

FIRST INTERSTATE BANCSYSTEM INC  
 Form 4  
 November 13, 2015

**FORM 4**

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

OMB APPROVAL

OMB Number: 3235-0287  
 Expires: January 31, 2015  
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Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. See Instruction 1(b).

**STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES**

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

(Print or Type Responses)

1. Name and Address of Reporting Person \*  
 Scott Jonathan R

2. Issuer Name and Ticker or Trading Symbol  
 FIRST INTERSTATE  
 BANCSYSTEM INC [FIBK]

5. Relationship of Reporting Person(s) to Issuer

(Check all applicable)

(Last) (First) (Middle)

3. Date of Earliest Transaction  
 (Month/Day/Year)  
 11/11/2015

Director  10% Owner  
 Officer (give title below)  Other (specify below)

PO BOX 30918

(Street)

4. If Amendment, Date Original Filed(Month/Day/Year)

6. Individual or Joint/Group Filing(Check Applicable Line)  
 Form filed by One Reporting Person  
 Form filed by More than One Reporting Person

BILLINGS, MT 59116-0191

(City) (State) (Zip)

**Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned**

1. Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)	4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)	5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Ownership (Instr. 4)
				(A) or (D)	Code V Amount (D) Price		
Class A Common Stock					3,499	I	By Trust
Class A Common Stock					4,232	D	

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

Persons who respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB control number.

SEC 1474 (9-02)

**Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned**  
(e.g., puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security (Instr. 3)	2. Conversion or Exercise Price of Derivative Security	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any (Month/Day/Year)	4. Transaction Code (Instr. 8)	5. Number of Derivative Securities Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)	6. Date Exercisable and Expiration Date (Month/Day/Year)	7. Title and Underlying Security (Instr. 3 and 4)
Class B Common Stock <sup>(1)</sup>	\$ 0					03/05/2010 <sup>(1)</sup> 12/31/2029 <sup>(1)</sup>	Class A Common Stock
Class B Common Stock <sup>(1)</sup>	\$ 0					03/05/2010 <sup>(1)</sup> 12/31/2029 <sup>(1)</sup>	Class A Common Stock
Stock Options	\$ 17	11/11/2015		M	1,400	01/26/2006 01/26/2016	Class B Common Stock
Class B common Stock <sup>(1)</sup>	\$ 0	11/11/2015		M	1,400	03/05/2010 <sup>(1)</sup> 12/31/2029 <sup>(1)</sup>	Class A Common Stock
Class B Common Stock <sup>(1)</sup>	\$ 0	11/11/2015		F	963 <sup>(2)</sup>	03/05/2010 <sup>(1)</sup> 12/31/2029 <sup>(1)</sup>	Class A Common Stock

## Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
Scott Jonathan R PO BOX 30918 BILLINGS, MT 59116-0191			X	

## Signatures

/s/ CAROL DONALDSON, Attorney-in-Fact for Reporting Person  
 11/13/2015  
 \*\*Signature of Reporting Person Date

## Explanation of Responses:

\* If the form is filed by more than one reporting person, see Instruction 4(b)(v).

\*\* Intentional misstatements or omissions of facts constitute Federal Criminal Violations. See 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

(1) The Class B Common Stock is convertible at any time into Class A Common Stock on a share for share basis at the discretion of the holder. The conversion feature of the Class B Common Stock does not expire.

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(2) Includes 799 shares for payment of option exercise price and 164 shares for payment of taxes, valued at \$29.79 per share.

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure.

Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number. rap align="right" valign="bottom"> 15,192

Preferred stock warrant liability

1,820

Convertible preferred stock

91,019

Deficit accumulated during the development stage

(108,838 ) (108,838 ) (108,838 )

Total shareholders equity (deficit)

(101,648 ) (8,809 ) 59,624

(1) A \$1.00 increase (decrease) in the assumed public offering price of \$11.00 would increase (decrease) each of cash, cash equivalents and short-term investments, working capital, total assets and total shareholders equity (deficit) by \$6.3 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 and estimated offering expenses payable by us.

