our convertible notes into shares of common stock (assuming a public offering price of $ per share), each of which will become effective upon the closing of this offering; and
- on a pro forma as adjusted basis to give effect to:
  - the sale of the shares of common stock by us in this offering at an assumed initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us, and
  - repayment of our outstanding promissory note, consisting of $20.6 million in principal and an aggregate of $ million in interest payments, assuming eight months of accrued interest since the issuance of the note on November 29, 2005.

You should read this table together with our financial statements and the related notes included in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information included in this prospectus.

	As of December 31, 2005		
	Actual	Pro forma	Pro forma as adjusted
	(in thousands)		
Total long-term obligations	$ 53,800	$	$
Mandatorily redeemable convertible preferred stock, $0.001 par value; 3,750 shares designated, 3,213 shares issued and outstanding	64,267		
Stockholders' equity (deficit)			
Convertible preferred stock, par value, 16,250 shares authorized, 12,250 shares designated and 10,651 shares outstanding	32,746		
Common stock, $0.001 par value, 90,000 shares authorized, 36,390 shares issued and outstanding	36		
Additional paid-in capital(1)	36,377		
Deferred compensation	(277)		
Accumulated deficit	(142,544)		
Total stockholders' equity (deficit)(1)	(73,662)		
Total capitalization(1)	$ 44,405	$	$

(1)

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) each of additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. The pro forma information presented above is illustrative only and following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

The table above does not include:

- 2,265,916 shares of our common stock issuable upon exercise of options outstanding as of December 31, 2005, at a weighted average exercise price of $0.10 per share, of which, as of that date;
  - options to purchase 714,549 shares were exercisable; and
  - management-owned options to purchase 930,000 shares were outstanding and will be exercisable upon the closing of this offering; and
- 8,500,000 shares of our common stock issuable upon exercise of warrants outstanding as of December 31, 2005, at a weighted average exercise price of $0.10 per share, all of which warrants were exercisable as of that date, and of which 5,000,000 have subsequently been cancelled.

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our net tangible book value as of December 31, 2005 was a deficit of approximately $(73.7 million), or $(2.30) per share of common stock. Our pro forma net tangible book value as of December 31, 2005, after giving effect to the conversion of all of our preferred stock outstanding as of that date into shares of common stock and the conversion of $ of our convertible notes into shares of common stock (assuming a public offering price of $ per share), was approximately $ million, or $ per share of common stock. Net tangible book value per share is determined by dividing our total tangible assets less total liabilities by the number of shares of common stock outstanding at December 31, 2005.

Our pro forma net tangible book value as of December 31, 2005 after this offering would have been $ million or $ per share. This represents an immediate increase in pro forma net tangible book value of $ per share to existing stockholders and an immediate dilution in pro forma net tangible book value of $ per share to new investors. Dilution in pro forma net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the net tangible book value per share of our common stock immediately afterwards, after giving effect to the sale of shares in this offering at an assumed public offering price of $ per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses. The following table illustrates this per share dilution:

Assumed initial public offering price per share		$
Historical net tangible book value per share	$ (2.30)	
Change attributable to conversion of convertible preferred stock		
Change attributable to conversion of convertible notes		
Pro forma net tangible book value per share before this offering		
Increase per share attributable to this offering		
Pro forma net tangible book value per share after this offering		
Dilution per share to new investors		$

The following table summarizes, on a pro forma basis as of December 31, 2005, after giving effect to this offering and assuming a public offering price of $ per share, the total number of shares of common stock purchased from us and the total consideration and the average price per share paid by existing shareholders and by new investors, calculated before deduction of underwriting discounts and commissions and estimated offering expenses.

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Average Price Per Share
Existing stockholders		%	$	%	$
New investors					
Total		%	$	%	

The number of shares of common stock outstanding in the table above is based on the number of shares outstanding as of December 31, 2005 and excludes:

- 2,265,916 shares of our common stock issuable upon exercise of options outstanding as of December 31, 2005, at a weighted average exercise price of $0.10 per share, of which, as of that date;
  - options to purchase 714,549 shares were exercisable; and
  - management-owned options to purchase 930,000 shares were outstanding and will be exercisable upon the closing of this offering; and
- 8,500,000 shares of our common stock issuable upon exercise of warrants outstanding as of December 31, 2005, at a weighted average exercise price of $0.10 per share, all of which warrants were exercisable as of that date, and of which 5,000,000 have subsequently been cancelled.

SELECTED FINANCIAL DATA

The following selected financial data for the years ended December 31, 2003, 2004 and 2005 has been derived from our audited financial statements included elsewhere in this prospectus. The following selected financial data for the years ended December 31, 2001 and 2002 has been derived from our audited financial statements not included in this prospectus. This information is only a summary and should be read together with our financial statements and the related notes included in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information included in this prospectus.

The pro forma net loss attributable to common stockholders per share information is computed using the weighted average number of common shares outstanding, after giving pro forma effect to the conversion of all outstanding shares of our convertible preferred stock into shares of common stock, the conversion of all our mandatorily redeemable convertible preferred stock into shares of common stock, and the conversion of certain convertible notes into shares of common stock, all concurrently with the completion of this offering, as if the conversion had occurred at the dates of the original issuances.

	Year Ended December 31,				
	2001	2002	2003	2004	2005
	(in thousands, except per share data)				
Statement of Operations Data:					
Product sales	$	$	$	$	$ 957
Cost of goods sold					444
Gross profit					513
Revenue from collaborative research licenses and grants	1,345	1,217	3,981	3,911	3,013
Operating expenses:					
Research and development	14,135	11,206	18,639	11,888	16,927
General and administrative	4,198	4,096	4,467	1,704	2,294
Total operating expenses	18,333	15,302	23,106	13,592	19,221
Loss from operations	(16,988)	(14,085)	(19,125)	(9,681)	(15,695)
Interest expense, net	(1,360)	(5,033)	(605)	(847)	(4,300)
Net loss	$ (18,348)	$ (19,118)	$ (19,730)	$ (10,528)	$ (19,995)
Basic and diluted net loss per share	$ (2.26)	$ (2.17)	$ (0.90)	$ (0.30)	$ (0.56)
Weighted average shares of common stock used in computing basic and diluted net loss per share	8,104	8,805	21,901	35,255	35,837
Pro forma basic and diluted net loss per share applicable to common stockholders (unaudited)					$
Shares used to compute pro forma basic and diluted net loss per share					

	As of December 31,				
	2001	2002	2003	2004	2005
	(in thousands)				
Balance Sheet Data:					
Cash and short-term investments	$ 4,792	$ 394	$ 1,399	$ 488	$ 43,371
Working capital	(4,344)	(29,645)	(5,314)	(5,459)	38,103
Total assets	15,364	8,525	9,748	5,972	51,014
Long-term debt, less current portion	8,310	245	179	7,519	47,411
Mandatorily redeemable convertible preferred stock					64,267
Convertible preferred stock			13,000	15,243	32,746
Accumulated deficit	(73,173)	(92,291)	(112,021)	(122,549)	(142,544)
Total stockholders' deficit	(7,879)	(26,291)	(5,563)	(13,004)	(73,662)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis by our management of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the accompanying notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Risk Factors."

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 five clinical trials ongoing. Our lead biologic drug candidate Prochymal is entering a Phase III clinical trial for steroid refractory Graft versus Host Disease, or GvHD, and is in Phase II clinical trials for acute GvHD and Crohn's Disease. In addition, we have two other clinical stage biologic drug candidates, Chondrogen for regenerating cartilage in the knee, and Provacel for repairing heart tissue following a heart attack. We have developed stem cell capabilities in research and development, manufacturing, marketing and distribution. We manufacture Osteocel and clinical batches of our biologic drug candidates. We distribute Osteocel in orthopedic indications and jointly distribute Osteocel with Blackstone Medical for spinal procedures.

We have never been profitable. As of December 31, 2005, we had an accumulated deficit of $142.5 million. 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 a result, we are dependent upon external financing to finance our operations. We intend to seek additional financing through public or private issuance of equity or through the debt market. We have two collaborative research arrangements that provide for the partial financing of research expenses. However, these arrangements do not cover the entire estimated costs of the pivotal clinical trials that are required to bring us to market. There can be no assurance that additional financing or partnering revenues will be available to us in the future or on terms that will be acceptable to us. Although we have sought collaborative relationships in the past, we do not anticipate seeking them in the future.

We have historically financed the majority of our operations and capital expenditures though the issuance of privately placed debt and equity securities and, to a much lesser extent, through payments we have received from our collaborators.

While we have achieved commercialization of our Osteocel product, our principal focus is on the successful development and commercialization of our biologic drug candidates, the most clinically advanced of which is Prochymal. We expect Osteocel sales to increase moderately as we achieve greater market penetration and increase our manufacturing capacity. We expect to incur increased capital and operating expenses relating to Osteocel to increase distribution capabilities and manufacturing capacity and, ultimately, move our manufacturing facilities to a new location. However, our principal capital requirements, and greatest source of operating losses over the next several years, will likely relate to the continued preclinical and clinical development of our biologic drug candidates and related

regulatory and pre-commercialization activities. We believe these potential products have the greatest long-term potential for revenue and profitability, and we expect to focus our management and financial resources principally on them.

Financial Operations Overview

Revenue

Osteocel is our only commercial product. Sales of Osteocel generated revenue of approximately $1.0 million for the year ended December 31, 2005. 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 2003, we entered into an agreement with Boston Scientific Corporation 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 fee is being recognized as revenue over a 63-month period, $0.9 million of which was recognized in each of 2004 and 2005 and $0.8 million was recognized in 2003. Also in 2003, we entered into an agreement with JCR Pharmaceuticals granting it exclusive rights to Prochymal for the treatment of GvHD in Japan. We recognized $0.5 million of revenue in 2005, $2.0 million in 2004, and $1.0 million in 2003 from our collaboration with JCR Pharmaceuticals. We do not expect to enter into collaborations in the future.

Historically, 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. We earned $0.8 million and $2.1 million from governmental research grants in 2004 and 2003, respectively. Revenue from research grants is recognized as the related research expenditures are incurred. We do not expect to solicit governmental grants in the future.

Other than Osteocel, we have no commercial products for sale and do not anticipate that we will have any other commercial products for sale for at least the next several years. 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, which we launched in July 2005. Cost of goods sold consist primarily of the costs of obtaining tissue and other chemicals and supplies. Our manufacturing processes are still being refined, and therefore, we expense manufacturing labor costs as incurred. These labor costs are reported as research and development costs. We expect that once we have achieved adequate production experience, we will include certain labor costs in cost of goods sold. We expect that cost of goods sold as a percentage of product sales will improve due to continuing refinements in our Osteocel manufacturing processes as well as scale efficiencies resulting from increased production.

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, the legal costs of pursuing patent protection for our

intellectual property, 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.

We expect our research and development expenses to increase substantially following the completion of this offering 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 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. Following this offering, we anticipate 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. These increases will also likely include the hiring of additional operational, financial, accounting, facilities engineering and information systems personnel.

Interest Expense

Interest expense consists of interest incurred on our debt. We pay interest on our bank loan and capital leases and accrue non-cash interest on some of our convertible long-term debt. At December 31, 2005, we had debt of approximately $47.5 million that bears interest at stated rates between 5% and 8% per year and the majority of which is expected to be converted into equity or repaid upon successful completion of an initial public offering. Certain redemption of premiums result in an effective yield of 15% on certain issues. Upon conversion we expect that the majority of the $4.8 million of interest expense we incurred in 2005 will eventually be paid through the issuance of common stock, and not in cash. At December 31, 2004, we had debt of approximately $9.9 million that bears interest at between 5% and 10% per year resulting in interest expense of approximately $0.9 million in 2004.

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 carryforwards. In the event that we become profitable within the next several years, we have net deferred tax assets of approximately $57.3 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 carryforwards in any one year may be limited however, 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, deferred tax assets, stock-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.

Milestones 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 milestones 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. Milestones 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 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, 2005 and 2004, there was no allowance for doubtful accounts as we believe the reported amounts are fully collectible. We did not recognize any bad debt expense for the years ended December 31, 2005, 2004 and 2003. Accounts receivable balances are not collateralized.

Stock-Based Compensation

As permitted by the provisions of Statement of Financial Accounting Standards, SFAS, No. 148, "Accounting for Stock-Based Compensation Transition and Disclosure," and SFAS No. 123, "Accounting for Stock-Based Compensation," our employee stock option plan is accounted for under Accounting Principles Board Opinion No. 25, APB 25, "Accounting for Stock Issued to Employees." We grant qualified stock options for a fixed number of shares to employees and directors with an exercise price equal to the fair market value of the shares at the date of grant. In these circumstances and in accordance with APB 25, we recognize no compensation expense for qualified stock option grants. We have issued non-qualified stock options for a fixed number of shares to employees and directors with an exercise price less than the fair market value of the shares at the date of grant. When such options vest, we will recognize the difference between the exercise price and fair market value at date of grant as compensation expense in accordance with APB 25. For shares of common stock granted to directors, we record the intrinsic value of the shares granted based upon the estimated fair value on the date of grant.

In December 2004, FASB issued SFAS No. 123(R) (revised 2004), "Share-Based Payments." This Statement is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation." This Statement supersedes APB 25 and its related implementation guidance. Upon the adoption of SFAS No. 123(R), we will be required to expense stock options using a fair-value method in our Statement of Operations. We will be required to apply SFAS No. 123(R) as of the first annual reporting period starting on or after June 15, 2005, which is our first quarter beginning January 1, 2006. Adoption of the expensing requirements will increase our net loss. See "Stock-based Compensation" in Note 1 of our financial statements for year ended December 31, 2005 for disclosures regarding the effect on net earnings and earnings per share if we had applied the fair value recognition provisions of SFAS No. 123(R). Upon adoption, we intend to use the modified prospective method. Under this method, compensation cost is recognized beginning with the effective date of adoption (a) based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date of adoption and (b) based on the requirements of SFAS 123(R) for all awards granted to employees prior to the effective date of adoption that remain unvested on the date of adoption. We currently utilize the Black-Scholes option pricing model to estimate the fair value. The Black-Scholes model meets the requirements of SFAS 123(R) but the fair values generated by the model may not be indicative of the actual fair values of our stock-based awards. Actual compensation expense that is expected to be recorded in 2006 and thereafter will depend on several factors, including the amount of future option grants. Based upon the expected vesting of existing options, we estimate stock-based compensation expense to be $70,000 for the year ending December 31, 2006. Upon the occurance of certain future events, the vesting of stock options may be accelerated which could affect future stock-based compensation expense.

Results Of Operations

Comparison of Years ended December 31, 2005 and 2004

Revenue

Total revenues were $4.0 million for the year ended December 31, 2005, compared to $3.9 million in the prior year. Our revenues in 2005 resulted primarily from $1.0 million generated from the sale of Osteocel, the recognition of $0.9 million in licensing fees resulting from our agreement with Boston Scientific for our cardiac technology, royalty fees of $0.5 million recognized upon completion of the transfer of technology to JCR Pharmaceuticals, and $1.4 million in revenues recognized upon completion of work in furtherance of governmental grants. In 2004, we recognized $2.0 million in license fees from JCR Pharmaceuticals for the future distribution of our products in Japan, $0.9 million in licensing fees from Boston Scientific, and $0.8 million relating to completion of work in furtherance of our grants from the U.S. government. These grants were completed during the second quarter of 2005. We do not expect that future grant revenue will be material.

Cost of Goods Sold

Cost of goods sold were $0.4 million for the year ended December 31, 2005 compared to $0.0 in the prior year. We launched Osteocel in July 2005. The cost of goods sold associated with sales of Osteocel was comprised of payments to tissue banks and the costs of processing, testing and preserving Osteocel.

Research and Development Expenses

Research and development costs were approximately $16.9 million for the year ended December 31, 2005 compared to $11.9 million in the prior year. The increase in research and development expenses in 2005 reflects the costs we incurred in the initiation 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 I/II clinical trial for Chondrogen, and a Phase I clinical trial for Provacel during the year.

General and Administrative Expenses

General and administrative expenses were $2.3 million for the year ended December 31, 2005 compared to $1.7 million in the prior year. The increase in general and administrative expenses in 2005 compared to 2004 primarily reflects the costs of our new management team. In the third quarter of 2004, our Chief Executive Officer and Chief Operating Officer joined us and, in the fourth quarter of 2004, our Chief Financial Officer was hired. These three positions were previously vacant.

Interest Expense, Net

Interest expense, net was $4.3 million for the year ended December 31, 2005 compared to $0.8 million in the prior year. The increase was attributable to a higher average level of debt in 2005 than in the prior year. The non-cash portion of our interest expense was $3.5 million in 2005 compared to $0.5 in 2004.

Comparison of Years ended December 31, 2004 and 2003

Revenues

We had no product sales in 2004 or 2003. Revenues for the year ended December 31, 2004 were $3.9 million compared to $4.0 million in the prior year. Our revenues in 2004 resulted primarily from the recognition of license fees of $0.9 million, resulting from our agreement with Boston Scientific for our cardiac technology, license fees of $2.0 million from JCR Pharmaceuticals for the future distribution of our products in Japan, and $0.8 million in revenues recognized upon completion of work in furtherance of grants from the U.S. government. In 2003, we recognized $1.4 million relating to work on two grants with the U.S. Defense Advanced Research Projects Agency, DARPA, for research, license fees of $1.0 million from JCR Pharmaceuticals for the future distribution of our products in Japan, license fees of $0.8 million, resulting from our agreement with Boston Scientific for our cardiac technology, and $0.7 million in revenues recognized upon completion of work in furtherance of grants from the U.S. government.

Research and Development Expenses

Research and development costs were approximately $11.9 million for the year ended December 31, 2004 compared to $18.6 million in the prior year. The decrease in research and development expenses in 2004 was driven by lower employee headcount and a reduction in research costs as we transitioned to a company centered on the development and commercialization of stem cell products. Additionally, in 2004 we began outsourcing the management of our clinical trials to third parties who we believe can achieve better results at a lower cost to us. This change helped further reduce our 2004 research and development expenses as compared to 2003.

General and Administrative Expenses

General and administrative expenses were $1.7 million for the year ended December 31, 2004 compared to $4.5 million in the prior year. The decrease in general and administrative expenses in 2004 compared to 2003 primarily reflects vacancies in our executive officer positions, a reduction of our workforce and a focus on operational efficiency. Our Chief Executive Officer and Chief Operating Officer positions were vacant until the third quarter of 2004 and our Chief Financial Officer was hired in the fourth quarter of 2004.

Interest Expense, Net

Interest expense, net was $0.8 million for the year ended December 31, 2004 compared to $0.6 million for 2003. The increase was attributable to an approximately $0.4 million non-cash charge to interest expense in 2004 as a result of 5,000,000 warrants issued in conjunction with certain debt financing.

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed the majority of our operations and capital expenditures though the issuance of privately placed debt and equity securities. Friedli Corporate Finance Inc. and its affiliates, and investors solicited by Friedli Corporate Finance, have provided funding for the majority of our operations to date. The sole owner of Friedli Corporate Finance is Peter Friedli, the chairman of our Board of Directors and the beneficial owner of approximately 53% of our common stock as of May 10, 2006. In addition to the sources described above, at December 31, 2005, we had drawn only $5.0 million of the $50.0 million line of credit available for the development of Provacel under a loan agreement with Boston Scientific. In connection with this line of credit, we have granted Boston Scientific a security interest in the intellectual property, equipment and books and records involved in the development, manufacture and distribution of Provacel. Boston Scientific is also obligated to make additional investments in our Company and pay licensing fees up to $45.0 million to us upon completion of certain milestones.