**Table of Contents**

**RISK FACTORS**

*You should carefully consider the risks described below before making an investment decision. Our business, prospects, financial condition or operating results could be materially adversely affected by any of these risks, as well as other risks not currently known to us or that we currently deem immaterial. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this prospectus, including our consolidated financial statements and the related notes, before deciding to purchase any shares of our common stock.*

**Risks Related to Our Product Candidates and Operations**

**Our success largely depends on the success of our lead PharmacoSurgery<sup>tm</sup> product candidate, OMS103HP, and we cannot be certain that it will receive regulatory approval or be successfully commercialized. If we are unable to commercialize OMS103HP, or experience significant delays in doing so, our business will be materially harmed.**

We are a biopharmaceutical company with no products approved for commercial sale and we have not generated any revenue from product sales. We have incurred, and will continue to incur, significant costs relating to the clinical development and commercialization of our lead product candidate, OMS103HP, for use during arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery as well as arthroscopic meniscectomy surgery. We have not yet obtained regulatory approval to market this product candidate for ACL reconstruction surgery, arthroscopic meniscectomy surgery or any other indication in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize this product candidate successfully. If OMS103HP does not receive regulatory approval for ACL reconstruction surgery or arthroscopic meniscectomy surgery, or if it is not successfully commercialized for one or both uses, we may not be able to generate revenue, become profitable, fund the development of our other product candidates or preclinical development programs or continue our operations.

We do not know whether our clinical trials for OMS103HP will be completed on schedule or result in regulatory approval or in a marketable product. If approved for commercialization, we do not anticipate that OMS103HP will reach the market until 2011 at the earliest.

**Our success is also dependent on the success of our additional PharmacoSurgery product candidates, OMS302 and OMS201, and we cannot be certain that either will advance through clinical testing, receive regulatory approval or be successfully commercialized.**

In addition to OMS103HP, our success will depend on the successful commercialization of one or both of two additional PharmacoSurgery product candidates, OMS302 and OMS201. We are currently conducting a Phase 2 concentration-ranging clinical trial to assist in determining the optimal concentration of the mydriatic API contained in OMS302 as a mydriasis induction agent in patients undergoing cataract surgery. We are also conducting a Phase 1/Phase 2 clinical trial evaluating the efficacy, safety and systemic absorption of OMS201 when used during ureteroscopy for removal of ureteral or renal stones. We have incurred and will continue to incur significant costs relating to the clinical development and commercialization of these PharmacoSurgery product candidates. We have not obtained regulatory approval to market these product candidates for any indication in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize these product candidates successfully. If OMS302 and OMS201 do not receive regulatory approval, or if they



**Table of Contents**

are not successfully commercialized, we may not be able to generate revenue, become profitable, fund the development of our other product candidates or our preclinical programs or continue our operations.

We do not know whether our planned and current clinical trials for OMS302 and OMS201 will be completed on schedule, if at all. In addition, we do not know whether any of our clinical trials will be successful or result in approval of either product for marketing.

**We have a history of operating losses and we may not achieve or maintain profitability.**

We have not been profitable and have generated substantial operating losses since we were incorporated in June 1994. We had net losses of approximately \$11.6 million, \$23.8 million, \$23.1 million and \$22.8 million for the six months ended June 30, 2009 and for the years ended December 31, 2008, 2007 and 2006, respectively. As of June 30, 2009, we had an accumulated deficit of approximately \$108.8 million. We expect to incur additional losses for at least the next several years and cannot be certain that we will ever achieve profitability. As a result, our business is subject to all of the risks inherent in the development of a new business enterprise, such as the risks that we may be unable to obtain additional capital needed to support the preclinical and clinical expenses of development and commercialization of our product candidates, to develop a market for our potential products, to successfully transition from a company with a research and development focus to a company capable of commercializing our product candidates and to attract and retain qualified management as well as technical and scientific staff. In addition, the audit report covering our 2008 consolidated financial statements contains an explanatory paragraph stating that our recurring losses and negative cash flows from operations, due to our negative working capital prior to the successful completion of this offering, raise substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will eliminate this doubt and enable us to continue as a going concern; however, if we are unable to raise sufficient capital in this offering, we will need to obtain alternative financing or significantly modify our operational plans for us to continue as a going concern.