Cash Flows

Net cash used in operating activities was $14.6 million for the year ended December 31, 2005 primarily reflecting our net loss of $20.0 million, partially offset by $3.5 million in non-cash interest expense. Net cash used for operating activities was $12.1 million for the year ended December 31, 2004. Net cash used in operating activities for 2004 primarily reflecting our net loss of $10.5 million and previously deferred non-cash revenue of $3.0 million, associated with our collaboration agreements with JCR Pharmaceuticals and Boston Scientific. Net cash used for operating activities was $10.1 million for the year ended December 31, 2003 primarily reflecting our net loss of $19.7 million, partially offset by the receipt of $6.2 million from our collaborations with Boston Scientific and JCR Pharmaceuticals, which was deferred and will be recognized in accordance with the terms of those collaborations.

Net cash used in investing activities was $43.1 million for the year ended December 31, 2005; $50,000 for the year ended December 31, 2004; and $1.2 million for the year ended December 31, 2003, respectively. Net cash used in investing activities in 2005 includes cash flows used to purchase $45.0 million of short-term investments.

Net cash provided by financing activities was $57.8 million for the year ended December 31, 2005 and consisted principally of $40.0 million in net proceeds from the issuance of convertible notes and $21.4 million in net proceeds from the issuance of common and preferred stock, partially offset by $2.5 million in debt financing costs. Net cash provided by financing activities was $11.3 million for the year ended December 31, 2004 and consisted principally of $9.7 million in net proceeds from the issuance of convertible notes and $2.5 million in net proceeds from the issuance of common and preferred stock. Net cash provided by financing activities was $12.3 million for the year ended December 31, 2003 and consisted principally of $13.1 million in net proceeds from the issuance of common and preferred stock.

Capital Resources

Our future cash requirements will depend on many factors, including continued progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, and the cost of product commercialization. We do not expect to generate positive cash flow from operations for at least the next several years due to these factors. We intend to seek additional funding through public or private financing transactions and may seek research and development agreements or distribution and marketing agreements. In the past, we have entered into collaborative arrangements with partners relating to research and development and sales and marketing of our products, however, we do not intend to pursue this strategy going forward. The future success of our operations is subject to several technical and business risks, including our continued ability to obtain future funding, satisfactory product development, obtaining regulatory approval, and market acceptance for our products.

We expect that our available cash and interest income, including the proceeds from this offering, will be sufficient to finance currently planned activities through the middle of 2008. 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 other than operating leases, and we have not entered into any transactions involving unconsolidated subsidiaries or special purpose entities.

Recent Accounting Pronouncements

As permitted by SFAS No. 123, "Accounting for Stock-Based Compensation," we currently account for share-based payments to employees using the intrinsic value method under Accounting Principles Board, or APB, Opinion No. 25. We grant qualified stock options for a fixed number of shares to employees with an exercise price equal to the fair market value of the shares at the date of grant. In these circumstances and in accordance with APB 25, we recognize no compensation expense for qualified stock option grants. We have issued non-qualified stock options for a fixed number of shares to employees with an exercise price less than the fair market value of the shares at the date of grant. When such options vest, we will recognize the difference between the exercise price and fair market value at date of grant

as compensation expense in accordance with APB 25. For shares of common stock granted to directors, we record the intrinsic value of the shares granted based upon the estimated fair value on the date of grant.

In December 2004, the Financial Accounting Standards Board issued Statement No. 123(R), "Share-Based Payment," which is a revision of Statement No. 123. We plan to adopt the standard effective January 1, 2006. We intend to use the modified prospective method of adoption and continue to use the Black-Scholes option pricing model to value share-based payments, although we are continuing to review our alternatives for calculating the estimated fair value under this new pronouncement. The modified prospective method requires companies to recognize compensation cost beginning with the effective date of adoption based on (a) the requirements of Statement No. 123(R) for all share-based payments granted after the effective date of adoption and (b) the requirements of Statement No. 123 for all unvested awards granted to employees prior to the effective date of adoption.

Statement No 123(R) requires all share-based payments to employees and directors to be recognized in the financial statements based on their fair values, using prescribed option-pricing models. Upon adoption of Statement No. 123(R), pro forma disclosure will no longer be an alternative to financial statement recognition. Accordingly, the adoption of the fair-value method prescribed by Statement No. 123(R) may have a significant impact on our results of operations, although it will not have an impact on our overall financial position or cash flows. Based upon the expected vesting of existing options, we estimate our stock-based compensation to be approximately $70,000 for the year ended December 31, 2006. Upon the occurrence of certain events, the vesting of stock options may be accelerated which could affect future stock-based compensation expense.

In March 2005, the FASB issued Interpretation No. 47, "Accounting for Conditional Asset Retirement Obligations," which is an interpretation of Statement No. 143, "Accounting for Asset Retirement Obligations." The interpretation requires that a liability for the fair value of a conditional asset retirement obligation be recognized if the fair value of the liability can be reasonably estimated. The interpretation is effective for years ending after December 15, 2005. The interpretation did not have a material impact on our results of operations, financial position or cash flows.

In May 2005, the FASB issued Statement No. 154, "Accounting Changes and Error Corrections." SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It established, unless impracticable, retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. SFAS No. 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The provisions of this Statement are effective for accounting changes and corrections of errors made in fiscal periods beginning after December 15, 2005.

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 and commitments as of December 31, 2005. The information in the table reflects future unconditional payments and is based on the terms of the relevant agreements, appropriate classification of items under generally accepted accounting principles currently in effect, certain assumptions such as interest rates on our debt that accrues interest at variable rates, and the timing of conversion

of our convertible debt. Future events could cause actual payments to differ from these amounts.

	Total	2006	2007	2008	2009	2010	Thereafter
	(in thousands)						
Long-term debt	$ 47,476	$ 65	$ 49	$ 42,362	$	$	$ 5,000
Interest on long-term debt	10,992	5,033	3,126	1,634	400	400	400
Mandatorily redeemable convertible preferred stock	64,267		64,267				
Capital leases	3,051	1,027	1,129	885	7	3	
Interest on capital leases	342	196	115	29	1		
Total obligations	$ 126,128	$ 6,321	$ 68,686	$ 44,910	$ 408	$ 403	$ $5,400

The long-term debt balance principally includes $5.0 million outstanding under the loan agreement with Boston Scientific and approximately $42.3 million of convertible promissory notes due in 2008. The mandatorily redeemable Series D convertible preferred stock will convert into common stock upon closing of this offering, and are not expected to be redeemed in cash. In the event the offering does not take place and the mandatorily redeemable preferred stock is not otherwise converted, it must be redeemed for $20.00 per share in June 2007. Upon closing of this offering, approximately $21.8 million of the promissory notes will be concurrently converted into common shares. In addition, $2.0 million of the interest on long-term debt will also be concurrently converted into common shares upon the closing of this offering.

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. Accordingly, 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-collectibility and establishment of appropriate allowances in connection with our internal controls and policies.

We have not and do not expect to enter into hedging or derivative instrument arrangements.

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. We currently market and sell Osteocel for regenerating bone in orthopedic indications. It is the first commercially available product in the U.S. containing stem cells. We believe that our lead biologic drug candidate Prochymal, for the treatment of inflammatory disease, is the only stem cell therapeutic entering a Phase III clinical trial and is the first stem cell therapeutic to receive FDA Fast Track and Orphan Drug designations. Our pipeline of internally developed biologic drug candidates also includes Chondrogen, for regenerating cartilage in the knee, and Provacel, for repairing heart tissue following a heart attack. We are a fully integrated company, having developed stem cell capabilities in research and development, manufacturing, marketing and distribution. We have developed an extensive intellectual property portfolio to protect our technology in the United States and a number of foreign countries including 45 U.S. and 132 foreign patents owned or licensed.

Osteocel and our three biologic drug candidates utilize human mesenchymal stem cells, or MSCs. MSCs are progenitor cells that differentiate into various connective tissues when they receive appropriate biochemical and biomechanical signals. 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 32 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 5,000 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 this product 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	U.S. Commercialization Rights	Status
Osteocel	Spinal Procedures	Osiris and Blackstone	Marketing
	Orthopedics	Osiris	Marketing
Prochymal	Steroid Refractory GvHD	Osiris	Entering Phase III
	Acute GvHD	Osiris	Phase II
	Crohn's Disease	Osiris	Phase II
Chondrogen	Meniscus Regeneration	Osiris	Phase I/II
Provacel	Heart Attack	Boston Scientific	Phase I

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 first commercially available product containing stem cells in the United States. We launched Osteocel in July 2005 and to date it has been used in over 1,100 surgical procedures. We produce Osteocel from the marrow-rich bone of organ and tissue donors and it is 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 exclusively by us for orthopedic indications and jointly with Blackstone Medical for spinal procedures.

Prochymal is our biologic drug candidate for the treatment of inflammatory disease. We are currently entering a pivotal Phase III trial for the treatment of steroid refractory Graft versus Host Disease, or 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 steroid refractory GvHD, we enrolled patients that did not respond to treatment with steroids and at least one other therapy. Of these patients, 59% responded to Prochymal. We are also enrolling a Phase II trial evaluating Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD.

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 are currently enrolling Crohn's Disease patients in a Phase II trial under a separate Investigational New Drug application.

Chondrogen is our biologic drug candidate for regeneration of meniscus, a type of cartilage that cushions the knee joint. Each year approximately 800,000 people in the United States have surgery to remove damaged or torn meniscus. 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 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.

Provacel is our biologic drug candidate for the repair of heart muscle in patients who have suffered a heart attack. In the United States approximately 700,000 individuals each year experience their first heart attack. 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, Provacel targeted the damaged area of the heart following a single treatment. These studies also indicate that Provacel prevents scar formation that typically occurs after a heart attack and improves cardiac function eight to ten weeks after its administration. We recently completed enrollment in a Phase I clinical trial for Provacel to evaluate its safety and efficacy to restore heart function in patients experiencing a first time heart attack.

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 has 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 5,000 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 therapy. Our goal is to be the leading stem cell therapy company through the development and commercialization of stem cell therapies to address disease areas with significant unmet medical need and commercial potential. To achieve this goal, we are pursuing the following strategies:

Successfully commercialize our lead stem cell therapy, Prochymal. We are currently entering a pivotal Phase III clinical trial for Prochymal. It is our highest priority to complete the development of Prochymal and achieve marketing approval. Assuming marketing approval, we plan to develop a sales and marketing force to promote Prochymal initially for the treatment of steroid refractory GvHD. 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. To increase the probability of success, we intend to gain the support of key opinion leaders and to utilize our clinical investigator relationships to gain market adoption. We estimate that the clinical investigators we intend to use in our pivotal Phase III clinical trial for steroid refractory GvHD treat approximately 30% of the patients with this disease in the United States.

Leverage Osteocel's orthopedic sales infrastructure for Chondrogen. In the field of orthopedics, we intend to expand our network of sales professionals for the distribution of Osteocel. We plan to use our commercial experience with Osteocel to build a specialized sales organization trained and experienced in stem cell orthopedic sales. Given the overlap of potential customers for Osteocel and Chondrogen, we believe our relationships with orthopedic surgeons established through sales of Osteocel will help drive commercial adoption of Chondrogen and other orthopedic biologic drug candidates.

Expand our pipeline of biologic drug candidates where our stem cell technology has a therapeutic potential. We intend to continue investing in our biologic drug candidate pipeline by pursuing additional diseases and disorders where we believe MSCs have potential therapeutic benefit. For example, Prochymal reduced gastrointestinal inflammation in some patients in our Phase II steroid refractory GvHD clinical trial. Therefore, we have begun a Phase II clinical trial for Prochymal in patients with Crohn's Disease. As we demonstrate a potential therapeutic benefit from our biologic drug candidates in preclinical studies and clinical trials, we will prioritize which biologic drug candidates to pursue based on the clinical and regulatory path and commercial opportunity.

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. We also believe our manufacturing experience can be applied across all of our current and future biologic drug candidates, enhancing manufacturing efficiencies.

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 first commercially available product in the United States containing stem cells. We launched Osteocel in July 2005 and to date it has been used in over 1,100 surgical procedures. Osteocel is currently distributed exclusively by us for orthopedic indications and jointly with Blackstone Medical for spinal procedures.

Each year in the United States over 900,000 surgical procedures are performed 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. Complications from the autograft harvest

occur in up to 35% of patients having the procedure. As such, there is a significant medical need for a product that can provide reliable bone forming characteristics and eliminate the need for autograft.

Spinal fusion is used to treat damage to the intervertebral disc, including herniated discs, and is one of the most common and expensive surgeries in orthopedics. There were 450,000 spine fusion surgeries in 2005, associated with multibillion 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.
- 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. We are currently 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 are currently expanding our manufacturing capacity and increasing the number of organ and tissue agencies that supply us with tissue. Osteocel is 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. Our initial target indication for Osteocel-XC will be for the treatment of avascular necrosis, or AVN, of the femoral head, a disorder characterized by restriction or interruption of the blood supply to bone that results in death of bone cells. Without living bone cells, surrounding tissue erodes leading to mechanical failure of the bone and/or joint. This condition afflicts approximately 20,000 people per year in the United States, resulting in significant morbidity. It is estimated

that without surgical intervention, 70 to 80% of patients diagnosed with AVN of the femur will progress to hip failure. Even with today's surgical standard of care, over 40% of patients will require a total hip replacement. There is no drug therapy approved for the treatment of AVN.

Clinical Programs

Prochymal

Prochymal is our biologic drug candidate for the treatment of inflammatory disease. We are currently entering a pivotal Phase III trial for the treatment of steroid refractory 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. We are also evaluating Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD and as a therapy for the treatment of Crohn's Disease, a chronic condition that results in inflammation of the gastrointestinal tract.

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 Graft versus Host Disease. This condition gets its name because the bone marrow transplant, or the graft, begins to attack the recipient, or the host. 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 Transplant, the estimated one year survival 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. 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 initiated a Phase II trial to evaluate Prochymal as a first-line treatment for patients diagnosed with Grade II through Grade IV acute GvHD. Patients are treated with doses of 2 or 8 million cells per kilogram of body weight administered in two infusions of Prochymal 72 hours apart. The treatment commences within 48 hours of GvHD diagnosis. In this study, we are evaluating safety, dose, and response to treatment by day 28. Patients will be followed for safety for two years after trial enrollment. A total of 17 patients have been treated under this protocol, and an interim review of the data revealed approximately 70% of the patients meet the study criteria for complete response and had no signs of acute GvHD at the end of the 28-day study treatment period. Our trial protocol allows enrollment of up to 50 patients, however, we may terminate the trial early based on patient response rate.

Starting 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. A total of four 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.

As a result of the compassionate use requests, we initiated a second Phase II trial to investigate the use of Prochymal in patients diagnosed with Grade III or Grade IV GvHD that did not respond to treatment with steroids and at least one other therapy. This was an open label study in which we evaluated safety, dose, and response to treatment by day 28. Patients were treated with 8 million cells per kilogram every 72 hours as needed for response, for a maximum of eight treatments. Fourteen patients were treated under this protocol. The subjects enrolled in this trial had failed to respond to an average of 4.4 other drug therapies prior to enrollment. 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. We are following patients for safety for one year after trial enrollment.

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 doses of 1.0, 2.5, and 5.0 million cells per kilogram of body weight. No safety concerns related to the use of Prochymal were observed in the 46 subjects who were evaluated.

We recently held an end of Phase II meeting with the FDA to discuss the results of the trials described above and seek FDA guidance on the design of our pivotal Phase III trial for the treatment of steroid refractory GvHD. We anticipate opening enrollment in the pivotal Phase III trial in the second quarter of 2006.

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, seven years of marketing exclusivity and a waiver of the Biologic License Application fee of approximately $700,000. We believe that Prochymal is the first stem cell biologic drug candidate to be granted Fast Track and Orphan Drug designations.

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. There are over 500,000 cases of diagnosed Crohn's Disease in the United States, and at any given time approximately 10% of these 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. With current medical therapies, about 50% of patients with severe Crohn's Disease will relapse within a year. Also, one year post-surgical recurrence rates of over 85% have been reported in such patients.

We recently started enrolling patients in 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 plan on enrolling between 10 and 12 patients in this study and investigating patient response to doses of 2 and 8 million cells per kilogram of body weight. We will evaluate patients for efficacy 28 days after treatment. The target response is a reduction of at least 100 points on the Crohn's Disease Activity Index, a patient assessment scale designed to measure the severity of Crohn's Disease. The study will also evaluate the ability of Prochymal to induce remission of Crohn's Disease. We plan on evaluating each patient for safety two years after the patient enrolled in the trial.

Chondrogen

Chondrogen is our biologic drug candidate for regeneration of meniscus, a type of cartilage that cushions the knee joint. There are currently no products available to regenerate meniscal tissue. In several preclinical studies, Chondrogen regenerated meniscus and prevented osteoarthritis in animal models. We recently completed enrollment in a Phase I/II clinical trial for Chondrogen. This trial is designed to evaluate the safety and efficacy of Chondrogen 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. Each year approximately 800,000 people in the United States have surgery to remove damaged or torn meniscus. 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.

In November 2005, we began enrolling patients in a randomized, double blind, placebo controlled Phase I/II clinical trial evaluating Chondrogen. In this study, we are evaluating Chondrogen's ability to regenerate meniscus in patients who have had a significant portion of their meniscus surgically removed. Only patients with the surgical removal of at least 50% of the damaged portion of their medial meniscus and without major cartilage damage were eligible to participate in the study. The trial will investigate patient response to doses of 50 million cells, 150 million cells, or placebo. We completed enrollment for this trial at the end of the first quarter in 2006, treating a total of 55 patients. The endpoint of the trial is a six-month efficacy evaluation with magnetic resonance imaging to measure the regeneration of meniscus following treatment with Chondrogen. We plan on evaluating each patient for safety two years after the patient enrolled in the trial. The last patient treated in this trial will receive their six-month efficacy evaluation in October 2006, and we plan on conducting the final safety evaluation in April 2007. We plan to enter into a Phase III trial in the first half of 2007 if the efficacy evaluations are positive.

In preclinical studies of Chondrogen, we demonstrated the potential for MSCs to regenerate mensicus. To date, we have studied the effect of MSCs in the knee in over 140 animals. In early studies, the entire meniscus was removed followed by an injection of MSCs or placebo to the joint space. Regeneration of a meniscus was seen in the MSC treated knees as early as six weeks after surgery. In the most severe model, new meniscus was found in 78% of joints at 20 weeks. Examination of the joints showed that the new meniscus had the correct anatomical location and geometry. Histology and biochemical analysis showed that the new meniscus also had similar composition to normal meniscus, predominantly type 1 collagen with smaller amounts of type II collagen and proteoglycan. Joints receiving injections of placebo regrew no functional mensical tissue.

In later preclinical studies, time to treatment was evaluated between one and six weeks following surgery. Earlier delivery of MSCs at one week after surgery resulted in more meniscus regrowth compared to six weeks. Further studies evaluated meniscal regeneration following single and multiple injections of MSCs. A single high dose injection of MSCs resulted in a larger meniscus volume at three months than multiple low dose injections. Additionally, the joints receiving MSCs showed significantly fewer degenerative changes to the articular cartilage and the bone than placebo-treated joints, indicating the potential for Chondrogen to protect the joint from osteoarthritic-like changes.