**We are subject to extensive government regulation, including the requirement of approval before our products may be marketed.**

Both before and after approval of our product candidates, we, our product candidates, and our suppliers and contract manufacturers are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution, and import and export. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: warning letters; fines and other monetary penalties; unanticipated expenditures; delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating restrictions; injunctions; and criminal prosecution. We or the U.S. Food and Drug Administration, or FDA, or an institutional review board, or IRB, may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk.

Our product candidates cannot be marketed in the United States without FDA approval. The FDA has not approved any of our product candidates for sale in the United States. All of our product candidates are in development, and will have to be approved by the FDA before they can be marketed in the United States. Obtaining FDA approval requires substantial time, effort, and financial resources, and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on a timely basis, if at all.

**Table of Contents**

The FDA may decide that our data are insufficient for approval of our product candidates and require additional preclinical, clinical or other studies. As we develop our product candidates, we periodically discuss with the FDA clinical, regulatory and manufacturing matters, and our views may, at times, differ from those of the FDA. For example, the FDA has questioned whether our studies evaluating OMS103HP in patients undergoing ACL reconstruction surgery are adequately designed to evaluate efficacy. If these studies fail to demonstrate efficacy, we will be required to provide additional information, including possibly the results of additional clinical trials. Also, the FDA regulates those of our product candidates consisting of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's effectiveness. The FDA has questioned the means by which we intend to demonstrate such contribution and whether available data and information demonstrate contribution for each active ingredient in OMS103HP. If we are unable to resolve these questions, we may be required to provide additional information, which may include the results of additional preclinical studies or clinical trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate for regulatory approval, if we are unable to successfully complete our clinical trials or other testing, or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may be delayed in obtaining marketing approval for our product candidates, or may never be able to obtain marketing approval.

Even if regulatory approval of a product candidate is obtained, such approval may be subject to significant limitations on the indicated uses for which that product may be marketed, conditions of use, and/or significant post approval obligations, including additional clinical trials. These regulatory requirements may, among other things, limit the size of the market for the product. Even after approval, discovery of previously unknown problems with a product, manufacturer, or facility, such as previously undiscovered side effects, may result in restrictions on any product, manufacturer, or facility, including, among other things, a possible withdrawal of approval of the product.

**If our clinical trials are delayed, we may be unable to develop our product candidates on a timely basis, which may increase our development costs and could delay the potential commercialization of our products and the subsequent receipt of revenue from sales, if any.**

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory agencies, institutional review boards or us to delay our clinical trials or suspend or delay the analysis of the data from those trials. Clinical trials can be delayed for a variety of reasons, including:

discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;

delays or the inability to obtain required approvals from institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;

delays in enrolling patients into clinical trials;

lower than anticipated retention rates of patients in clinical trials;

the need to repeat or conduct additional clinical trials as a result of problems such as inconclusive or negative results, poorly executed testing or unacceptable design;

an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;





**Table of Contents**

the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval;

an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation;

the occurrence of drug-related side effects or adverse events experienced by participants in our clinical trials; or

the placement of a clinical hold on a trial.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues or any determination that a trial presents unacceptable health risks; or

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our contract research organizations, or CROs, and other third parties.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to file for regulatory approval or conduct additional clinical trials on the schedule we currently anticipate. Any delays in completing our clinical trials may increase our development costs, would slow down our product development and approval process, would delay our receipt of product revenue and would make it difficult to raise additional capital. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products and may harm our business.

**If we are unable to raise additional capital when needed or on acceptable terms, we may be unable to complete the development and commercialization of OMS103HP and our other product candidates, or continue our other preclinical development programs.**

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

complete the Phase 3 clinical trials of OMS103HP for use in arthroscopic ACL reconstruction surgery;

initiate, conduct and complete the Phase 3 clinical trials of OMS103HP for use in arthroscopic meniscectomy surgery;

conduct and complete the clinical trials of OMS302 for use during lens replacement surgery;

conduct and complete the clinical trials of OMS201 for use in endoscopic surgery of the urological tract;

**Table of Contents**

continue our research and development;

make milestone payments to our collaborators;

make principal and interest payments due under our debt facility with BlueCrest Venture Finance Master Fund Limited, or BlueCrest;

initiate and conduct clinical trials for other product candidates; and

launch and commercialize any product candidates for which we receive regulatory approval.

In addition, if we elect under our Exclusive Technology Option Agreement with Patobios Limited to purchase assets for use in our GPCR program, we will be required to pay Patobios approximately \$10.8 million CAD, of which approximately \$7.8 million CAD is payable in cash and the remaining is payable in shares of our common stock.

Our clinical trials for OMS103HP may be delayed for many of the reasons discussed in these Risk Factors, which would increase the development expenses of OMS103HP and may require us to raise additional capital beyond what we raise in this offering to complete the clinical development and commercialization of OMS103HP and to decrease spending on our other clinical and preclinical development programs. We have no commitments for additional funding and cannot be certain that it will be available on acceptable terms, if at all. Continued disruptions in the global equity and credit markets may further limit our ability to access capital. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience significant dilution. Any debt financing, if available, may restrict our operations as further described in the following risk factor. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might be available; or relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves. Any of these events could significantly harm our business and prospects and could cause our stock price to decline.

**The terms of our debt facility place restrictions on our operating and financial flexibility and if we raise additional capital through debt financing the terms of any new debt could further restrict our ability to operate our business.**

In 2008 we borrowed \$17.0 million pursuant to the terms of a loan and security agreement with BlueCrest and pledged substantially all of our assets, other than intellectual property, as collateral for this loan. Our agreement with BlueCrest restricts our ability to incur additional indebtedness, pay dividends and engage in significant business transactions such as a change of control of Omeros, so long as we owe any amounts to BlueCrest under the agreement. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. In addition, if we default under our agreement, BlueCrest may have the right to accelerate all of our repayment obligations under the agreement and to take control of our pledged assets, which include our cash, cash equivalents and short-term investments, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, BlueCrest's right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. An event of default under the loan and security agreement includes the occurrence of any material adverse effect upon our business operations, properties, assets, results of operations or financial condition, taken as whole with



**Table of Contents**

respect to our viability, that would reasonably be expected to result in our inability to repay the loan. Although we believe that the breadth of our clinical and preclinical programs makes it unlikely that any single event would impact our viability, BlueCrest could nonetheless declare a default upon the occurrence of any event that it interprets as having a material adverse effect upon us as defined under our agreement, thereby requiring us to repay the loan immediately or to attempt to reverse BlueCrest's declaration through negotiation or litigation. Any declaration by BlueCrest of an event of default could significantly harm our business and prospects and could cause our stock price to decline. If we raise any additional debt financing, the terms of such debt could further restrict our operating and financial flexibility.

**Our lead product candidate OMS103HP or future product candidates may never achieve market acceptance even if we obtain regulatory approvals.**

Even if we receive regulatory approvals for the commercial sale of our lead product candidate OMS103HP or future product candidates, the commercial success of these product candidates will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product candidate that we may develop and commercialize will depend on many factors, including:

our ability to provide acceptable evidence of safety and efficacy;

availability, relative cost and relative efficacy of alternative and competing treatments;

the effectiveness of our marketing and distribution strategy to, among others, hospitals, surgery centers, physicians and/or pharmacists;

prevalence of the surgical procedure or condition for which the product is approved;

acceptance by physicians of each product as a safe and effective treatment;

perceived advantages over alternative treatments;

relative convenience and ease of administration;

the availability of adequate reimbursement by third parties;

the prevalence and severity of adverse side effects;

publicity concerning our products or competing products and treatments; and

our ability to obtain sufficient third-party insurance coverage.

The number of operations in which our PharmacoSurgery products, if approved, would be used may be significantly less than the total number of operations performed according to the market data obtained from industry sources. If our lead product candidate OMS103HP or future product candidates do not become widely accepted by physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable, and if we are unable to increase market penetration of OMS103HP or our other product candidates, our growth will be significantly harmed.

**We rely on third parties to conduct portions of our preclinical research and clinical trials. If these third parties do not perform as contractually required or otherwise expected, we may not be able to obtain regulatory approval for or commercialize our product candidates.**

We rely on third parties, such as CROs and research institutions, to conduct a portion of our preclinical research. We also rely on third parties, such as medical institutions, clinical investigators and CROs, to assist us in conducting our clinical trials. Nonetheless, we are responsible for confirming that our preclinical research is conducted in accordance with applicable regulations, and that our clinical trials are conducted in accordance with applicable

**Table of Contents**

regulations, the relevant protocol and within the context of approvals by an institutional review board. Our reliance on these third parties does not relieve us of responsibility for ensuring compliance with FDA regulations and standards for conducting, monitoring, recording and reporting the results of preclinical research and clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical and clinical development processes may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates. For example, we engaged Scottish Biomedical, Ltd., or SBM, to assist us in developing compounds for our PDE10 and PDE7 programs. We believe that, among other things, SBM breached its obligations under our agreement and committed fraud, requiring us to re-perform certain services provided by SBM and delaying the advancement of our programs.