Provacel

Provacel is our biologic drug candidate for the repair of heart muscle in patients who have suffered a heart attack. Preclinical studies indicate that Provacel prevents scar formation that typically occurs after a heart attack and improves cardiac function eight to ten weeks after its administration. We recently completed enrollment in a Phase I clinical trial for Provacel. This trial is designed to evaluate the safety and efficacy of Provacel 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. In the United States approximately 700,000 individuals each year experience their first heart attack. Approximately 20% of patients experiencing their first heart attack suffer extensive damage to their heart muscle, leading to heart failure within six years. Despite improvements in the standard of care, this progression from myocardial infarction to heart failure remains largely unavoidable in patients with AMIs.

Provacel 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 Provacel improves myocardial function includes preventing pathological scarring of the heart muscle and growing new blood vessels. We are developing Provacel as a therapy to be delivered through a standard intravenous line up to 10 days post-myocardial infarction.

In March 2006, we completed enrollment of a 53 patient Phase I randomized, double blind, placebo controlled clinical study to evaluate Provacel in patients following AMI. The trial is designed to investigate patient response to doses of 0.5, 1.6, and 5.0 million cells per kilogram of body weight or placebo. Exploratory efficacy endpoints include 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 preclinical studies, Provacel selectively targeted the damaged area of the heart when a single infusion is administered. These studies also indicated that Provacel has the effect of

retarding or stopping the progress of further cardiac tissue deterioration and limit 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 10 weeks after administration of Provacel. 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 when compared to control animals. MSCs were detected in the damaged area of the heart muscle of treated animals, but not in the remote, undamaged regions.

We entered into a collaboration with Boston Scientific Corporation in 2003, and assuming successful completion of our clinical trials and regulatory approval, it will market and distribute Provacel.

Other

In addition to the indications described above, we intend to investigate alternative uses for MSCs and our biologic drug candidates. For example, we intend to submit an Investigational New Drug application for Prochymal for the treatment of acute renal failure, the sudden inability of the kidneys to function properly. We may also evaluate the use of Provacel for additional cardiovascular indications and Chondrogen for the regeneration of cartilage in other areas of the body.

Safety Profile

To date, we have collected safety data from over 200 patients enrolled in our stem cell clinical trials. Among other things, we monitor patients for the occurrence of serious adverse events, or SAEs. An adverse event is considered serious if it is life threatening or results in death, causes a disability or congenital abnormality, or results in hospitalization or medical intervention to prevent disability. All SAEs are recorded and analyzed regardless of the known or suspected cause. Each time an SAE arises, the investigator must determine the relationship between the study drug and the SAE. Categories for indicating the study drug causality include probably related, possibly related, and unlikely related, as discussed below.

Probably related the SAE follows a strong temporal relationship to the administration of the study drug and cannot be reasonably explained by the patient's clinical condition or other treatments.

Possibly related the SAE follows a reasonable temporal relationship to the administration of the study drug, but an alternative cause seems more likely.

Unlikely related the SAE does not follow a reasonable temporal relationship relative to the administration of the study drug and is readily produced by the patient's clinical condition or other treatments.

Patients with GvHD are typically very ill as a result of their underlying genetic or oncologic condition. Similarly, patients who have had a heart attack face a number of health risks. As a result, unrelated SAEs are routinely observed in these patient populations. To date, there have been no SAEs that have been deemed probably related, and a total of three SAEs that have been deemed possibly related to the infusion of our biologic drug candidates. The first was a case of ectopic calcifications in a GvHD patient with malignant osteopetrosis. Malignant osteopetrosis is a genetic disorder of the bone cells leading to bone overgrowth. Subsequent analysis of the biopsied calcifications indicated that no DNA from our stem cells

was present. The second SAE was in a GvHD patient who had increased levels of cytomegalovirus in the blood, which is often seen in patients with acute GvHD. The third SAE was a case of deep vein thrombosis in a patient in the Provacel trial, however the study remains blinded and it is not known if the patient received MSC treatment or placebo.

Collaborations

Boston Scientific Corporation Research, Development and Commercialization Collaboration

In March 2003, we entered into a collaboration with Boston Scientific Corporation, or Boston Scientific, to develop applications of our MSC technology to treat acute myocardial infarction and chronic ischemia. Our biologic drug candidate under development pursuant to this collaboration is Provacel.

Under the terms of the collaboration, we are responsible for the preclinical development of an MSC biologic drug candidate having application in the covered field, and for associated regulatory filings, and Boston Scientific is responsible for the research and development activities performed following completion of preclinical development of a biologic drug candidate, including, without limitation, development of the clinical protocols, clinical trial management and Phase II efficacy research testing. The collaboration provides for us to manufacture the MSC clinical trial materials, and provides that, upon regulatory approval for commercial sale, we will manufacture and Boston Scientific will have exclusive rights to distribute and sell the product globally. Boston Scientific may also assume the manufacturing rights and responsibilities from us and if it does so the royalty rate payable to us is subject to increase. This collaboration may be terminated at any time upon mutual agreement of the parties. Also, Boston Scientific can terminate the collaboration prior to obtaining FDA approval of a product, provided that it gives us at least 120 days notice of such termination.

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. Unless earlier terminated, the license terminates on the expiration of the last to expire licensed patent covering the product, and with regard to member states of the European Economic Area, or EEA, on the later of the tenth anniversary of the commercial launch of a product in the EEA or the expiration of the last to expire patent. This license automatically terminates upon termination of the collaboration prior to FDA approval of a product as described above.

Boston Scientific paid a $5.0 million licensing fee to us upon the effectiveness of the license and it is required to pay up to $25.0 million to us in pre-commercialization milestones per product, as well as royalty payments for MSC products acquired or manufactured by Boston Scientific outside of the terms of the contract manufacturing agreement. In addition, any and all MSC products sold by us to parties other than Boston Scientific must be sold with a limited label license that states that the product may only be used in a specified field or application which does not fall within the exclusive field granted to Boston Scientific.

We have a $50.0 million line of credit with Boston Scientific, of which we have drawn $5.0 million to date. This advance, and any future advances drawn under the loan agreement, are secured by an interest granted to Boston Scientific in the license agreement, including the right to develop, market and distribute MSC products in the covered field and our right to receive payments under the license; all equipment, books and records relating to the manufacture of Provacel; and all future proceeds or payments received in connection with such collateral. We must commence quarterly repayment of the advance during the first fiscal quarter following commercialization of Provacel up to maximum of 2.5% of sales of Provacel per quarter, or if commercialization has not occurred prior to December 31, 2009, we must issue shares of our common stock in repayment of the loan at a rate of 20% per year up to a

maximum repayment term of five years. Alternatively, upon any termination of the collaboration with Boston Scientific or any default under the loan agreement, Boston Scientific may require us to satisfy the full balance of the outstanding loan through an issuance of shares of our common stock. We can elect to repay the amounts borrowed from Boston Scientific at any time.

In conjunction with this collaboration, Boston Scientific made a $10.0 million investment in our preferred stock, which will convert at the closing of this offering into 2.0 million shares of our common stock. Upon the enrollment of the first patient in a Phase III clinical trial for Provacel, Boston Scientific is obligated to purchase from us and we are obligated to sell, 666,667 shares of common stock for an aggregate purchase price of $10.0 million, or $15.00 per share. Upon FDA approval of Provacel, Boston Scientific is obligated to purchase from us and we are obligated to sell, 357,143 shares of common stock for an aggregate purchase price of $10.0 million, or $28.00 per share. Boston Scientific was granted registration rights in respect of the shares of our common stock received by it, which rights have been waived to the extent that they relate to this offering. Boston Scientific was also granted a preemptive right to purchase its pro rata share of securities issued and sold by us, which right has been permanently waived.

JCR Pharmaceuticals Co., Ltd. License Agreement

In August 2003, we entered into a license agreement with JCR Pharmaceuticals Co., Ltd., or 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 including the treatment of GvHD with Prochymal.

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 $500,000 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.

Under the terms of the collaborative arrangement, 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 will convert at the closing of this offering into 545,454 shares of our common stock. JCR was granted registration rights in respect of the shares of our capital stock received by it, which rights have been waived to the extent that they relate to offering. JCR was also granted a preemptive right to purchase its pro rata share of securities issued and sold by us, which right has been permanently waived.

Blackstone Medical, Inc. Distribution Agreement

In November 2005, we entered into a distribution and supply arrangement for Osteocel with Blackstone Medical, Inc. 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.

Intellectual Property

We have established a considerable patent position in adult stem cell technology. We currently own or have exclusive licenses to 45 issued U.S. patents. Foreign counterparts to these patents, including composition of matter claims, have been filed, and we own or hold licenses to 132 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 14 additional U.S. patents pending and 55 foreign patent applications on file but not yet allowed.

For most of our biologic drug candidates, we rely on multiple patents in combination. The following provides a description of our key patents and pending applications and is not intended to represent an assessment of claims limitations or scope.

Patent	Subject Matter	Related Product(s)	Expiry
US5,486,359	Composition of Matter for mesenchymal stem cells.	Chondrogen, Prochymal, Osteocel XC, Provacel	2013
US5,811,094	Therapeutic use of MSCs for the repair of connective tissue.	Chondrogen, Osteocel XC	2015
US6,355,239	Basis for universal use of MSCs without recipient matching.	Chondrogen, Osteocel XC	2018
US6,387,369	Use of MSCs for cardiac muscle repair.	Provacel	2020
US6,328,960	Use of MSCs in transplantation, e.g. marrow, tissues and organs.	Prochymal,e.g. GvHD	2019
Pending Applications			
	Use of MSC for inflammation.	Prochymal, e.g. Crohn's Disease	
	Use of matrix-associated MSCs for bone repair.	Osteocel	

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 has 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 sublicensee of ours.

Under terms of a Marketing, Collaboration and License Agreement with BioWhittaker, Inc., we have licensed our MSC technology to BioWhittaker to sell MSCs, MSC descendants, cells produced from MSCs and materials used with MSCs for commercial and non-commercial research purposes. Under the terms of this agreement, BioWhittaker 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 IND and the submission date of an 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 5,000 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 eight 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 we believe can be scaled up at additional sites. A second manufacturing site was successfully qualified in September 2003. In addition, JCR Pharmaceuticals, our partner in Japan, has begun manufacturing product for clinical trials in Japan. We believe that we perform all of our manufacturing activities in compliance with FDA current Good Manufacturing Practice requirements.

Our manufacturing process begins with the collection of bone marrow aspirate from qualified volunteer donors, 18-32 years of age. Prior to donation, these individuals are screened and tested for a battery of diseases including HIV and hepatitis according to FDA donor suitability guidance. We contract to 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 by an adherent culture process. Our stem cells 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 over the course of a month. Once expanded, the cells are 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 three agencies under contract. 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. for the distribution of Osteocel. To increase Osteocel's market penetration, we intend to further expand our network of sales professionals in the United States. Except for Provacel, 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 Boston Scientific Corporation to commercialize Provacel upon marketing approval. We also have 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 also distributed 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, 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.

Chondrogen

There are approximately 800,000 surgeries performed each year to remove damaged meniscus. The majority of these surgeries are performed by orthopedic surgeons at the top 1,000 surgery centers and hospitals. Given the similarity in call points between Osteocel and our biologic drug candidate Chondrogen, we intend to utilize our Osteocel sales force to penetrate this market if we successfully develop and obtain marketing approval. Current Osteocel sales training includes modules on basic stem cell biology, immunology, and the preclinical and clinical data pertaining to Chondrogen. This cross-training will help the existing sales force in marketing Chondrogen to orthopedic surgeons.

Provacel

We entered into a collaboration with Boston Scientific Corporation in 2003. Boston Scientific will market and distribute Provacel if we successfully complete our clinical trials and obtain marketing approval.

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 three 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 Acromed's CELLECT .

Prochymal. If approved, Prochymal will compete with approved products such as Novartis' Neoral® for the prevention of organ rejection in kidney, liver, and heart allogeneic transplant patients, Centocor's Remicade® for Crohn's Disease and if approved DOR BioPharma's orBec® for gastrointestinal GvHD.

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.

Provacel. If approved, Provacel will compete with pharmaceutical therapies, mechanical therapies and cellular based therapies. Pharmaceutical therapies include anti-thrombotics, calcium channel blockers such as Pfizer's Norvasc® and ACE inhibitors such as Sanofi's Delix®. Mechanical therapies such as biventricular pacing, ventricular restraint devices and mitral valve therapies have been developed by companies such as Medtronic, Acorn Cardiovascular and Edwards Lifesciences. Cellular based therapies such as skeletal myoblasts and embryonic stem cells are being pursued by companies such as Bioheart, MG Biotherapeutics, a joint venture created by Medtronic and Genzyme, and Geron.

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.

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 drugs 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 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, 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 FDA's Good Clinical Practice, or GCP, requirements;

- compliance with 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, 2006, the user fee for an application requiring clinical data, such as an NDA or BLA, is $767,400. PDUFA also imposes an annual product fee for prescription drugs and biologics ($42,130), and an annual establishment fee ($264,000) 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 a 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 GMP 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 Prochymal was designated by the FDA as a Fast Track product for the treatment of GvHD. 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 other countries of 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, FDA's regulations include other requirements to prevent the introduction, transmission and spread of communicable disease. Specifically, 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.

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 March 31, 2006, our headcount was 83 individuals, comprising 63 full-time employees and 20 full-time contract employees. Forty of the total were engaged in manufacturing and operations, 32 were engaged in research and development and clinical trials and 11 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.

Facilities

Our corporate headquarters are located in Baltimore, Maryland, where we lease approximately 127,000 square feet, currently at a rent of approximately $1.2 million per annum. This lease expires in September 2008. We have an option to renew this lease through 2023. We are currently in the process of locating additional or replacement manufacturing facilities.

Legal Proceedings

We are not a party to or engaged in any material legal proceedings.

MANAGEMENT

The members of our Board of Directors and the principal management team are:

Name	Age	Function
Peter Friedli	52	Chairman
C. Randal Mills, Ph.D.	34	Director, President and Chief Executive Officer
Harry E. Carmitchel	55	Chief Operating Officer
Cary J. Claiborne	45	Chief Financial Officer
Felix Gutzwiller, M.D., Dr.P.H.	58	Director
Jay M. Moyes	51	Director Nominee

A short biographical description of each of the members of our Board of Directors and management team at the consummation of the offering is set out below.

Peter Friedli, was co-founder of Osiris and, except for the period between February and June 2004, has been a director since January 1996. He has been a principal of the investment-banking firm Friedli Corporate Finance, Inc. since 1986. Friedli Corporate Finance, Inc., a leading Swiss venture capital firm, has made significant investments in the biotechnology industry. Friedli Corporate Finance, Inc. has been the primary source of financing for Osiris. Mr. Friedli is also President of New Venturetec Ltd., a Swiss publicly traded investment company. Mr. Friedli has extensive experience as an independent investment manager in venture capital and has specialized in investments domiciled in the United States in the areas of biotechnology and technology. Prior thereto, he worked in the field of international management consulting for service and industrial companies in Europe and the United States. Mr. Friedli is a director of E-centives, Inc., a publicly traded provider of interactive database marketing technologies and services. He also serves as a director in certain private companies.

C. Randal Mills, President and Chief Executive Officer, joined Osiris in May 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 Operations and R&D and is credited with several key initiatives including the development and commercialization of RTI's core technology, BioCleanse®. Prior to RTI, Dr. Mills was a member of the founding management team of the University of Florida Tissue Bank, Inc. The University of Florida Tissue Bank was the predecessor company to RTI. Dr. Mills received a bachelor's degree in microbiology and cell science and a Ph.D. in drug development, both from the University of Florida.

Harry E. Carmitchel, Chief Operating Officer, joined Osiris in September 2004. Mr. Carmitchel has over 20 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. Previously, he also served as Vice President of Operations and Vice President of Marketing for Everest and Jennings, Inc. Mr. Carmitchel earned an M.B.A. from the University of Southern California and a Bachelors degree in electrical engineering from the General Motors Institute.

Cary J. Claiborne, Chief Financial Officer, joined Osiris in December 2004. Mr. Claiborne previously was Vice President, Financial Planning and Analysis at Constellation Energy, a diversified energy company from December 2001 to June 2004. At Constellation he oversaw a budget consisting of $12 billion in revenue and over $500 million in net income. Prior to Constellation Energy, he served as Vice President, Financial Planning and Analysis for Home Depot from April 2000 to July 2001, overseeing a budget of $46 billion in revenue and $3 billion in net income. Mr. Claiborne spent the first 15 years of his career at GE, in several leadership positions, including CFO for GE Capital Business Services and President of New Enterprise Wholesale Services. Mr. Claiborne earned an M.B.A. from Villanova University and a B.A. in business administration from Rutgers University.

Felix Gutzwiller, M.D., Dr.P.H., elected to the Board of Directors in 2003, is Professor and Chairman of the Department of Public Health of the University of Zurich Medical School. Dr. Gutzwiller is also an elected member of the Swiss Parliament. Dr. Gutzwiller received a medical degree from the University of Basel in 1974 and did his post-graduate training at both Harvard University and Johns Hopkins University. He received his Dr.P.H. from the Johns Hopkins University School of Hygiene and Public Health in 1977. Dr. Gutzwiller has received many honors and awards over the years in the health profession.

Jay M. Moyes, will serve on our Board of Directors upon completion of this offering. Mr. Moyes has served as the Chief Financial Officer of Myriad Genetics, Inc. since June 1996. Mr. Moyes previously served as Myriad's Vice President of Finance from July 1993 until July 2005. From 1991 into 1993, Mr. Moyes served as Vice President of Finance and Chief Financial Officer of Genmark, Inc. Mr. Moyes held various positions with the accounting firm of KPMG LLP from 1979 through 1991, most recently as a Senior Manager. He holds an M.B.A. degree from the University of Utah, a B.A. degree in economics from Weber State University, and is a Certified Public Accountant. Mr. Moyes has also served as a member of the Board of Trustees of the Utah Life Science Association from 1999 through 2006.

Other Matters

The Swiss authorities have been conducting a criminal investigation of the 2000 initital public offering of Think Tools AG, a Swiss company, regarding the allocation of shares to officers and directors of the company. Mr. Friedli was a member of the Board of Directors of Think Tools AG at the time of the initial public offering, was allocated shares in the offering and is one of several persons whose participation in the offering is under investigation. No action or charges have been instituted against Think Tools AG or Mr. Friedli; however, the investigation is ongoing.

Composition of our Board of Directors

Upon completion of this offering, our Board will consist of five members and our charter and bylaws will divide our Board into three classes of directors serving staggered three-year overlapping terms, with one class of directors elected at each annual meeting of stockholders. Each director will serve until his or her successor is elected or until his or her earlier death, resignation or removal as provided by our bylaws.

Our directors will be divided among the three classes as follows:

the Class I directors will be Jay M. Moyes and , and their terms will expire at the annual meeting of stockholders to be held in 2007;

the Class II directors will be C. Randal Mills and Felix Gutzwiller, and their terms will expire at the annual meeting of stockholders to be held in 2008; and

the Class III director will be Peter Friedli and his term will expire at the annual meeting of stockholders to be held in 2009.

We intend to elect an additional independent director to our Board of Directors prior to completion of this offering.

Following this offering, our charter and bylaws will provide that the authorized number of directors may be changed only by resolution of the Board of Directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

Our Code of Conduct for Executive Officers and Directors requires that all transactions that we enter into with any related party must be approved by our independent directors.

Director Compensation

Each director who is not an employee is eligible to receive compensation from us for his or her services as a member of our board or any of its standing committees. Each such non-employee director will be entitled to receive an annual retainer of 10,000 shares of our common stock per year of service plus an additional amount of common stock up to 10,000 shares based on active board participation.