**If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate product revenue.**

We do not have a sales and marketing organization and have no experience in the sales, marketing and distribution of biopharmaceutical products. Developing an internal sales force is expensive and time-consuming and should be commenced 12 to 18 months in advance of product launch. Any delay in developing an internal sales force could impact the timing of any product launch. If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any approved product candidates that we develop ourselves. Factors that may inhibit our efforts to commercialize our approved product candidates without collaboration partners include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of hospitals, surgery centers, physicians and/or pharmacists to purchase, use or prescribe our approved product candidates;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unsuccessful in building a sales and marketing infrastructure or unable to partner with one or more third parties to perform sales and marketing services for our product candidates, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

**We have no ability to manufacture clinical or commercial supplies of our product candidates and currently intend to rely solely on third parties to manufacture clinical and commercial supplies of all of our product candidates.**

We currently do not intend to manufacture our product candidates for our clinical trials or on a commercial scale and intend to rely on third parties to do so. Our clinical supplies of OMS103HP have been manufactured in a freeze-dried, or lyophilized, form by Catalent Pharma Solutions, Inc. in its Albuquerque, New Mexico facility. In May 2008, Catalent announced that it sold this facility to OSO Biopharmaceuticals Manufacturing, LLC, or OSO. OSO announced that





**Table of Contents**

it intends to continue the manufacture of lyophilized drug products at this facility. We have not entered into a binding agreement with Catalent or OSO for the commercial supply of lyophilized OMS103HP, and cannot be certain that we will be able to do so on commercially reasonable terms. Qualification of any other facility to manufacture lyophilized OMS103HP would require transfer of manufacturing methods, the production of an additional registration batch of lyophilized OMS103HP and the generation of additional stability data, which could delay the availability of commercial supplies of lyophilized OMS103HP.

We have also formulated OMS103HP as a liquid solution and, if approved for marketing, intend to launch OMS103HP as a liquid solution. We have entered into an agreement with Hospira Worldwide, Inc. for the commercial supply of liquid OMS103HP. We do not believe that the inactive ingredients in liquid OMS103HP, which are included in the FDA's Inactive Ingredient Guide due to being present in drug products previously approved for parenteral use, impact its safety or effectiveness. The FDA will require us to provide comparative information and complete a stability study and may require us to conduct additional studies, which we expect would be nonclinical and/or clinical pharmacokinetic studies, to demonstrate that liquid OMS103HP is as safe and effective as lyophilized OMS103HP. Delays or unexpected results in these studies could delay the commercial availability of liquid OMS103HP. Any significant delays in the manufacture of clinical or commercial supplies could materially harm our business and prospects.

**If the contract manufacturers that we rely on experience difficulties with manufacturing our product candidates or fail FDA inspections, our clinical trials, regulatory submissions and ability to commercialize our product candidates and generate revenue may be significantly delayed.**

Contract manufacturers that we select to manufacture our product candidates for clinical testing or for commercial use may encounter difficulties with the small- and large-scale formulation and manufacturing processes required for such manufacture. These difficulties could result in delays in clinical trials, regulatory submissions, or commercialization of our product candidates. Once a product candidate is approved and being marketed, these difficulties could also result in the later recall or withdrawal of the product from the market or failure to have adequate supplies to meet market demand. Even if we are able to establish additional or replacement manufacturers, identifying these sources and entering into definitive supply agreements and obtaining regulatory approvals may require a substantial amount of time and cost and such supply arrangements may not be available on commercially reasonable terms, if at all.

In addition, we and our contract manufacturers must comply with current good manufacturing practice, or cGMP, requirements strictly enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. We or our contract manufacturers may be unable to comply with cGMP requirements or with other FDA, state, local and foreign regulatory requirements. We have little control over our contract manufacturers' compliance with these regulations and standards or with their quality control and quality assurance procedures but we are responsible for their compliance. Large-scale manufacturing processes have been developed only for lyophilized OMS103HP. For the liquid formulation of OMS103HP and our other product candidates, development of large-scale manufacturing processes will require validation studies, which the FDA must review and approve. Failure to comply with these requirements by our contract manufacturers could result in the issuance of untitled letters and/or warning letters from authorities, as well as sanctions being imposed on us, including fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product candidate supplied by contract manufacturers is compromised due to their failure to adhere to applicable laws or for other reasons, we may not be able to obtain or maintain

## **Table of Contents**

regulatory approval for or successfully commercialize one or more of our product candidates, which would harm our business and prospects significantly.

If one or more of our contract manufacturers were to encounter any of these difficulties or otherwise fail to comply with its contractual obligations, our ability to provide product candidates to patients in our clinical trials or on a commercial scale would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending on the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must first approve these manufacturers' facilities and processes, which would require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our product candidates.

### **Ingredients necessary to manufacture our PharmacoSurgery product candidates may not be available on commercially reasonable terms, if at all, which may delay the development and commercialization of our product candidates.**

We must purchase from third-party suppliers the ingredients necessary for our contract manufacturers to produce our PharmacoSurgery product candidates for our clinical trials and, if approved, for commercial distribution. Suppliers may not sell these ingredients to us at the time we need them or on commercially reasonable terms, if at all. Although we intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of ingredients for our PharmacoSurgery product candidates, we have not yet entered into and we may be unable to secure any such supply agreements or guarantees. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients in a timely manner or in the minimum guaranteed quantities. If we are unable to obtain and then supply these ingredients to our contract manufacturer for our clinical trials, potential regulatory approval of our product candidates would be delayed, significantly impacting our ability to develop our product candidates, which would materially affect our ability to generate revenue from the sale of our product candidates.

### **We may need licenses for active ingredients from third parties so that we can develop and commercialize some products from some of our current preclinical programs, which could increase our development costs and delay our ability to commercialize products.**

Should we decide to use active ingredients in any of our product candidates that are proprietary to one or more third parties, we would need to obtain licenses to those active ingredients from those third parties. For example, we are likely to use proprietary active ingredients in some product candidates that we develop from our PDE7 program and possibly in some of our future GPCR product candidates. We do not have licenses to any of the proprietary active ingredients we may elect to use in these programs. If we are unable to access rights to these active ingredients prior to preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, we may not be able to commercialize product candidates from these programs.

### **Our ability to pursue the development and commercialization of product candidates from our MASP-2 program depends on the continuation of licenses from third parties.**

Our MASP-2 program is based in part on intellectual property rights that we licensed on a worldwide exclusive basis from the University of Leicester and from the UK Medical Research



**Table of Contents**

Council, or MRC. The continued maintenance of these agreements requires us to undertake development activities if and when a clinical candidate has been selected and, if regulatory approval for marketing is obtained, to pay royalties to the University of Leicester and MRC upon commercialization of a MASP-2 product candidate. Our ability to continue development and commercialization of product candidates from our MASP-2 program depends on our maintaining these exclusive licenses, which cannot be assured.

**Our ability to pursue the development and commercialization of product candidates from our MASP-2 program could be jeopardized by third-party patent rights.**