Mr. Friedli and Mr. Gutzwiller each received 20,000 shares of our common stock for their board service in 2005.

Committees of the Board of Directors

Upon the close of this offering, our Board of Directors will have the following standing committees:

Audit Committee

The members of our Board's audit committee are Jay M. Moyes, Felix Gutzwiller and ; is the chairman of the committee. The Board has determined that Mr. Moyes is an "audit committee financial expert," as defined by the rules and regulations of the Securities and Exchange Commission. The audit committee assists our Board of Directors with its oversight responsibilities regarding the integrity of our financial statements; our compliance with legal and regulatory requirements; the independent auditors' qualifications and independence; and the performance of our internal audit function, if any, and independent auditors. We believe that each member of our audit committee meets the requirements for independence under the current requirements of the Sarbanes-Oxley Act of 2002, The NASDAQ National Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

The members of our Board's compensation committee are Felix Gutzwiller and ; Felix Gutzwiller is the chairman of the committee. The compensation committee provides assistance to the Board of Directors by designing and recommending to the Board of Directors for approval and evaluating our compensation plans, policies and programs, especially those regarding executive compensation; reviewing and approving the compensation of our Chief Executive Officer and other officers and directors; and will assist the Board of Directors in producing an annual report on executive compensation for inclusion in our proxy materials in accordance with applicable rules and regulations.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2005, we did not have a compensation committee of the Board of Directors, and our full Board decided executive compensation.

Dr. Mills, a member of the Board of Directors, serves as our President and Chief Executive Officer. Mr. Friedli, the chairman of our Board of Directors, provided us with consulting and advisory services and engaged in other business transactions with us during 2005. These transactions are discussed more fully in "Certain Relationships and Related Transactions."

Executive Compensation

The table below summarizes the compensation paid to or earned by our chief executive officer and our other executive officers during 2005. We refer to these three people as the named executive officers.

Summary Compensation Table

		Annual Compensation		Long-Term Compensation	
Name and Principal Position	**Year**	**Salary**	**Bonus**	**Restricted Stock Awards($)**	**All Other Compensation(1)**
C. Randal Mills, Ph.D. President and Chief Executive Officer	2005	$ 300,000	$ 60,000	$ 50,000(2)	$ 18
Harry E. Carmitchel Chief Operating Officer	2005	150,000	17,000		405
Cary J. Claiborne Chief Financial Officer & Secretary	2005	180,000			81

(1) Represents taxable value of group life insurance benefit.

(2) Represents the fair market value of 500,000 shares of restricted stock units that vested in September 2005 and were converted to common stock.

Stock Options

Option Grants in Fiscal Year 2005

None of our named executive officers were granted options in 2005.

Option Exercises and Year-End Option Values

The table below provides information regarding unexercised stock options held on December 31, 2005 by each of the named executive officers. As our common stock is not publicly traded, a readily ascertainable market value for these options is not available. Therefore, the value of the unexercised in-the-money options listed below has been calculated on the basis of the assumed initial public offering price of $ per share, less the applicable exercise price per share multiplied by the number of shares underlying the options.

Name	**Number of Shares Acquired on**	**Value Realized**	**Number of Securities Underlying Unexercised Options at December 31, 2005**	**Value of Unexercised In-the-Money Options at December 31, 2005**

	Exercise		Number of Securities Underlying Unexercised Options at December 31, 2005		Value of Unexercised In-the-Money Options at December 31, 2005	
			Exercisable	Unexercisable	Exercisable	Unexercisable
C. Randal Mills			150,000	450,000		
Cary J. Claiborne			60,000	180,000		
Harry Carmitchel			100,000	300,000		

Employment Agreements

All of our current employees have entered into agreements with us which contain restrictions and covenants. These provisions include covenants relating to the protection of our confidential information, the assignment of inventions and restrictions on soliciting our clients, employees or independent contractors. Except in the case of Dr. Mills and Messrs. Claiborne and Carmitchel, as described below, none of our employees is employed for a specified term, and each employee's employment with us is subject to termination at any time by either party for any reason, with or without cause. We have entered into employment agreements with Dr. Mills and Messrs. Claiborne and Carmitchel.

Under Dr. Mills' employment agreement, dated as of May 15, 2004, he serves as our Chief Executive Officer for an initial three-year term. Thereafter, the agreement renews automatically each May 15 for successive one-year terms, unless either party provides notice of termination at least ninety days prior to May 15. Dr. Mills' agreement provides for a base salary of $300,000 per year, subject to yearly adjustment, and performance-based bonuses granted at amounts determined by the Board of Directors in its discretion. Under the agreement, we granted Dr. Mills an option to purchase 600,000 shares of our common stock at $0.10 per share upon the effective date of the agreement. In addition, Dr. Mills was granted an option to purchase an additional 400,000 shares of our common stock at $0.10 per share following the first anniversary of his employment and upon meeting certain milestones set by mutual agreement of us and Dr. Mills. Our Board of Directors granted Dr. Mills these additional options in January 2006. Such stock options will become fully vested upon the conclusion of this offering. We may terminate Dr. Mills' employment (i) if he is unable to perform his duties due to some incapacity for three or more consecutive months or for four or more non-consecutive months, (ii) if he fails to perform his duties and such failure is not cured within thirty days after specific written notice by the board, or (iii) for cause. Dr. Mills may terminate his employment for good reason. If we terminate Dr. Mills for failure to perform his duties, in addition to paying any amount otherwise owed, we must pay him a lump sum in an amount equal to one half of his annual base salary and provide six months of medical, life and disability benefits. If we terminate Dr. Mills without cause or if he terminates his employment for good reason, in addition to paying any amount otherwise owed, we must pay him a lump sum in an amount equal to one full year of base salary and provide one full year of medical, life, and disability benefits.

Under Mr. Claiborne's employment agreement, dated as of December 3, 2004, he serves as our Chief Financial Officer for an initial three-year term. Thereafter, the agreement renews automatically each December 3 for successive one-year terms, unless either party provides notice of termination at least ninety days prior to December 3. Mr. Claiborne's agreement provides for a base salary of $180,000 per year, subject to yearly adjustment, and performance-based bonuses granted at amounts determined by the board of directors in its discretion. Under the agreement, we granted Mr. Claiborne an option to purchase 240,000 shares of our common stock at $0.10 per share upon the effective date of the agreement. In addition, the agreement provides that Mr. Claiborne may be granted an option to purchase an additional 60,000 shares of our common stock at $0.10 per share upon meeting certain milestones set by mutual agreement of us and Mr. Claiborne. Our Board of Directors granted Mr. Claiborne these additional options in January 2006. Such stock options will become fully vested upon the conclusion of this offering. We may terminate Mr. Claiborne's employment (i) if he is unable to perform his duties due to some incapacity for three or more consecutive months or for four or more non-consecutive months, (ii) if he fails to perform his duties and such failure is not cured within thirty days after specific written notice by the board, or (iii) for cause. Mr. Claiborne may terminate his employment for good reason. If we terminate Mr. Claiborne for failure to perform his duties, in addition to paying any amount otherwise

owed, we must pay him a lump sum in an amount equal to one half of his annual base salary and provide six months of medical, life and disability benefits. If we terminate Mr. Claiborne without cause or if he terminates his employment for good reason, in addition to paying any amount otherwise owed, we must pay him a lump sum in an amount equal to one full year of base salary and provide one full year of medical, life, and disability benefits.

Under Mr. Carmitchel's employment agreement, dated as of September 1, 2004, he serves as our Chief Operating Officer for an initial three-year term. Thereafter, the agreement renews automatically each September 1 for successive one-year terms, unless either party provides notice of termination at least ninety days prior to September 1. Mr. Carmitchel's agreement provides for a base salary of $150,000 per year, subject to yearly adjustment, and performance-based bonuses granted at amounts determined by the Board of Directors in its discretion. Under the agreement, we granted Mr. Carmitchel an option to purchase 400,000 shares of our common stock at $0.10 per share upon the effective date of the agreement. In addition, the agreement provides that Mr. Carmitchel may be granted an option to purchase an additional 100,000 shares of our common stock at $0.10 per share upon meeting certain milestones set by mutual agreement of us and Mr. Carmitchel. Our Board of Directors granted Mr. Carmitchel these additional options in January 2006. Such stock options will become fully vested upon the conclusion of this offering. We may terminate Mr. Carmitchel's employment (i) if he fails to perform his duties and such failure is not cured within thirty days after specific written notice by the board or (ii) for cause. Mr. Carmitchel may terminate his employment for good reason. If we terminate Mr. Carmitchel for failure to perform his duties or without cause, or if Mr. Carmitchel terminates his employment for good reason, in addition to paying any amount otherwise owed, we must pay Mr. Carmitchel a lump sum in an amount equal to one half of his annual base salary and provide six months of medical, life and disability benefits.

For purposes of the employment agreements with Messrs. Mills, Claiborne and Carmitchel, "cause" is defined to include (i) the commission of a felony or a crime of moral turpitude or any other act or omission involving dishonesty or fraud with respect to us or any of our subsidiaries, customers, or suppliers, (ii) conduct tending to bring Osiris or any subsidiary into substantial public disgrace or disrepute, (iii) gross negligence or willful misconduct with respect to us or any subsidiary, or (iv) any breach of a material section of the agreement.

For purposes of the employment agreements with Messrs. Mills, Claiborne and Carmitchel, "good reason" means (i) our failure to perform or observe any material term or provision of the agreement and our continued failure to cure such default within thirty days after written demand for performance from the executive specifically describing the alleged default, (ii) a material reduction in the scope of the executive's responsibilities and duties, or (iii) absent a written agreement between us and the executive, a material reduction in the executive's base pay or incentive compensation.

Employee Benefits Plans

Amended and Restated 1994 Stock Incentive Plan

We have an Amended and Restated 1994 Stock Incentive Plan under which options to purchase 2,655,060 shares of common stock have been issued as of March 31, 2006. All of these options are subject to vesting requirements based on duration of employment, typically 25% per year of employment, or satisfaction of certain performance milestones. As of March 31, 2006, 554,513 of our options had vested.

Our Amended and Restated 1994 Stock Incentive Plan is administered by our Board of Directors. Subject to limitations set forth in the Amended and Restated 1994 Stock Incentive Plan, our Board of Directors determines to whom options are granted, the option term, the

exercise price, vesting schedules and the rate at which options may be exercised. The maximum term of options granted under the Amended and Restated 1994 Stock Incentive Plan is ten years and the exercise price may be equal to, less than or greater than the fair value of such shares, except that the exercise price of an incentive stock option shall be equal to or greater than the market value of the share on the date of grant. Under the Amended and Restated 1994 Stock Incentive Plan, the exercise price may be payable in cash or, at the discretion of the Board of Directors, in common stock or a combination of cash and common stock, or in any other legal consideration that the Board of Directors deemed appropriate.

2006 Omnibus Plan

We have adopted a 2006 Omnibus Plan under which officers, directors and employees may receive (i) options to purchase common stock of the Company, $0.001 par value, including incentive stock options intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended, and non-qualified stock options that do not so qualify, (ii) restricted stock, (iii) stock appreciation rights, (iv) performance shares, and (v) performance units. The option price of each stock option granted under this plan must be at least equal to the fair market value of a share of our common stock on the date the option is granted. The fair market value of a share of our common stock means, on any day, (i) the closing sales price on the immediately preceding business day of a share of our common stock as reported on the principal securities exchange on which shares of our common stock are then listed or admitted to trading, or (ii) if not so reported, the closing sales price on the immediately preceding business day of a share of our common stock as published in The NASDAQ National Market Issues report in the Eastern Edition of The Wall Street Journal, or (iii) if not so reported, the average of the closing bid and asked prices on the immediately preceding business day as reported on The NASDAQ National Market System, or (iv) if not so reported, as furnished by any member of the National Association of Securities Dealers, Inc. selected by our Compensation Committee. In the event that the price of a share of our common stock shall not be so reported or furnished, the fair market value of a share of common stock shall be determined by our Compensation Committee in good faith. As of April 19, 2006, 3,400,000 shares of our common stock were reserved for issuance under the 2006 Omnibus Plan.

The 2006 Omnibus Plan is administered by our Compensation Committee, which has the discretion to determine the number and purchase price of shares subject to each award, and other applicable terms and conditions, including vesting schedules. The term of an option may not be more than ten years from the grant date, or five years from the grant date in the case of an incentive stock option granted to a 10% stockholder. Options granted under the 2006 Omnibus Plan generally terminate three months after an optionee ceases to be employed by us (twelve months in the case of death or disability), unless otherwise provided in the related option agreement or extended by the Compensation Committee.

401(k) Plan

We have a 401(k) defined contribution retirement plan covering substantially all full-time employees. Our 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by employees and by us to our 401(k) plan and income earned on plan contributions are not taxable to employees until withdrawn or distributed from the plan, and so that contributions, including employee salary deferral contributions, will be deductible by us when made.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

General. Peter Friedli, the Chairman of our Board of Directors, has been responsible for procuring since 1993, either directly or through affiliated entities, an aggregate of approximately $200 million in debt and equity financing for us and our predecessor company. Mr. Friedli is the beneficial owner of approximately 53% of our common stock as of May 10, 2006. Of the shares beneficially owned by Mr. Friedli, 80,000 shares were received by him as Board compensation since 1996, 50,000 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.

Consulting Agreement. Since 1995, we and our predecessor company have been party to a Consulting Agreement, originally with Friedli Corporate Finance AG, and now 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 has provided general business, financial and investment advice to us, and has served as a liaison between us and FCF clients who have invested in us, many of which are located in Switzerland. This Consulting Agreement had also granted to FCF a right of first refusal with respect to any debt or equity financings by us, and contains a provision requiring us to allocate ten percent of the shares in this offering to FCF. However, the right of first refusal was terminated in 2003 and the allocation right has been waived in connection with this offering, and we and FCF have agreed to terminate the Consulting Agreement upon the closing of this offering. The base compensation paid by us under this agreement was $65,000 in 2005, $63,000 in 2004 and $63,000 in 2003. In addition, pursuant to this Consulting Agreement, we paid $50,000 as expense reimbursements in 2005, to or as directed by FCF.

Referral Fees and Costs. Separate from the Consulting Agreement, FCF served as our agent in Europe in connection with:

- the issuance and sale in 2004 of 400,000 shares of our Series C Convertible Preferred Stock at a purchase price of $4.50 per share, representing aggregate gross proceeds of $1.8 million;
- the issuance and sale in 2004 of $4.8 million of our Convertible Preferred Notes;
- 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; and
- 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.

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 $71.9 million in gross proceeds was raised for us. We paid referral fees and costs of $3.4 million to accounts designated by Mr. Friedli, including accounts of third parties unrelated to Mr. Friedli. We also paid expense reimbursement of $350,000 to Mr. Friedli and issued 50,000 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, we paid placement agency fees to the European investment bank.

New Venturetec/Pine Loans. In 2004, we obtained $2,350,000 in debt financing through two entities affiliated with Mr. Friedli. The first of these entities was a wholly owned subsidiary of New Venturetec, Inc., a Swiss publicly traded company. Mr. Friedli owns 3% of New Venturetec and is its president. The other entity is Pine, Inc., a company which at the time of the financing was majority owned and managed by Mr. Friedli.

In this financing, the New Venturetec subsidiary lent us $1,350,000, and Pine lent us $1,000,000. In consideration of these loans, we issued to the lenders promissory notes in the principal amount of the sums lent to us. 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 5,000,000 shares at an exercise price of $0.10 per share. Mr. Friedli subsequently arranged for the acquisition of those warrants and they have since been cancelled.

The loans made by the New Venturetec subsidiary and Pine, plus premium and accrued interest totaling $355,000, were converted into 1,352,325 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock in early 2005, representing an effective price of $2.00 per share. Each share of our Series D Mandatorily Redeemable Convertible Preferred Stock will convert into 10 shares of our common stock upon completion of this offering.

Other Financings. We have engaged in the following additional financings that involved Mr. Friedli, either directly or indirectly:

The New Venturetec subsidiary described above purchased in 2005 an additional 47,244 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock at $2.00 per share, representing aggregate gross proceeds of $94,488. It also purchased in 2005 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 $133,332. 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 $680,990.

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 $976,236.

Merger and Related Litigation. In February 2001, a predecessor of our company was merged into a subsidiary of a Swiss company. This action was taken in contemplation of a Swiss initial public offering, which did not occur. Stockholders of our predecessor became stockholders of the Swiss company as a result of this merger. At the time of the merger, Mr. Friedli and a group of controlling stockholders, pursuant to the terms of the merger, received per share merger consideration which was greater than that which was received by the minority stockholders of the predecessor. The validity of the merger was challenged by certain minority stockholders and former directors of the predecessor in litigation that also

challenged a loan made by Mr. Friedli to the predecessor. This litigation was settled in August 2003 pursuant to an agreement among the parties. This agreement provided, among other things, for unwinding of the merger, payment of $300,000 to one of the plaintiffs and the allocation of shares of common stock to that plaintiff, the establishment of a special committee of the board of the predecessor to review the terms of the challenged loan, and that all future transactions with related parties be approved by independent directors. Following the settlement, counsel for the special committee determined that the terms and Mr. Friedli's interest in the loan had been disclosed to the Board prior to its approval, and no further action has been taken by the special committee.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of May 10, 2006 and on an as adjusted basis to reflect the sale of the common stock offered in this offering by:

- each of our directors;
- each of our named executive officers;
- each person or group of affiliated persons known by us to beneficially own 5% or more of our common stock; and
- all of our directors and executive officers as a group.

The number of shares of common stock beneficially owned by each stockholder is determined under rules issued by the Securities and Exchange Commission and includes voting or investment power with respect to securities. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power and includes any shares that an individual or entity has the right to acquire beneficial ownership of within 60 days of May 10, 2006 through the exercise of any warrant, stock option or other right. Unless otherwise indicated, the address of all listed stockholders is c/o Osiris Therapeutics, Inc., 2001 Aliceanna St., Baltimore, Maryland 21231. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

		Percentage of Shares Beneficially Owned(1)	
Name of Beneficial Owner	**Number of Shares Beneficially Owned**	**Before Offering**	**After Offering**
5% Stockholders			
Peter Friedli(2)	50,503,050	%	%
Venturetec, Inc.(3)(4)	14,400,000	%	%
Executive Officers and Directors			
C. Randal Mills(5)	1,500,000	%	%
Harry E. Carmitchel, Jr.(6)	500,000	%	%
Cary J. Claiborne(7)	300,000	%	%
Felix Gutzwiller	170,000	%	%
All directors and executive officers as a group (5 persons)(8)	52,973,050	%	%

(1) Percentage of beneficial ownership before this offering is based on shares of our common stock outstanding as of May 10, 2006, assuming the conversion of outstanding shares of our preferred stock into shares of our common stock and the conversion of $ of our convertible notes into shares of our common stock, based on a conversion price of $, each of which will become effective upon the closing of this offering. Percentage of beneficial ownership after this offering is based on shares outstanding immediately after this offering, assuming such conversion and after giving effect to sale of shares of our common stock in this offering.

(2) Includes 28,747,096 shares owned directly by Peter Friedli and 2,482,000 shares issuable upon exercise of outstanding warrants, assuming the warrants are exercised in full for cash. Includes 2,500 shares owned by Margrit Friedli, Mr. Friedli's mother; 13,450,000 shares and 950,000 shares of common stock issuable upon exercise of stock warrants

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exercisable within 60 days of May 10, 2006 owned by Venturetec, Inc.; 4,000,000 shares owned by US Venture 05, Inc.; and 871,454 owned by Nikatech, Inc. Peter Friedli is President of Venturetec, Inc. and US Venture 05, Inc., and is the investment manager for Nikatech, Inc. and owns 17% of Nikatech, Inc.

(3) Includes 950,000 shares of common stock issuable upon exercise of warrants exercisable within 60 days of May 10, 2006.

(4) The address of Venturetec is Freigutstrasse 5, 8002 Zürich Switzerland.

(5) Includes 1,000,000 shares of common stock issuable upon exercise of stock options exercisable within 60 days of May 10, 2006.

(6) Includes 400,000 shares of common stock issuable upon exercise of stock options exercisable within 60 days of May 10, 2006.

(7) Includes 240,000 shares of common stock issuable upon exercise of stock options exercisable within 60 days of May 10, 2006.

(8) Includes 2,073,372 shares of common stock issuable upon exercise of stock options exercisable within 60 days of May 10, 2006 and 8,42,000 shares issuable upon exercise of outstanding warrants, assuming the warrants are exercised in full for cash.

DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 90,000,000 shares of common stock and 20,000,000 shares of convertible preferred stock. As of December 31, 2005, there were outstanding 36,390,028 shares of common stock held of record by a total of 374 stockholders and 13,863,899 shares of convertible preferred stock.

Upon the closing of this offering:

- Our corporate charter will be amended and restated to provide for total authorized capital consisting of shares of common stock and shares of undesignated preferred stock;
- All outstanding shares of convertible preferred stock will convert into shares of common stock, and no shares of preferred stock will be outstanding; and
- Based on the number of shares outstanding as of December 31, 2005, a total of shares of common stock will be outstanding after giving effect to the sale of common stock we are offering hereunder, which does not include any exercise of the underwriters' over-allotment option or of any options or warrants.

Common Stock

Under our corporate charter, as amended and restated upon the closing of this offering, a total of shares of common stock will be authorized for issuance. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive dividends out of assets legally available therefore as the Board may from time to time determine. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Cumulative voting for the election of directors is not provided for in our certificate of incorporation, which means that the holders of a majority of the shares voted can elect all of the directors then standing for election. The common stock is not entitled to preemptive rights and is not subject to conversion or redemption. Each outstanding share of common stock is, and all shares of common stock to be outstanding upon completion of this offering will be, fully paid and nonassessable.

Preferred Stock

Under our corporate charter, as amended and restated upon the closing of this offering, a total of shares of preferred stock will be authorized for issuance, none of which will be designated in any series. Our Board of Directors is authorized, without further stockholder action, to authorize and issue any of the undesignated shares of preferred stock in one or more series and to fix the voting rights, liquidation preferences, dividend rights, repurchase rights, conversion rights, preemption rights, redemption rights, and terms, including sinking fund provisions and certain other rights and preferences of such shares of our preferred stock. The issuance of any class or series of preferred stock could adversely affect the rights of the holders of common stock by restricting dividends on, diluting the power of, impairing the liquidation rights of common stock, or delaying, deferring, or preventing a change in control of our company.

Anti-Takeover Effects of our Amended and Restated Certificate of Incorporation and Bylaws and Certain Provisions of the Delaware General Corporation Law

Under Delaware law, all stockholder actions must be effected at a duly called annual or special meeting. Our bylaws provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our Chairman of the Board, by a majority of our Board of Directors, or upon the request of stockholders holding at least 20% of our

capital stock. In addition, our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to the board. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board of Directors or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our Secretary of the stockholder's intention to bring such business before the meeting. The holders of a majority of our outstanding shares will constitute a quorum for the transaction of business. Each stockholder has one vote per share of stock. Except as provided by Delaware law, approval of a majority of those stockholders who are present is required to take any action.

Our Board of Directors is divided into three classes of the same or nearly the same number of directors serving staggered three-year terms, which means that only one class of directors may be elected at a particular stockholders meeting. Also, the authorized number of directors comprising our Board of Directors may only be changed by resolution of our Board of Directors. As a result, the replacement of incumbent directors may be more difficult and third parties may be discouraged from seeking to circumvent the anti-takeover provisions of our certificate of incorporation and bylaws by replacing our incumbent directors.

These provisions of our certificate of incorporation and bylaws are intended to discourage transactions that may involve an actual or threatened change of control of us. Such provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and, accordingly, could discourage potential acquisition proposals and could delay or prevent our change in control. Such provisions are also intended to discourage tactics that may be used in proxy fights but could, however, have the effect of discouraging others from making tender offers for our shares and, consequently, may also inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. These provisions may also have the effect of preventing changes in our management.

We are subject to Section 203 of the Delaware General Corporation Law, or the anti-takeover law, which regulates corporate acquisitions. The anti-takeover law prevents certain Delaware corporations, including those whose securities are listed for trading on The NASDAQ National Market, from engaging under certain circumstances in a business combination with any interested stockholder for three years following the date that such stockholder became an interested stockholder. For purposes of the anti-takeover law, a business combination includes, among other things, a merger or consolidation involving us, and the interested stockholder and the sale of more than 10% of our assets. In general, the anti-takeover law defines an interested stockholder as any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. In addition, the restrictions contained in Section 203 are not applicable to any of our existing stockholders. A Delaware corporation may opt out of the anti-takeover law with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from amendments approved by the holders of at least a majority of the corporation's outstanding voting shares. We have not opted out of the provisions of the anti-takeover law.

The NASDAQ National Market Listing

We have applied to have our common stock approved for quotation on The NASDAQ National Market under the symbol "OSIR."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is StockTrans, Inc. Its address is 44 West Lancaster Avenue, Ardmore, PA 19003, and its telephone number is (610) 649-7300.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur, could adversely affect the price of our common stock.

Based on the number of shares outstanding as of March 31, 2006, we will have approximately shares of our common stock outstanding after the completion of this offering, or approximately shares if the underwriters exercise their over-allotment option in full. Of those shares, the shares of common stock sold in this offering, or shares if the underwriters exercise their over-allotment option in full, will be freely transferable without restriction, unless purchased by our affiliates. The remaining shares of common stock to be outstanding immediately following the completion of this offering, which are "restricted securities" under Rule 144 of the Securities Act, or Rule 144, as well as any other shares held by our affiliates, may not be resold except pursuant to an effective registration statement or an applicable exemption from registration, including an exemption under Rule 144.

Lock-Up Agreements

The holders of approximately shares of outstanding common stock as of the closing of this offering and the holders of shares of common stock underlying options and warrants as of the closing of this offering, including all of our officers and directors, have entered into lock-up agreements pursuant to which they have generally agreed, subject to certain exceptions, not to offer or sell any shares of common stock or securities convertible into or exchangeable or exercisable for shares of common stock for a period of at least 180 days from the date of this prospectus without the prior written consent of Deutsche Bank Securities Inc. See "Underwriting."

Rule 144

In general, under Rule 144, as currently in effect, an affiliate of ours who beneficially owns shares of our common stock that are not restricted securities, or a person who beneficially owns for more than one year shares of our common stock that are restricted securities, may generally sell, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; and
- the average weekly trading volume of our common stock on The NASDAQ National Market during the four preceding calendar weeks.

Sales under Rule 144 are also subject to requirements with respect to manner of sale, notice and the availability of current public information about us. Generally, a person who was not our affiliate at any time during the three months before the sale, and who has beneficially owned shares of our common stock that are restricted securities for at least two years, may sell those shares without regard to the volume limitations, manner of sale provisions, notice requirements or the requirements with respect to availability of current public information about us.

Rule 144 does not supercede the contractual obligations of our security holders set forth in the lock-up agreements described above.

Rule 701

Generally, an employee, officer, director or consultant who purchased shares of our common stock before the effective date of the registration statement of which this prospectus is a part, or who holds options as of that date, pursuant to a written compensatory plan or contract, may rely on the resale provisions of Rule 701 under the Securities Act. Under Rule 701, these persons who are not our affiliates may generally sell their eligible securities, commencing 90 days after the effective date of the registration statement of which this prospectus is a part, without having to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. These persons who are our affiliates may generally sell their eligible securities under Rule 701, commencing 90 days after the effective date of the registration statement of which this prospectus is a part, without having to comply with Rule 144's one-year holding period restriction.

Neither Rule 144 nor Rule 701 supercedes the contractual obligations of our security holders set forth in the lock-up agreements described above.

Sale of Restricted Shares

The shares of our common stock that were outstanding on March 31, 2006, as adjusted to reflect the conversion of our preferred stock and convertible notes in connection with this initial public offering, will become eligible for sale, pursuant to Rule 144 or Rule 701, without registration approximately as follows:

shares of common stock will be immediately eligible for sale in the public market without restriction;

shares of common stock will be eligible for sale in the public market under Rule 144 or Rule 701, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the volume, manner of sale and other limitations under those rules; and

the remaining shares of common stock will become eligible under Rule 144 for sale in the public market from time to time after the effective date of the registration statement of which this prospectus is a part upon expiration of their respective holding periods.

The above does not take into consideration the effect of the lock-up agreements described above.

Stock Options

As of March 31, 2006, options to purchase a total of 2,655,060 shares of common stock at a weighted average exercise price of $0.10 per share have been issued and are outstanding pursuant to our amended and restated 1994 stock incentive plan, and 418,792 options remain available under this plan for future grant. A total of 3,400,000 shares of common stock are reserved for future issuance pursuant to our 2006 Omnibus Plan.

Warrants

As of March 31, 2006, we had outstanding warrants to purchase 8,500,000 shares of common stock, with an average exercise price of $0.10 per share. 5,000,000 of these warrants have since been cancelled.

The warrants contain anti-dilution provisions providing for adjustments of the exercise price and the number of shares underlying the warrants upon the occurrence of certain

events, including any recapitalization, reclassification, stock dividend, stock split, stock combination or similar transaction.

Registration Rights

Following this offering, the holders of approximately million shares of our common stock (including shares issued upon the conversion of our preferred stock and convertible notes upon completion of this offering) and up to an additional approximately million shares of our common stock issuable upon exercise of outstanding warrants have the right to require us to register their shares for sale in the public market upon meeting specific requirements set forth in our agreements with such holders. In addition, there may be stockholders with shares of our common stock who have registration rights that we are not aware of. Also, if we propose to register any of our securities under the Securities Act, other than in connection with registrations requested by the holders of registrable shares and registrations on Form S-8, all holders of registrable shares are entitled to notice of and to include in the registration shares of common stock owned by, or issuable to, them. The holders of these registration rights have waived their rights with respect to this offering. All of these registration rights are subject to various conditions and limitations, among them certain rights of the underwriters of an offering to limit the number of shares included in a registration. We will bear all of the expenses incurred in connection with all exercises of these registration rights, other than underwriting discounts and selling commissions.

Equity Plan

We intend to file, shortly after the effectiveness of this offering, a registration statement on Form S-8 under the Securities Act covering all shares of common stock reserved for issuance under our amended and restated 1994 stock incentive plan and 2006 Omnibus Plan. Shares of common stock issued upon exercise of options under the Form S-8 will be available for sale in the public market, subject to limitations under Rule 144 applicable to our affiliates and subject to the lock-up agreements described above.

MATERIAL UNITED STATES FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO NON-UNITED STATES HOLDERS

The following is a general discussion of the material U.S. federal income and estate tax consequences of the ownership and disposition of our common stock by a non-U.S. Holder that acquires our common stock pursuant to this offering. The discussion is based on provisions of the Internal Revenue Code of 1986 (the "Code"), applicable U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations, all as in effect on the date of this prospectus, and all of which are subject to change, possibly on a retroactive basis. The discussion is limited to non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). As used in this discussion, the term "non-U.S. Holder" means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation or partnership (including any entity treated as a corporation or partnership for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any State of the United States or the District of Columbia, other than a partnership treated as foreign under U.S. Treasury regulations;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust (1) if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust, or (2) that has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

This discussion does not consider:

- U.S. federal gift tax consequences, or U.S. state or local or non-U.S. tax consequences;
- specific facts and circumstances that may be relevant to a particular non-U.S. Holder's tax position, including, if the non-U.S. Holder is a partnership, that the U.S. tax consequences of holding and disposing of our common stock may be affected by certain determinations made at the partner level;
- the tax consequences for partnerships or persons who hold their interests through a partnership or other entity classified as a partnership for U.S. federal income tax purposes;
- the tax consequences for the stockholders or beneficiaries of a non-U.S. Holder;
- all of the U.S. federal tax considerations that may be relevant to a non-U.S. Holder in light of its particular circumstances or to non-U.S. Holders that may be subject to special treatment under U.S. federal tax laws, such as financial institutions, insurance companies, tax-exempt organizations, certain trusts, hybrid entities, certain former citizens or residents of the United States, holders subject to U.S. federal alternative minimum tax, broker-dealers, and traders in securities; or
- special tax rules that may apply to a non-U.S. Holder that holds our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security," or other integrated investment.

This discussion is for general purposes only. Prospective investors are urged to consult their own tax advisors regarding the application of the U.S. federal income and estate tax

laws to their particular situations and the consequences under U.S. federal gift tax laws, as well as foreign, state, and local laws and tax treaties.

U.S. Trade or Business Income

For purposes of this discussion, dividend income and gain on the sale or other taxable disposition of our common stock will be considered to be "U.S. trade or business income" if such income or gain is (i) effectively connected with the conduct by a Non-U.S. Holder of a trade or business within the United States and (ii) in the case of a Non-U.S. Holder that is eligible for the benefits of an income tax treaty with the United States, attributable to a permanent establishment (or, for an individual, a fixed base) maintained by the Non-U.S. Holder in the United States. Generally, U.S. trade or business income is not subject to U.S. federal withholding tax (provided the Non-U.S. Holder complies with applicable IRS certification and disclosure requirements); instead, U.S. trade or business income is subject to U.S. federal income tax on a net income basis at regular U.S. federal income tax rates in the same manner as a U.S. person. Any U.S. trade or business income received by a Non-U.S. Holder that is a corporation also may be subject to a "branch profits tax" at a 30% rate, or at a lower rate prescribed by an applicable income tax treaty, under specific circumstances.

Dividends

If, contrary to our intended policy of not paying dividends, as described under "Dividend Policy," we make a distribution of cash or property on our common stock, any such distributions of cash or property that we pay on our common stock will be taxable as dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). A Non-U.S. Holder generally will be subject to U.S. federal withholding tax at a 30% rate, or at a reduced rated prescribed by an applicable income tax treaty, on any dividends received in respect of our common stock. If the amount of a distribution exceeds our current and accumulated earning and profits, such excess first will be treated as a tax-free return of capital to the extent of the Non-U.S. Holder's tax basis in our common stock, and thereafter will be treated as capital gain. In order to obtain a reduced rate of U.S. federal withholding tax under an applicable income tax treaty, a Non-U.S. Holder will be required to provide a properly executed IRS Form W-8BEN (or appropriate substitute or successor form) certifying its entitlement to benefits under the treaty. A Non-U.S. Holder of our common stock that is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS. A Non-U.S. Holder should consult its own tax advisor regarding its possible entitlement to benefits under an income tax treaty.

The U.S. federal withholding tax does not apply to dividends that are U.S. trade or business income, as defined above, of a Non-U.S. Holder who provided the properly executed IRS Form W-8ECI, or appropriate substitute or successor form.

Dispositions Of Our Common Stock

A Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax in respect of any gain on a sale or other disposition of our common stock unless:

the gain is U.S. trade or business income, as defined above;

the Non-U.S. Holder is an individual who is present in the United States for 183 or more days in the taxable year of the disposition and meets certain other conditions; or

we are or have been a "U.S. real property holding corporation," or USRPHC, under Section 897 of the Code at any time during the shorter of the five-year period ending on the date of disposition and the Non-U.S. Holder's holding period for our common stock.

In general, a corporation is a USRPHC if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide (domestic and foreign) real property interests and its other assets used or held for use in a trade or business. For this purpose, real property interests include land, improvements and associated personal property. We believe that we currently are not a USRPHC. In addition, based on our financial statements and current expectations regarding the value and nature of our assets and other relevant data, we do not anticipate becoming a USRPHC. If we become a USRPHC, a Non-U.S. Holder nevertheless will not be subject to U.S. federal income tax if our common stock is regularly traded on an established securities market, within the meaning of the Code and applicable Treasury regulations, and the Non-U.S. Holder does not hold more than five percent of our outstanding common stock, directly or indirectly, during the five-year testing period for USRPHC status identified above. We expect that our common stock will be listed on The NASDAQ National Market and may be regularly traded on an established securities market in the United States so long as it is so listed.

Federal Estate Tax

Common stock owned or treated as owned by an individual who is a non-U.S. Holder at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax or other treaty provides otherwise and, therefore, may be subject to U.S. federal estate tax.

Information Reporting and Backup Withholding Tax

We must report annually to the IRS and to each non-U.S. Holder the amount of dividends paid to that holder and the amount of tax, if any, withheld from those dividends. These reporting requirements apply regardless of whether withholding was reduced or eliminated by an applicable income tax treaty. Copies of the information returns reporting those dividends and the amount of tax withheld may also be made available under the provisions of an applicable income tax treaty or agreement to the tax authorities in the country in which the non-U.S. Holder is a resident.

Under some circumstances, U.S. Treasury regulations require backup withholding and additional information reporting on reportable payments on common stock. The gross amount of dividends paid to a non-U.S. Holder that fails to properly certify its non-U.S. Holder status in accordance with applicable U.S. Treasury regulations generally will be reduced by backup withholding at the applicable rate (currently 28%).

The payment of the proceeds of the sale or other disposition of our common stock made to a non-U.S. Holder (a) by or through the U.S. office of any broker, U.S. or non-U.S., or (b) by or through a non-U.S. office of a broker that is a U.S. person or has certain enumerated connections with the United States generally will be reported to the IRS and reduced by backup withholding, unless the non-U.S. Holder either certifies its status as a non-U.S. Holder under penalties of perjury or otherwise establishes an exemption. The payment of the proceeds from the disposition of our common stock made to a non-U.S. Holder by or through a non-U.S. office of a non-U.S. broker will not be reduced by backup withholding or reported to the IRS, unless the non-U.S. broker has certain enumerated connections with the United States or the broker has certain other documentary evidence in its files establishing that the holder is a non-U.S. Holder.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. Holder can be refunded or credited against the non-U.S. Holder's U.S. federal income tax liability, if any, provided that the required information is furnished to the IRS in a timely manner. These backup withholding and information reporting rules are complex and non-U.S. Holders are urged to consult their own tax advisors regarding the application of these rules to them.

The foregoing discussion of U.S. federal income and estate tax considerations is not tax advice. Accordingly, each prospective non-U.S. Holder of our common stock should consult that holder's own tax advisor with respect to the federal, state, local and non-U.S. tax consequences of the ownership and disposition of our common stock.

UNDERWRITING

Subject to the terms and conditions of the underwriting agreement, the underwriters named below, through their representative Deutsche Bank Securities Inc., have severally agreed to purchase from us the following respective number of shares of common stock at a public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus:

Underwriters	Number of Shares
Deutsche Bank Securities Inc.	
Total	

The underwriting agreement provides that the obligations of the several underwriters to purchase the shares of common stock offered hereby are subject to certain conditions precedent and that the underwriters will purchase all of the shares of common stock offered by this prospectus, other than those covered by the over-allotment option described below, if any of these shares are purchased.

We have been advised by the representatives of the underwriters that the underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus and to dealers at a price that represents a concession not in excess of $ per share under the public offering price. The underwriters may allow, and these dealers may re-allow, a concession of not more than $ per share to other dealers. After the initial public offering, representatives of the underwriters may change the offering price and other selling terms.

We have granted to the underwriters an option, exercisable not later than 30 days after the date of this prospectus, to purchase up to additional shares of common stock at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus. The underwriters may exercise this option only to cover over-allotments made in connection with the sale of the common stock offered by this prospectus. To the extent that the underwriters exercise this option, each of the underwriters will become obligated, subject to conditions, to purchase approximately the same percentage of these additional shares of common stock as the number of shares of common stock to be purchased by it in the above table bears to the total number of shares of common stock offered by this prospectus. We will be obligated, pursuant to the option, to sell these additional shares of common stock to the underwriters to the extent the option is exercised. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting discounts and commissions per share are equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting discounts and commissions are % of the initial public offering price. We have agreed to pay the underwriters the following discounts and

commissions, assuming either no exercise or full exercise by the underwriters of the underwriters' over-allotment option:

		Total Fees	
	Fee per share	Without Exercise of Over-Allotment Option	With Full Exercise of Over-Allotment Option
Discounts and commissions paid by us	$	$	$

In addition, we estimate that our share of the total expenses of this offering, excluding underwriting discounts and commissions, will be approximately $.

We have agreed to indemnify the underwriters against some specified types of liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect of any of these liabilities.

Each of our officers and directors, and substantially all of our stockholders and holders of options and warrants to purchase our stock, have agreed not to offer, sell, contract to sell or otherwise dispose of, or enter into any transaction that is designed to, or could be expected to, result in the disposition of any shares of our common stock or other securities convertible into or exchangeable or exercisable for shares of our common stock or derivatives of our common stock owned by these persons prior to this offering or common stock issuable upon exercise of options or warrants held by these persons for a period of 180 days after the effective date of the registration statement of which this prospectus is a part without the prior written consent of Deutsche Bank Securities Inc. This consent may be given at any time without public notice. Transfers or dispositions can be made during the lock-up period in the case of gifts or for estate planning purposes where the donee signs a lock-up agreement. There are no agreements between the representative and any of our stockholders or affiliates releasing them from these lock-up agreements prior to the expiration of the 180-day period.

The representative of the underwriters has advised us that the underwriters do not intend to confirm sales to any account over which they exercise discretionary authority.

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, purchases to cover positions created by short sales and stabilizing transactions.

Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of common stock from us in the offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are any sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if underwriters are concerned that there may be downward pressure on the price of the shares in the open market prior to the completion of the offering.

Stabilizing transactions consist of various bids for or purchases of our common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may impose a penalty bid. This occurs when a particular underwriter repays to the other underwriters a portion of the underwriting discount received by it because the representative of the underwriters has repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions may have the effect of preventing or slowing a decline in the market price of our common stock. Additionally, these purchases, along with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The NASDAQ National Market, in the over-the-counter market or otherwise.

A prospectus in electronic format may be made available on Internet web sites maintained by one or more of the lead underwriters of this offering and may be made available on web sites maintained by other underwriters. Other than the prospectus in electronic format, the information on any underwriter's web site and any information contained in any other web site maintained by an underwriter is not part of the prospectus or the registration statement of which the prospectus forms a part.

Pricing of this Offering

Prior to this offering, there has been no public market for our common stock. Consequently, the initial public offering price of our common stock will be determined by negotiation among us and the representative of the underwriters. Among the primary factors that will be considered in determining the public offering price are:

prevailing market conditions;

our results of operations in recent periods;

the present stage of our development;

the market capitalizations and stages of development of other companies that we and the representatives of the underwriters believe to be comparable to our business; and

estimates of our business potential.

NOTICE TO INVESTORS

You should rely only on the information contained in this prospectus. We and the underwriters have not authorized anyone to give you different or additional information. We are offering to sell, and seeking offers to by, shares of our common stock only in jurisdictions where those offers and sales are permitted. You should not assume that the information in this prospectus is accurate as of any date after the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of common stock.

European Economic Area

In relation to each Member State of the European Economic Area, or EEA, which has implemented the Prospectus Directive (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, our common stock will not be offered to the public in that Relevant Member State prior to the publication of a prospectus in relation to our common stock that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, our common stock may be offered to the public in that Relevant Member State at any time:

to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 443,000,000 and (3) an annual net turnover of more than 450,000,000, as shown in its last annual or consolidated accounts; or

in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

As used above, the expression "offered to the public" in relation to any of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and our common stock to be offered so as to enable an investor to decide to purchase or subscribe for our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

The EEA selling restriction is in addition to any other selling restrictions set out below.

United Kingdom

Our common stock may not be offered or sold and will not be offered or sold to any persons in the United Kingdom other than to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or as agent) for the purposes of their businesses and in compliance with all applicable provisions of the Financial Services and Markets Act 2000, or the FSMA, with respect to anything done in relation to our common stock in, from or otherwise involving the United Kingdom. In addition, each underwriter has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us. Without limitation to the other restrictions

referred to herein, this prospectus is directed only at (1) persons outside the United Kingdom, (2) persons having professional experience in matters relating to investments who fall within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005; or (3) high net worth bodies corporate, unincorporated associations and partnerships and trustees of high value trusts as described in Article 49(2) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. Without limitation to the other restrictions referred to herein, any investment or investment activity to which this prospectus relates is available only to, and will be engaged in only with, such persons, and persons within the United Kingdom who receive this communication (other than persons who fall within (2) or (3) above) should not rely or act upon this communication.

Israel

Neither the offering contemplated by this prospectus nor the securities offered hereunder have been or will be registered with the Securities Commission of the State of Israel. Accordingly, the securities offered by this prospectus may not be offered or sold to the general public. The securities offered by this prospectus may only be offered to, and may only be acquired by, those parties that are "accredited investors" as defined in Section 15 of the Securities Law, 5728-1968, of the State of Israel and the rules and regulations adopted thereunder.

France

No prospectus (including any amendment, supplement or replacement thereto) has been prepared in connection with the offering of our common stock that has been approved by the Autorit?e des march?es financiers or by the competent authority of another State that is a contracting party to the Agreement on the European Economic Area and notified to the Autorit?e des march?es financiers; no common stock has been offered or sold and will be offered or sold, directly or indirectly, to the public in France except to permitted investors, consisting of persons licensed to provide the investment service of portfolio management for the account of third parties, qualified investors (investisseurs qualifi?es) acting for their own account and/or corporate investors meeting one of the four criteria provided in Article 1 of Decree N_2004-1019 of September 28, 2004 and belonging to a limited circle of investors (cercle restraint d'investisseurs) acting for their own account, with "qualified investors" and "limited circle of investors" having the meaning ascribed to them in Article L. 411-2 of the French Code Mon?etaire et Financier and applicable regulations thereunder; none of this prospectus or any other materials related to the offer or information contained therein relating to our common stock has been released, issued or distributed to the public in France except to Permitted Investors; and the direct or indirect resale to the public in France of any common stock acquired by any Permitted Investors may be made only as provided by articles L. 412-1 and L. 621-8 of the French Code Mon?etaire et Financier and applicable regulations thereunder.

Italy

The offering of shares of our common stock has not been cleared by the Italian Securities Exchange Commission (Commissione Nazionale per le Societ`a e la Borsa, or the CONSOB) pursuant to Italian securities legislation and, accordingly, shares of our common stock may not and will not be offered, sold or delivered, nor may or will copies of this prospectus or any other documents relating to shares of our common stock or the offering be distributed in Italy other than to professional investors (operatori qualificati), as defined in Article 31, paragraph 2 of CONSOB Regulation No. 11522 of July 1, 1998, as amended, or Regulation No. 11522.

Any offer, sale or delivery of shares of our common stock or distribution of copies of this prospectus or any other document relating to shares of our common stock or the offering in

Italy may and will be effected in accordance with all Italian securities, tax, exchange control and other applicable laws and regulations, and, in particular, will be: (i) made by an investment firm, bank or financial intermediary permitted to conduct such activities in Italy in accordance with the Legislative Decree No. 385 of September 1, 1993, as amended, or the Italian Banking Law, Legislative Decree No. 58 of February 24, 1998, as amended, Regulation No. 11522, and any other applicable laws and regulations; (ii) in compliance with Article 129 of the Italian Banking Law and the implementing guidelines of the Bank of Italy; and (iii) in compliance with any other applicable notification requirement or limitation which may be imposed by CONSOB or the Bank of Italy.

Any investor purchasing shares of our common stock in the offering is solely responsible for ensuring that any offer or resale of shares of common stock it purchased in the offering occurs in compliance with applicable laws and regulations.

This prospectus and the information contained herein are intended only for the use of its recipient and are not to be distributed to any third party resident or located in Italy for any reason. No person resident or located in Italy other than the original recipients of this document may rely on it or its content.

In addition to the above (which shall continue to apply to the extent not inconsistent with the implementing measures of the Prospective Directive in Italy), after the implementation of the Prospectus Directive in Italy, the restrictions, warranties and representations set out under the heading "European Economic Area" above shall apply to Italy.

Germany

Shares of our common stock may not be offered or sold or publicly promoted or advertised by any underwriter in the Federal Republic of Germany other than in compliance with the provisions of the German Securities Prospectus Act (Wertpapierprospektgestz WpPG) of June 22, 2005, as amended, or of any other laws applicable in the Federal Republic of Germany governing the issue, offering and sale of securities.

Spain

Neither the common stock nor this prospectus have been approved or registered in the administrative registries of the Spanish National Securities Exchange Commission (Comisio? n Nacional del Mercado de Valores). Accordingly, our common stock may not be offered in Spain except in circumstances which do not constitute a public offer of securities in Spain within the meaning of articles 30bis of the Spanish Securities Markets Law of 28 July 1988 (Ley 24/1988, de 28 de Julio, del Marcado de Valores), as amended and restated, and supplemental rules enacted thereunder.

Sweden

This is not a prospectus under, and has not been prepared in accordance with the prospectus requirements provided for in, the Swedish Financial Instruments Trading Act (lagen (1991:980) om handel med finasiella instrument) nor any other Swedish enactment. Neither the Swedish Financial Supervisory Authority nor any other Swedish public body has examined, approved, or registered this document.

Switzerland

The common stock may not and will not be publicly offered, distributed or re-distributed on a professional basis in or from Switzerland and neither this prospectus nor any other solicitation for investments in our common stock may be communicated or distributed in Switzerland in any way that could constitute a public offering within the meaning of Articles

1156 or 652a of the Swiss Code of Obligations or of Article 2 of the Federal Act on Investment Funds of March 18, 1994. This prospectus may not be copied, reproduced, distributed or passed on to others without the underwriters' prior written consent. This prospectus is not a prospectus within the meaning of Articles 1156 and 652a of the Swiss Code of Obligations or a listing prospectus according to article 32 of the Listing Rules of the Swiss Exchange and may not comply with the information standards required thereunder. We will not apply for a listing of our common stock on any Swiss stock exchange or other Swiss regulated market and this prospectus may not comply with the information required under the relevant listing rules. The common stock offered hereby has not and will not be registered with the Swiss Federal Banking Commission and has not and will not be authorized under the Federal Act on Investment Funds of March 18, 1994. The investor protection afforded to acquirers of investment fund certificates by the Federal Act on Investment Funds of March 18, 1994 does not extend to acquirers of our common stock.

LEGAL MATTERS

The validity of the common stock we are offering will be passed upon for us by Ballard Spahr Andrews & Ingersoll, LLP, Baltimore, Maryland. Dewey Ballantine LLP, New York, New York is counsel for the underwriters in connection with this offering.

EXPERTS

The financial statements of Osiris Therapeutics, Inc. at December 31, 2005 and 2004, and for each of the three years in the period ended December 31, 2005, appearing in this prospectus and Registration Statement have been audited by Stegman & Company, an independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering. This prospectus does not contain all of the information in the registration statement and the exhibits to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits to the registration statement. Statements contained in this prospectus about the contents of any contract or any other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's Public Reference Room, which is located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's Public Reference Room. In addition, the SEC maintains an Internet website, which is located at http://www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website. Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, and we will file reports, proxy statements and other information with the SEC.

We maintain an Internet website at www.OsirisTx.com. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Osiris Therapeutics, Inc.
Baltimore, Maryland

We have audited the accompanying balance sheets of Osiris Therapeutics, Inc. as of December 31, 2005 and 2004, and the related statements of operations, stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2005. These financial statements are the responsibility of the Company's management. 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, 2005 and 2004, and its results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

/s/ STEGMAN & COMPANY

Baltimore, Maryland
April 17, 2006

Suite 100, 405 East Joppa Road Baltimore Maryland 21286 410-823-8000 1-800-686-3883 Fax: 410-296-4815

www.stegman.com

OSIRIS THERAPEUTICS, INC.

BALANCE SHEETS
(amounts in thousands)

	December 31,	
	2005	**2004**
ASSETS		
Current assets:		
Cash	$ 597	$ 488
Short-term investments	42,774	
Accounts receivable	974	61
Inventory and other current assets	367	92
Total current assets	44,712	641
Property and equipment, net	3,792	4,968
Restricted cash	190	213
Deferred financing costs, net	2,050	
Other assets	270	150
Total assets	$ 51,014	$ 5,972
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,565	$ 1,800
Notes payable, current portion	65	2,415
Capital lease obligations, current portion	1,027	933
Deferred revenue, current portion	952	952
Total current liabilities	6,609	6,100
Notes payable, net of current portion	47,411	7,519
Capital lease obligations, net of current portion	2,024	3,026
Deferred revenue, net of current portion	1,349	2,302
Long-term interest payable and other liabilities	3,016	29
Mandatorily redeemable convertible preferred stock Series D, 3,750 shares designated, 3,213 shares issued and outstanding in 2005	64,267	
Total liabilities	124,676	18,976
Stockholders' deficit:		
Convertible preferred stock, $0.001 par value, 16,250 shares authorized, 12,250 shares designated and 10,651 shares outstanding 2005, 3,094 shares outstanding 2004	32,746	15,243
Common stock, $.001 par value, 90,000 shares authorized, 36,390 shares outstanding 2005, 35,601 outstanding 2004	36	36
Additional paid-in capital	36,377	94,359
Deferred compensation	(277)	(93)
Accumulated deficit	(142,544)	(122,549)
Total stockholders' deficit	(73,662)	(13,004)

	December 31,	
Total liabilities and stockholders' deficit	$ 51,014	$ 5,972

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,		
	2005	**2004**	**2003**
Product sales	$ 957	$	$
Cost of goods sold	444		
Gross profit	513		
Revenue from collaborative research licenses and grants	3,013	3,911	3,981
Operating expenses:			
Research and development	16,927	11,888	18,639
General and administrative	2,294	1,704	4,467
Total operating expenses	19,221	13,592	23,106
Loss from operations	(15,695)	(9,681)	(19,125)
Interest income (expense):			
Interest income	504	25	78
Interest expense	(4,804)	(872)	(683)
Total interest expense, net	(4,300)	(847)	(605)
Net loss	$ (19,995)	$ (10,528)	$ (19,730)
Basic and diluted net loss per share	$ (0.56)	$ (0.30)	$ (0.90)
Weighted average common stock outstanding, in thousands (basic and diluted)	35,837	35,255	21,901

The accompanying notes are an integral part of these financial statements.

OSIRIS THERAPEUTICS, INC.
STATEMENTS OF STOCKHOLDERS' DEFICIT
YEARS ENDED DECEMBER 31, 2005, 2004 AND 2003
(amounts in thousands, except for share data)

	Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Total Stockholders' Deficit
Balance at January 1, 2003		$	8,807,798	$ 9	$ 66,896	$ (1,090)	$ (92,291)	$ (26,476)
Exercise of options to purchase common stock ($3.00 per share)			2,655		8			8
Conversion of debentures and accrued interest			26,152,940	26	26,969			26,995
Issuance of convertible preferred stock, Class 1	2,000,000	10,000						10,000
Issuance of convertible preferred stock, Series B	545,454	3,000						3,000
Issuance of common stock for services rendered by Directors ($1.50 per share)			30,000		45			45
Issuance of common stock and fractional shares			1,418					
Deferred compensation from stock options					209	(209)		
Repricing of stock options					417			417
Reversal of deferred compensation from repricing stock options					(862)	862		
Amortization of deferred compensation from stock option grants						178		178
Net loss							(19,730)	(19,730)
Balance at December 31, 2003	2,545,454	13,000	34,994,811	35	93,682	(259)	(112,021)	(5,563)
Exercise of options to purchase common stock ($.10 to $.20 per share)			145,622		16			16
Issuance of common stock for services rendered by Directors ($.10 per share)			50,000		5			5
Issuance of common stock to settle lawsuit ($.10 per share)			375,000	1	37			38
Issuance of common stock to settle debt ($4.50 per share)			36,000		162			162
Issuance of convertible preferred stock, Series C ($4.50 per share)	548,090	2,243						2,243
Fair value of warrants issued in connection with financing arrangements					400			400
Forfeiture of stock options					(10)	10		
Amortization of deferred compensation from stock option grants					67	37		104
Write-off of stockholder loans receivable						119		119
Net loss							(10,528)	(10,528)
Balance at December 31, 2004	3,093,544	15,243	35,601,433	36	94,359	(93)	(122,549)	(13,004)
Exercise of options to purchase common stock ($.10 to $.20 per share)			108,595		12			12
Issuance of common stock for services rendered by directors ($.10 per share)			180,000		18			18
Conversion of restricted stock units to management ($.10 per share)			500,000		50			50
Issuance of convertible preferred stock Series E ($2.50 per share)	7,557,000	17,503						17,503
Redemption premium on mandatorily redeemable convertible preferred stock, Series D, redeemable at $20.00 share					(58,305)			(58,305)
Deferred compensation from stock option grants					247	(247)		
Forfeiture of stock options					(17)	17		
Amortization of deferred compensation from stock option grants					13	46		59

	Convertible Preferred Stock							
Net loss							(19,995)	(19,995)
Balance at December 31, 2005	10,650,544	$ 32,746	36,390,028	$ 36	$ 36,377	$ (277)	$ (142,544)	$ (73,662)

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,		
	2005	**2004**	**2003**
Cash flows from operations:			
Net loss	$ (19,995)	$ (10,528)	$ (19,730)
Adjustments to reconcile net loss to net cash used in operations:			
Depreciation and amortization	1,515	1,790	1,753
Non cash stock based compensation expense	109	104	595
Stockholder loan write-off		119	
Impairment loss on property and equipment			590
Non cash interest expense	3,497	523	278
Increase (decrease) in cash resulting from changes in assets and liabilities:			
Accounts receivable	(913)	1,102	(1,163)
Inventory and other current assets	(276)	14	4
Other assets	(120)	47	(93)
Accounts payable	1,875	(1,789)	959
Deferred revenue	(952)	(2,952)	6,206
Accrued expenses and other	640	(562)	479
Net cash used in operations:	(14,620)	(12,132)	(10,122)
Cash flows from investing activities:			
Purchases of property and equipment	(338)	(50)	(1,185)
Sale of short-term investments	2,200		
Purchase of short-term investments	(44,974)		
Net cash used in investing activities	(43,112)	(50)	(1,185)
Cash flows from financing activities:			
Principal payments on capital lease obligations and notes payable	(1,000)	(845)	(825)
Restricted cash	23	22	23
Proceeds from notes payable	39,957	9,690	
Proceeds from borrowing on capital lease obligations	27		
Proceeds from the issuance of preferred and common stock, net of offering costs	21,360	2,464	13,053
Payment of debt financing costs	(2,526)		
Net cash provided by financing activities	57,841	11,331	12,251
Net increase (decrease) in cash	109	(851)	944
Cash at beginning of year	488	1,339	395
Cash at end of year	$ 597	$ 488	$ 1,339

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,		
	2005	**2004**	**2003**
Supplemental disclosure of cash flows information:			
Cash paid for interest	$ 448	$ 349	$ 405
Cash paid for taxes	$	$	$
Supplemental schedule of noncash investing and financing activities:			
Conversion of notes payable to common stock	$ 2,350	$	$ 23,792
Conversion of convertible notes payable accrued interest to common stock	$ 355	$	$ 3,202
Common stock issued to settle lawsuit	$	$ 38	$
Common stock issued to settle debt	$	$ 162	$
Common stock issued to directors for services rendered	$ 18	$ 5	$ 45
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, 2005, 2004 and 2003
(amounts in thousands, except for share and per share data)

1. Description of Business and Significant Accounting Policies

Description of business

Osiris Therapeutics, Inc. (the "Company") is a Delaware corporation operating from a single location in Baltimore, Maryland. The Company is a clinical stage biotechnology company founded to commercialize stem cell products from adult bone marrow. We began operations on December 23, 1992 and launched our first commercial product in July 2005. Our operations consist primarily of research, development and clinical activities to bring our other biologic drug candidates to the marketplace and efforts to secure adequate capital for anticipated growth and operations. Prior to 2005, we presented our financial statements as a development stage company.

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. Based on our current operating levels, we believe that we have sufficient levels of cash, short-term investments and access to funds through collaborative agreements that we will not require additional debt or equity financing during 2006. We have several research collaboration agreements that provide 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 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 revenue recognition, deferred tax assets, and stock-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, 2005 and 2004, there was no allowance for doubtful accounts as we believe the reported

amounts are fully collectible. We did not recognize any bad debt expense for the years ended December 31, 2005, 2004 and 2003. Accounts receivable balances are not collateralized.

Inventory

We commenced sales of our first commercial product in July 2005 and began carrying inventory on our balance sheet thereafter. We determine our inventory values using the first-in, first-out method. In 2004 and prior years, we expensed the costs of materials used to manufacture product prototypes as components of research and development expenses. Inventory is included in other current assets.

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 lease term.

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 2005 or 2004. A $590 impairment loss recognized in 2003 related to a partially built expanded manufacturing facility after management determined it would use a third-party to conduct a portion of our manufacturing process.

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 interest expense. 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 and for the year ended December 31, 2005, we recognized $957 in revenue from our tissue-based Osteocel product. 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, MD facilities. We have agreements with our customers that specify the terms of sale, including price.

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. This fee is being recognized as revenue over a 63-month period, $952 of which was recognized in each of 2005 and 2004, and $794 was recognized in 2003. 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 2005 and $2 million in 2004 and $1 million in 2003 from the JCR 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 at the time of receipt.

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. In 2004, we earned $844 from governmental research grants. Revenue from research grants is recognized as the related research expenditures are incurred. The Company no longer solicits governmental grants.

Cost of Goods Sold

In July 2005, we launched Osteocel. Costs of goods sold consists primarily of the costs to obtain the tissue and other chemicals and supplies. Our manufacturing processes are still being refined and, therefore, we expense manufacturing labor costs as incurred. These labor costs are reported as research and development costs.

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 carryforwards. 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.

Business Segments

Statement of Financial Accounting Standards No. 131 Disclosures about Segments of an Enterprise and Related Information ("SFAS No. 131") established standards for reporting information about operating segments in annual financial statements of public enterprises and in interim financial reports issued to stockholders. It also established standards for related disclosures about products and services, geographic areas and major customers. The Company currently operates as one business segment that produces commercialized stem cell products.

Comprehensive income

In 2005, 2004 and 2003, 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 plan, 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 antidilutive. At December 31, 2005 we had a valuation of our common stock performed which resulted in the estimated fair value of $1.71 per share. Previously in 2005 and 2004, our Board of Directors estimated the fair value of our common stock to be $0.10 per share. During 2003, our Board of Directors estimated the fair value of our common stock to be $1.50 per share. We do not have any options, warrants, preferred stock, or convertible debt conversion rights that provided for the issuance of common shares at less than $0.10 per share.

Stock-Based Compensation

We record compensation expense for stock-based compensation for employees and non-employee members of our Board or Directors using the intrinsic value method prescribed by Accounting Principles Board or APB, Opinion No. 25, "Accounting for Stock Issued to Employees." We granted qualified stock options for a fixed number of shares to employees with an exercise price equal to the fair market value of the shares at the date of grant. In these circumstances and in accordance with APB 25, we recognize no compensation expense for qualified stock option grants. We also issue non-qualified stock options for a fixed number of shares to employees with an exercise price less than the fair market value of the shares at the date of grant. When such options vest, we recognize the difference between the exercise price and fair market value at date of grant as compensation expense in accordance with APB 25. In 2005, for their services as directors of the Company, members of the Board of Directors were awarded 180,000 shares of our common stock, which was valued at the estimated fair market value or $0.10 per share. In 2004, 50,000 shares and in 2003, 30,000 shares of our common stock were issued at estimated market value, to members of our Board of Directors for their services. The fair value of these shares of common stock were expensed upon grant.

SFAS No. 123, "Accounting for Stock-Based Compensation," encourages companies to recognize expense for stock-based awards based on their estimated fair value on the date of grant. Statement No. 123 and No. 148, "Accounting for Stock-Based Compensation Transition and Disclosure" requires the disclosure of pro forma income and earnings per share data in the notes to the financial statements if the fair value method is not adopted. The following table illustrates the effect on net income and earnings per share if we had determined

compensation costs by applying the fair value recognition provisions of Statement No. 123 to stock-based employee awards.

	2005	2004	2003
Net loss, as reported	$ (19,995)	$ (10,528)	$ (19,730)
Add stock-based employee compensation included in reported net loss	109	104	595
Deduct total stock-based employee compensation determined under fair-value-based method for all awards	(8)	(46)	(71)
Pro forma net loss	$ (19,894)	$ (10,470)	$ (19,206)
Basic and diluted loss per share, as reported	$ (0.56)	$ (0.30)	$ (0.88)
Basic and diluted loss per share, pro forma	$ (0.56)	$ (0.30)	$ (0.88)

Certain employee options outstanding at the beginning of 2003 were repriced to below their initial exercise price and hence are subject instead to the variable method of accounting. These options give rise to compensation expense in accordance with APB No. 25.

The Black-Scholes option-pricing model and other models were developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of subjective assumptions, including the expected stock price volatility. The fair value of our stock-based awards was estimated on the measurement date using the Black-Scholes option-pricing model along with the following assumptions:

	2005	2004	2003
Assumptions			
Risk-free interest rate	4.21%	3.93%	3.40%
Dividend yield	0.0%	0.0%	0.0%
Expected life of option grants	5-years	5-years	5-years
Expected stock price volatility	85.64%	100%	100%

Because our common stock is not traded on an active market, we based our estimate of expected volatility for 2005 using similar entities whose share prices are publicly available. For options granted in 2004 and 2003, we estimated the expected volatility based upon what we believed to be estimates of the fair market value of our common stock.

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. Our receivables at December 31, 2005 consist primarily of amounts due from U.S.

Government research grant agencies, and three commercial customers, and we expect these receivables to be collected.

In 2005, we launched our first commercial product and recognized sales of $957, in sales to three customers. Customer demand for Osteocel exceeded our capability to manufacture the product in 2005 and we expect this to continue in 2006 while we refine the manufacturing process and expand our manufacturing staff and facilities.

Significant New Accounting Pronouncements

As permitted by SFAS No. 123, "Accounting for Stock-Based Compensation," we currently account for share-based payments to employees using the intrinsic value method under Accounting Principles Board, or APB, Opinion No. 25. In December 2004, the Financial Accounting Standards Board issued Statement No. 123(R), "Share-Based Payment," which is a revision of Statement No. 123. We are required to adopt and will adopt the provisions of Statement No. 123(R) in the first quarter of 2006. We intend to use the modified prospective method of adoption and continue to use the Black-Scholes option pricing model to value share-based payments, although we are continuing to review our alternatives for calculating estimated fair value under this new pronouncement. The modified prospective method requires companies to recognize compensation cost beginning with the effective date of adoption based on (a) the requirements of Statement No. 123(R) for all share-based payments granted after the effective date of adoption and (b) the requirements of Statement No. 123 for all unvested awards granted to employees prior to the effective date of adoption. Based upon expected vesting of existing options, we estimate our stock-based compensation to be approximately $70 for the year ended December 31, 2006. Upon the occurrence of certain future events, the vesting of stock options may be accelerated which could affect future stock-based compensation expense.

In March 2005, the FASB issued Interpretation No. 47, "Accounting for Conditional Asset Retirement Obligations," which is an interpretation of Statement No. 143, "Accounting for Asset Retirement Obligations." The interpretation requires that a liability for the fair value of a conditional asset retirement obligation be recognized if the fair value of the liability can be reasonably estimated. The interpretation is effective for years ending after December 15, 2005. The interpretation did not have a material impact on the Company's results of operations, financial position or cash flows.

In May 2005, the FASB issued Statement No. 154, "Accounting Changes and Error Corrections," SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It established, unless impracticable, retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. SFAS No. 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The provisions of this Statement are effective for accounting changes and corrections of errors made in fiscal periods beginning after December 15, 2005.

Reclassifications

Certain amounts in the 2004 financial statements have been reclassified to conform to the 2005 presentation.

2. Balance Sheet Details

	2005	2004
Accounts receivable		
Grants receivable	$ 579	$ 61
Customer receivables	395	
	$ 974	$ 61
Inventory and other current assets		
Inventory	$ 101	$
Interest receivable	95	
Prepaid expenses	171	92
	$ 367	$ 92
Property and equipment, net		
Laboratory and other equipment	$ 4,861	$ 4,618
Leased assets	11,725	11,699
Leasehold improvements	4,437	4,367
	21,023	20,684
Accumulated depreciation and amortization	(17,231)	(15,716)
	$ 3,792	$ 4,968
Accounts payable and accrued expenses		
Accounts payable	$ 2,946	$ 1,071
Accrued expenses	575	530
Accrued compensation	249	76
Accrued interest	795	123
	$ 4,565	$ 1,800

3. Notes Payable and Capital Lease Obligations

	2005	2004
Bank Loan, payable in quarterly installments and bearing interest at LIBOR plus applicable margins, 5.09% 5.59% in 2005	$ 114	$ 179
Boston Scientific Corporation, 8%, to be repaid from future product sales, up to $50 million may be borrowed for product development	5,000	5,000
Demand Note, 10%, converted into Series D Mandatorily Redeemable Convertible Preferred Stock in 2005		1,350
Demand Note, 10%, converted into Series D Mandatorily Redeemable Convertible Preferred Stock in 2005		1,000
Term Note, 5%, convertible into common stock at $1.50/share	2,000	2,000
Term Note, 6%, convertible at the sole option of the Holder, due in 2008	20,600	
Term Notes, 6%, convertible into common stock at initial public offering at specified prices	19,762	405
	47,476	9,934
Less current portion	(65)	(2,415)
Notes payable long-term	$ 47,411	$ 7,519
Total capital lease obligations	3,051	3,959
Less current portion	(1,027)	(933)
Capital lease obligations, long-term	$ 2,024	$ 3,026

During June 1995, we borrowed $750 from Wachovia Bank in connection with the acquisition and renovation of our Baltimore, Maryland facilities. This loan is partially guaranteed by an agency of the State of Maryland and matures in September 2007. This loan bears interest at LIBOR plus 2.0% to 2.5% (6.09% to 6.59% at December 31, 2005). Compensating balance arrangements with Wachovia Bank require us to maintain a cash balance of 105% of the non-guaranteed portion of this loan, which is shown as a component of Restricted Cash in the accompanying balance sheets. At December 31, 2005 and 2004, the compensating balance requirement was $40 and $63, respectively.

In the first quarter of 2005, loans from a Board Member and a company controlled by this Board Member were converted into Series D Mandatorily Redeemable Convertible Preferred Stock. These loans, totaling $2.35 million, plus accrued interest and loan premiums totaling $355 were converted into 1,352,325 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock, which is described in Note 4.

As of December 31, 2005, we have issued convertible promissory notes to twenty-six stockholders for a total of $19.8 million. These notes will pay interest at 6% per annum, payable after 12 months, 24 months, and at maturity. These notes are due and payable in June 2008, unless earlier converted into common stock. If we successfully close an underwritten initial public offering ("IPO") of common stock of $25 million or more, the holders of the notes will have the option of a) converting the note into common shares of the

Company or b) demand redemption of the principal and any accrued but unpaid interest. The notes provide for discounted conversion features providing the holder to convert to common stock at prices between 75% and 85% of the IPO price based upon specified dates. The notes are not convertible on the commitment date. In accordance with EITF 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios" the intrinsic value of the conversion feature will be recorded upon completion of an IPO.

In November 2005, we issued a $20.6 million convertible promissory note to a foreign investment bank. The note matures on November 28, 2008 and bears interest, payable annually at 6%. This note also provides for redemption premiums starting at 9% and escalating up to 27%, depending upon the date of redemption. This note is convertible into common stock at the sole discretion of the holder, if an IPO occurs after December 2006. We have accrued the redemption premium that we are presently obligated for as long-term interest payable with a corresponding charge to interest expense resulting in an effective yield of 15% for the year ended December 31, 2005.

In September 2004, we issued a convertible promissory note to a foreign investor for $2.0 million. This loan bears interest at 5% and the principal and accrued interest is convertible into our common stock at the conversion rate of $1.50 per share. If not converted, this loan becomes due on September 20, 2008. This note also provides for redemption premiums starting at 5% and escalating up to 20% depending upon the date of redemption. We have accrued the redemption premium we are presently obligated for as long-term interest payable with a corresponding charge to interest expense resulting in an effective yield of 15% for the year ended December 31, 2005.

In February 2003, all of our then outstanding convertible debentures totaling $23.8 million and related accrued interest totaling $3.2 million were converted into 26.2 million shares of common stock. This represents a conversion rate of $1.03 per share of common stock.

Future maturities of Notes Payable and Capital Lease Obligations

For years subsequent to 2005, scheduled annual maturities of notes payable and capital lease obligations outstanding as of December 31, 2005, are as follows:

	Notes Payable	Capital Lease Obligations	Total
2006	$ 65	$ 1,027	$ 1,092
2007	49	1,129	1,178
2008	42,362	885	43,247
2009		7	7
2010		3	3
Thereafter	5,000		5,000
	$ 47,476	$ 3,051	$ 50,527

4. Preferred Stock Rights and Preferences

Our convertible preferred stock consists of the following designated shares at December 31, 2005 and 2004:

	2005	2004
Convertible preferred stock, Class I, Series 2003, $0.001 par value, 3,023,810 shares designated, 2,000,000 issued and outstanding	$ 10,000	$ 10,000
Convertible preferred stock, Series B, $0.001 par value, 750,000 shares designated, 545,454 shares issued and outstanding	3,000	3,000
Convertible preferred stock, Series C, $0.001 par value, 3,500,000 shares designated, 548,090 shares issued and outstanding	2,243	2,243
Convertible preferred stock, Series E, $0.001 par value, 8,000,000 shares designated, 7,557,000 shares issued and outstanding in 2005	17,503	
	$ 32,746	$ 15,243
Mandatorily redeemable convertible preferred stock, Series D, 3,750,000 shares designated, 3,213,335 shares issued and outstanding in 2005	$ 64,267	$

The following Series of preferred stock, except for our Series D, are classified as equity because the conversion features are restricted to equity and they do not contain cash conversion provisions.

In March 2003, as part of our agreement with Boston Scientific Corporation ("BSC"), we authorized and agreed to sell to BSC certain classes of convertible preferred stock either concurrently or upon reaching certain milestones related to product development, clinical trials and FDA approval of our cardiac drug candidate. In 2003, we sold BSC 2,000,000 shares of the Class I Series 2003 Convertible Preferred Stock for $10 million. Each share of the Series 2003 Convertible Preferred Stock has the same basic liquidity, voting and conversion features. The conversion features generally allow for conversion of each share into one share of common stock at its conversion price per share. Shares may be converted at any time by the holder and are subject to an automatic conversion feature and have an anti-dilution feature in the event the Company issues shares of common stock at below the fair market value.

Our Series B Convertible Preferred Stock was issued in 2003, as part of an agreement with JCR Pharmaceuticals at the price of $5.50 per share. At the option of the holder, each share may be converted into one share of common stock and is subject to an automatic conversion feature. This series of convertible preferred stock also contains anti-dilution provisions in the event the Company issues shares of its common stock at below the fair market value.

Our Series C Convertible Preferred Stock was issued in 2004 at the price of $4.50 per share and is convertible into our common shares at the conversion rate of 2.25 shares of common stock for each share of Series C Convertible Preferred Stock.

Each of our Series 2003, Series B and Series C convertible preferred stock contain conversion features whereby the shares are automatically converted into common shares if we raise $20 million or more in public funds or have a 50% or more change in ownership of our common shares.

Our Series E Convertible Preferred Stock is convertible into our common shares at the conversion price of $2.50 per common share. This series of preferred stock also contains automatic conversion features in the event of a public stock offering, and the shares may otherwise be converted upon the demand of the stockholder.

Also in 2005, we issued 3,213,335 shares of Series D Mandatorily Redeemable Convertible Preferred Stock for $2.00 per share. These shares are convertible into common stock at the rate of ten shares of common for each Series D share. In addition, these shares include a mandatory redemption feature whereby if the Company does not complete an initial public offering prior to June 1, 2007 and the shares are not previously converted into common stock, the Company must redeem them for $20.00 per share. The Series D Mandatorily Redeemable Convertible Preferred Stock is 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 $5,962 from the Series D offering, a redemption premium of $58,305 was recorded as a liability.

5. Equity Compensation Plans

In 2005, our stockholders approved a 10-year extension of our 1994 Amended and Restated Stock Incentive Plan. Our 2005 Amended and Restated Stock Incentive Plan provides for the granting of restricted stock and options to officers, employees, consultants and advisors to purchase shares of our common stock at prices which may be equal to, less than or greater than the fair market value of the stock on the dates options are granted. Our stock option grants generally vest over four years and expire in no more than ten years. We have reserved 3,500,000 shares of our common stock for issuance under this Plan. At December 31, 2005, 579,792 options are available for future grants.

The following table summarizes the option activity under the Plan for the three years ended December 31, 2005.

	Options	Weighted Average Exercise Price
Balance, January 1, 2003	900,000	$ 2.10
Options cancelled for repricing	(505,464)	(2.10)
Options reissued and repriced	505,464	0.10
Options granted	964,692	0.13
Options exercised	(2,655)	3.00
Options forfeited or expired	(305,864)	(2.05)
Balance, December 31, 2003	1,556,173	$ 0.24

Balance, December 31, 2003	1,556,173	$ 0.24
Options granted	1,740,000	0.10
Options exercised	(145,622)	(0.11)
Options forfeited or expired	(975,945)	(0.13)
Balance, December 31, 2004	2,174,606	$ 0.17
Options granted	424,000	$ 0.10
Options exercised	(108,595)	(0.10)
Options forfeited or expired	(224,095)	(0.86)
Balance, December 31, 2005	2,265,916	$ 0.10
Options exercisable, December 31, 2005	714,549	$ 0.10

The weighted fair value of options granted during the years ended December 31, 2005, 2004 and 2003 were $0.71 and $0.08 and $0.08, respectively.

During 2003, we cancelled and reissued 505,464 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 $0.10 per share at a time when the estimated fair value of the common stock was $1.50 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 $35, $67 and $417 was recognized in 2005, 2004 and 2003, respectively.

Following is a summary of the status of stock options outstanding and exercisable at December 31, 2005.

	Options Outstanding		Options Exercisable	
Option Price	Shares	Weighted Average Remaining Contractual Life	Shares	Weighted Average Exercise Price
$ 0.10	2,245,416	8.7 years	704,299	$ 0.10
0.20	20,500	7.6 years	10,250	$ 0.20
	2,265,916	8.7 years	714,549	$ 0.10

Deferred Compensation. Deferred compensation has arisen in our financial statements as a result of granting stock options below fair market value at the time of the grant. The difference between the option exercise price and the fair market value of the common stock at the date of the grant multiplied by the number of options granted results in the total intrinsic value of the options. This value is recorded as an increase to additional paid-in capital and an increase in deferred compensation. This deferred compensation is presented as a contra amount in stockholders' equity and is recognized as expense over the vesting period of the underlying options in accordance with ABP No. 25. If the options are forfeited before they vest, the compensation expense is decreased prospectively. In addition, the additional paid-in capital and deferred compensation are both reduced for the related intrinsic value. At December 31, 2005 and 2004, the balance of deferred compensation was $277 and $93, respectively.

6. Related Party Transactions

General. Peter Friedli, the Chairman of our Board of Directors, has been responsible for procuring since 1993, either directly or through affiliated entities, an aggregate of approximately $200 million in debt and equity financing for us and our predecessor company. Mr. Friedli is the beneficial owner of approximately 56% of our common stock as of April 17, 2006. Of the shares beneficially owned by Mr. Friedli, 80,000 shares were received by him as Board compensation since 1996, 50,000 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.

Consulting Agreement. Since 1995, we and our predecessor company have been party to a Consulting Agreement, originally with Friedli Corporate Finance AG, and now 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 has provided general business, financial and investment advice to us, and has served as a liaison between us and FCF clients who have invested in us, many of which are located in Switzerland. This Consulting Agreement had also granted to FCF a right of first refusal with respect to any debt or equity financings by us, and contains a provision requiring us to allocate ten percent of the shares in this offering to FCF. However, the right of first refusal was terminated in 2003 and the allocation right has been waived in connection with this offering, and we and FCF have agreed to terminate the Consulting Agreement upon the closing of this offering. The base compensation paid by us under this agreement was $65 in 2005, $63 in 2004 and $63 in 2003. In addition, pursuant to this Consulting Agreement, we paid $50 as expense reimbursements in 2005, to or as directed by FCF.

Referral Fees and Costs. Separate from the Consulting Agreement, FCF served as our agent in Europe in connection with:

the issuance and sale in 2004 of 400,000 shares of our Series C Convertible Preferred Stock at a purchase price of $4.50 per share, representing aggregate gross proceeds of $1.8 million;

the issuance and sale in 2004 of $4.8 million of our Convertible Preferred Notes;

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; and

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.

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 $71.9 million in gross proceeds was raised for us. We paid referral fees and costs of $3.4 million to accounts designated by Mr. Friedli, including accounts of third parties unrelated to Mr. Friedli. We also paid expense reimbursement of $350 to Mr. Friedli and issued 50,000 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, we paid placement agency fees to the European investment bank.

New Venturetec/Pine Loans. In 2004, we obtained $2.35 million in debt financing through two entities affiliated with Mr. Friedli. The first of these entities was a wholly owned subsidiary of New Venturetec, Inc., a Swiss publicly traded company. Mr. Friedli owns 3% of New Venturetec and is its president. The other entity is Pine, Inc., a company which at the time of the financing was majority owned and managed by Mr. Friedli.

In this financing, the New Venturetec subsidiary 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. 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 5,000,000 shares at an exercise price of $0.10 per share. Mr. Friedli subsequently arranged for the acquisition of those warrants.

The loans made by the New Venturetec subsidiary and Pine, plus premium and accrued interest totaling $355, were converted into 1,352,325 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock in early 2005, representing an effective price of $2.00 per share. Each share of our Series D Mandatorily Redeemable Convertible Preferred Stock will convert into 10 shares of our common stock upon completion of this offering.

Other Financings. We have engaged in the following additional financings that involved Mr. Friedli, either directly or indirectly:

The New Venturetec subsidiary described above purchased in 2005 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. It also purchased in 2005 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.

Merger and Related Litigation. In February 2001, a predecessor of our company was merged into a subsidiary of a Swiss company. This action was taken in contemplation of a Swiss initial public offering, which did not occur. Stockholders of our predecessor became stockholders of the Swiss company as a result of this merger. At the time of the merger, Mr. Friedli and a group of controlling stockholders, pursuant to the terms of the merger, received per share merger consideration which was greater than that which was received by the minority stockholders of the predecessor. The validity of the merger was challenged by certain minority stockholders and former directors of the predecessor in litigation that also challenged a loan made by Mr. Friedli to the predecessor. This litigation was settled in August 2003 pursuant to an agreement among the parties. This agreement provided, among other things, for unwinding of the merger, payment of $300 to one of the plaintiffs and the allocation of shares of common stock to that plaintiff, the establishment of a special committee of the board of the predecessor to review the terms of the challenged loan, and that all future transactions with related parties be approved by independent directors. Following the settlement, counsel for the special committee determined that the terms and Mr. Friedli's interest in the loan had been disclosed to the Board prior to its approval, and no further action has been taken by the special committee.

7. Warrants

At December 31, 2005, the Company had warrants to purchase its common and preferred stock outstanding as shown in the following table.

	Common Stock		Preferred Stock	
	# of Shares	Weighted Average Price	# of Shares	Weighted Average Price
Warrants outstanding, January 1, 2004	3,702,500	$ 0.63	17,928	$ 12.00
Warrants granted	5,000,000	0.10		
Warrants exercised				
Warrants cancelled				
Warrants outstanding, January 1, 2005	8,702,500	0.29	17,928	12.00
Warrants granted				
Warrants exercised				
Warrants expired	(202,500)	9.77	(17,928)	12.00
Warrants outstanding, December 31, 2005	8,500,000	$ 0.10		$

There was no warrant activity during 2003.

Following is the summary of the status of outstanding warrants to purchase our common stock at December 31, 2005.

2005		
Warrant Price	Common Shares	Weighted Average Remaining Contractual Life
$ 0.10	8,500,000	4.2 years

In connection with a 2004 financing arrangement, we issued warrants to purchase 5,000,000 shares of our common stock at $0.10 per share. In accordance with APB No. 14 "Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants", the warrants were valued separately from the debt. The initial fair value of the warrants was estimated at approximately $400 using the Black-Scholes pricing model. The assumptions used in the Black-Scholes model are as follows: (1) dividend yield 0%; (2) expected volatility 100%; (3) risk-free rate of 3.93% and (4) expected life of 6 years. Because the notes had a demand provision, the entire fair value of the warrants was included in interest expense in 2004.

8. Income Taxes

The components of the Company's net deferred tax assets at December 31 are as follows:

	2005	2004
Deferred Tax Assets:		
Net operating loss carryforwards	$ 50,818	$ 42,558
Research and experimentation credit carryforwards	4,803	4,053
Property and equipment	1,662	1,733
Other	51	51
	57,334	48,395
Valuation allowance	(57,334)	(48,395)
Net deferred tax assets	$	$

The Company's deferred tax assets have been fully reserved in both 2005 and 2004 since their ultimate future realization cannot be assured. The valuation allowance increased by $8.9 million for the year ended December 31, 2005.

The Company presently has available for federal income tax purposes, approximately $130 million of net operating loss carryforwards and $4.8 million of research and experimentation credit carryforwards, which expire beginning in 2009 through 2025. However, as a result of changes in the Company's ownership since its inception, the amount of these carryforwards available to offset future taxable income and income taxes could be subject to annual limitations.

9. Research Collaboration Agreements and Deferred Revenue

Boston Scientific Agreement. In 2003, the Company entered into a long-term strategic 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, which entitles the Company to a licensing fee and to royalties on resulting revenue includes both a BSC equity investment and significant BSC debt financing for the cardiovascular project.

The Company received a $5 million licensing fee for the use of its technology by BSC. This revenue is being recognized as revenue over a 63 month period, $952 of which was recognized in both 2005 and 2004, and $794 was recognized in 2003. As provided for in the agreement, BSC purchased 2 million shares of the Company's Class 1, Series 2003 Convertible Preferred Stock for $10 million. If the Company achieves certain milestones, BSC will purchase up to an additional $20 million of this convertible preferred stock, at prices ranging from $15 to $28 per share and pay license fees of up to $25.0 million.

The BSC agreement includes a $50 million line of credit for future related cardiovascular clinical development expenses once certain FDA and other milestones are met. In March 2004, the Company drew $5 million under this line of credit, which is recorded as long-term debt

and accrues interest at 8%. At December 31, 2005, the Company estimates that it was entitled to draw approximately $3 million more on this line of credit.

JCR Pharmaceuticals Agreement. Also in 2003, we entered into a strategic alliance with JCR Pharmaceuticals Co., Ltd. ("JCR"). Under the JCR agreement, we have granted to 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. They also paid us a $3.0 million licensing fee, which was recognized as revenue over twelve months, including $2.0 million in 2004 and $1.0 million in 2003. In 2005, upon the completion of certain milestones, we received $500 in additional licensing fees, which was recognized as revenue.

10. Defined Contribution Plan

The Company has 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.

11. Commitments and Contingencies

We lease approximately 127,000 square feet of laboratory, production, warehouse and office space under an amended lease agreement that expires in 2008. 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, 2005 and 2004:

	2005	2004
Facilities leases	$ 8,568	$ 8,568
Equipment leases	3,157	3,131
	11,725	11,699
Less accumulated amortization	(9,635)	(8,894)
Leased property and equipment, net	$ 2,090	$ 2,805

Future minimum lease payments under these facilities and equipment arrangements are as follows:

	Facilities	Equipment	Total
2006	$ 1,216	$ 8	$ 1,224
2007	1,236	8	1,244
2008	906	8	914
2009		8	8
2010		3	3
	3,358	35	3,393
Less interest	(331)	(11)	(342)
Present value of minimum lease payments	3,027	24	3,057
Less current portion	(1,023)	(4)	(1,027)
Capital lease obligations, net of current portion	$ 2,004	$ 20	$ 2,024

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 2005, 2004 and 2003.

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

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Through and including , 2006 (25 days after the date of this prospectus), federal securities laws may require all dealers that effect transactions in our common stock, whether or not participating in this offering, to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Shares

Common Stock

Deutsche Bank Securities

Prospectus

, 2006

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance And Distribution

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, that we will pay in connection with the sale of common stock being registered. All amounts are estimates except the registration fee and the NASD filing fee.

	Amount
SEC registration fee	$
NASD filing fee	
The NASDAQ National Market listing fee	
Printing and engraving	
Legal fees and expenses	
Blue sky qualification fees and expenses	
Accounting fees and expenses	
Transfer agent fees	
Miscellaneous expenses	
Total	$

Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, by reason of the fact that the person is or was a director, officer, employee or agent of the corporation or is or was serving at the corporation's request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with the action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The power to indemnify applies to actions brought by or in the right of the corporation as well, but only to the extent of expenses, including attorneys' fees but excluding judgments, fines and amounts paid in settlement, actually and reasonably incurred by the person in connection with the defense or settlement of the action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that a court of competent jurisdiction shall determine that such indemnity is proper.

Section 145(g) of the Delaware General Corporation Law provides that a corporation shall have the power to purchase and maintain insurance on behalf of its officers, directors, employees and agents, against any liability asserted against and incurred by such persons in any such capacity.

We have obtained insurance covering our directors and officers against losses and insuring ourselves against certain obligations to indemnify our directors and officers.

Section 102(b)(7) of the General Corporation Law of the State of Delaware provides that a corporation may eliminate or limit the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the General Corporation Law of the State of Delaware, or (iv) for any transaction from which the director derived an improper personal benefit. No such provision shall eliminate or limit the liability of a director for any act or omission occurring prior to the date when such provision becomes effective.

Article VIII of our amended and restated Certificate of Incorporation provides that, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no director of Osiris shall be personally liable to Osiris or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability.

Item 15. Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold by us since January 1, 2003 which were not registered under the Securities Act of 1933 as amended.

(a) Issuances and Sales of Convertible Preferred Stock

In March 2003, we issued and sold an aggregate of 2.0 million shares of our Class I, Series 2003 Convertible Preferred Stock at a price of $5.00 per share for an aggregate offering price of $10.0 million. These shares were issued to Boston Scientific Corporation and were sold in connection with our collaborative agreement.

In August 2003, we issued and sold an aggregate of 545,454 shares of our Series B Convertible Preferred Stock at a price of $5.50 per share for an aggregate offering price of $3.0 million. These shares were issued to JCR Pharmaceuticals Co., Ltd. and were sold in connection with our collaborative agreement.

During February through April 2004, we issued and sold an aggregate of 548,090 shares of our Series C Convertible Preferred Stock at a price of $4.50 per share for an aggregate offering price of $2,243,000. These shares were sold to thirteen accredited investors in the United States, with 400,000 shares sold to investors in Switzerland.

During February through June 2005, we issued and sold an aggregate of 3,213,355 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock at a price of $2.00 per share for an aggregate offering price of $5,962,000. The Series D shares were offered only to existing stockholders and 26,299 shares were issued to existing investors in the United States with the remaining shares sold to foreign investors.

During July through December 2005, we issued and sold an aggregate of 7,557,000 shares of our Series E Convertible Preferred Stock at a price of $2.50 per share for an aggregate offering price of $17,503,000. All the Series E shares were sold outside of the United States.

(b) Issuances and Sales of Convertible Promissory Notes

In June 2004, we issued a $1.0 million convertible demand note and in November 2004 we issued a $1,350,000 convertible demand note to an entity that is affiliated with our Chairman. These notes accrued interest at 10%, and included a premium of 10%. In

February 2005, these notes, together with the accrued interest and premium were converted into 777,395 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock.

In August 2004, we issued two $500,000 convertible demand notes to an entity that is wholly owned by our Chairman. These notes accrued interest at 10% and included a premium of 10%. In February 2005, these notes, together with accrued interest and premium were converted into 574,930 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock.

In September 2004, we issued a $2.0 million convertible promissory note that accrues interest at 5% and is convertible into our common stock upon the completion of this offering. This Note was issued to a foreign investor.

In December 2004, we issued a $405,000 convertible promissory note that accrues interest at 6% and is convertible into our common stock upon the completion of this offering. This note was issued to a foreign investor.

During January through June 2005, we issued a series of 6% convertible promissory notes in the aggregate amount of $9,357,282 to holders of our Series D Mandatorily Redeemable Convertible Preferred Stock. These notes are convertible into our common stock upon the completion of this offering.

In November 2005, we issued a $20.6 million convertible promissory note to a foreign investor. This note bears interest at 6% and may be converted into our common stock at the sole option of the note holder.

In June 2005, we issued a $10.0 million convertible promissory note to a foreign investor. This note bears interest at 6% and may be converted into our common stock at the sole option of the note holder.

(c) Issuances of Common Stock

During the three years ended December 31, 2005, stock options for 256,872 shares of our common stock were exercised for the aggregate purchase price of $51,187.

In February 2003 we issued 26,152,940 shares of common stock in exchange for the transfer to us of certain convertible debentures of our predecessor.

During 2003, we issued 30,000 shares of our common stock to our non-management Directors as compensation.

During 2004, we issued 50,000 shares of our common stock to our non-management Directors as compensation.

Also in 2004, we issued 375,000 shares of our common stock to settle a lawsuit, and 36,000 shares to settle a debt.

In 2005, we issued 180,000 shares of our common stock to our non-management Directors as compensation.

In 2005, we issued 500,000 shares of our common stock to our President, pursuant to a restricted stock unit grant approved by our Board of Directors the prior year.

(d) Issuances of Warrants

In October 2004, we issued warrants to purchase 5,000,000 shares of our common stock to two foreign investors, with an exercise price of $0.10 per share. These warrants have since been cancelled.

No underwriters were involved in the sales of securities described above. The securities described above were issued to a combination of U.S., European and other investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and Rule 506 of Registration D promulgated thereunder relating to sales by an issuer not involving any public offering, to the extent an exemption from such registration was required. The purchasers of our securities described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. The sales of these securities were made without general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement.
3.1*	Amended and Restated Certificate of Incorporation of the Registrant.
3.2*	Bylaws of the Registrant.
4.1*	Form of Common Stock Certificate.
5.1*	Opinion of Ballard Spahr Andrews & Ingersoll, LLP, counsel to the Registrant, with respect to the legality of the securities being registered.
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	Loan Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003, as amended.
10.8	Amendment No. 1 to the Loan Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 12, 2004.
10.9	Security Agreement from the Registrant to Boston Scientific Corporation, dated as of March 12, 2004.
10.10*	Contract Manufacturing Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.11*	Development Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.

10.12*	Investment Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.13*	Investor Rights Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.14*	License Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.15*	Investor Rights Agreement by and between the Registrant and JCR Pharmaceuticals, Inc. dated August 26, 2003.
10.16*	License Agreement by and between the Registrant and JCR Pharmaceuticals, Inc. dated August 26, 2003.
10.17*	Technology Transfer and License Agreement by and between the Registrant and Case Western University, dated as of January 1, 1993, as amended.
10.18*	Marketing Collaboration and License Agreement by and between the Registrant and BioWhittaker, Inc., dated as of August 11, 1999.
10.19*	Lease Agreement by and between the Registrant and SAGA Limited Partnership, dated as of January 18, 1995, as amended.
10.20*	Second Amended and Restated Sublease Agreement by and between the Registrant and Maryland Economic Development Corporation, dated as of June 30, 1998.
23.1	Consent of Stegman & Company.
23.2*	Consent of Ballard Spahr Andrews & Ingersoll, LLP (see Exhibit 5.1).
24.1	Powers of Attorney (included on signature page).

*
To be filed by amendment.

(b) Financial Statement Schedules

Financial Statement Schedules are omitted because the information is included in our financial statements or notes to those financial statements.

Item 17. Undertakings

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions referenced in Item 14 of this Registration Statement, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and

registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to 424(b)(1) or (4), or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Baltimore, State of Maryland, on the 11th day of May 2006.

POWER OF ATTORNEY

KNOW ALL BY THESE PERSONS PRESENT, that the persons whose signatures appear below do hereby constitute and appoint C. Randal Mills and Cary J. Claiborne, or any of them, our true and lawful attorneys-in-fact and agents, each with full power to sign for us or any of us in our names and in any and all capacities, any and all amendments (including post-effective amendments) to this Registration Statement, or any related registration statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto and other documents required in connection therewith with the Securities and Exchange Commission hereby do ratifying and confirming all that each of said attorneys-in-fact, or either of them, or his substitute or substitutes, shall do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ C. RANDAL MILLS C. Randal Mills	Chief Executive Officer and Director (Principal Executive Officer)	
/s/ CARY J. CLAIBORNE Cary J. Claiborne	Chief Financial Officer (Principal Financial Officer)	
/s/ PETER FRIEDLI Peter Friedli	Director	
/s/ FELIX GUTZWILLER Felix Gutzwiller	Director	

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