Our MASP-2 program is based in part on the results of research conducted by collaborators at MRC, the University of Leicester and Aarhus Universitet, and on intellectual property rights that we licensed on a worldwide exclusive basis from the University of Leicester and from MRC stemming from that collaborative research and from subsequent research performed by the University of Leicester and by MRC. Researchers at Aarhus Universitet have obtained a U.S. Patent that claims antibodies that bind MASP-2, and have filed other patents and patent applications related to MASP-2. While we do not hold any direct license from Aarhus Universitet or its researchers, our license from MRC includes MRC's joint ownership interest in this U.S. Patent claiming antibodies that bind MASP-2, which joint ownership interest arises from an MRC employee having been added as a named inventor in this patent by the U.S. Patent and Trademark Office, or USPTO. We also believe that we hold lawful rights to other patents and patent applications related to MASP-2 filed by researchers at Aarhus Universitet by virtue of our licenses with MRC and the University of Leicester. Our ability to commercialize any MASP-2 antibody product candidate depends on the exclusive licenses we hold from MRC and the University of Leicester to at least joint ownership interest in the patents and patent applications filed by researchers at Aarhus Universitet. We have been in discussions with parties related to the Aarhus Universitet researchers regarding the terms of a potential additional license that could, if we deemed it to be advantageous, expand our position with respect to these patents and patent applications from exclusive licenses of at least joint ownership rights to exclusive licenses of all ownership rights. We cannot be certain that we would be able to reach agreement on favorable terms, if any, of any such additional license, if determined to be advantageous, or that the Aarhus Universitet researchers or the parties related to them will not contest our licensed rights to these patents and patent applications, or that they will not seek through legal action to block the commercialization of any antibody product candidate from our MASP-2 program based on these or other patent applications that they filed. Perfecting, asserting or defending our rights to this intellectual property may be costly and time-consuming and, if unsuccessful, may limit our ability to pursue the development and commercialization of product candidates from our MASP-2 program.

**Our ability to pursue the development and commercialization of product candidates from our MASP-2 program depends on third-party antibody developers and manufacturers.**

Any product candidates from our MASP-2 program would be antibodies and we do not have the internal capability to sequence, hybridize or clone antibodies or to produce antibodies for use in clinical trials or on a commercial scale. We have entered into development agreements with Affitech AS and North Coast Biologics for the development of MASP-2 antibodies; however, we do not have agreements in place with antibody manufacturers and cannot be certain that such agreements could be entered into on commercially reasonable terms, if at all. There are only a limited number of antibody manufacturers. If we are unable to obtain clinical supplies of MASP-2 antibody product candidates, clinical trials or the development of any such product candidate could be substantially delayed until we can find and qualify a manufacturer, which may increase our development costs, slow down our

## **Table of Contents**

product development and approval process, delay receipt of product revenue and make it difficult to raise additional capital.

### **Our programs may not produce product candidates that are suitable for clinical trials or that can be successfully commercialized.**

Any product candidates from our preclinical programs, including our MASP-2, Addiction, PDE10, PDE7 and GPCR programs, must successfully complete preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before entering clinical trials. Many pharmaceutical and biological product candidates do not successfully complete preclinical testing and, even if preclinical testing is successfully completed, may fail in clinical trials. We cannot be certain that any of our preclinical product development programs will generate product candidates that are suitable for clinical testing. For example, we have not yet generated any product candidates from our GPCR program. Although we believe that we have the capability to de-orphanize orphan GPCRs, we have not yet attempted to do so. When we do attempt to de-orphanize orphan GPCRs, we may discover that there are fewer druggable targets among the orphan GPCRs than we currently estimate and that, for those de-orphanized GPCRs that we develop independently, we are unable to develop related product candidates that successfully complete preclinical or clinical testing. We also cannot be certain that any product candidates that do advance into clinical trials, such as OMS103HP, OMS302 and OMS201, will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

### **Because we have a number of development programs and are considering a variety of product candidates, we may expend our limited resources to pursue a particular candidate or candidates and fail to capitalize on candidates or indications that may be more profitable or for which there is a greater likelihood of success.**

Because we have limited resources, we must focus on preclinical development programs and product candidates that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Further, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, license or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

### **It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.**

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our product candidates and the methods used to manufacture them, and related to therapeutic targets and methods of treatment, as well as successfully defending these patents against potential third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States, and tests used for determining the patentability of patent claims in all technologies are in flux. The pharmaceutical, biotechnology and other life sciences patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent



**Table of Contents**

laws in the United States and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. For example, in the United States, a determination of patentability by the USPTO or validity by a court or other trier of fact requires a determination that the claimed invention has utility and is both novel and non-obvious to those of ordinary skill in the art in view of prior known publications and public information, and that the patent specification supporting the claim adequately describes the claimed invention, discloses the best mode known to the inventors for practicing the invention, and discloses the invention in a manner that enables one of ordinary skill in the art to make and use the invention. The ultimate determination by the USPTO or by a court of other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may impact the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, our licensed patents or patent applications or in third-party patents.

Our issued PharmacoSurgery patents have terms that will expire December 12, 2014 and, if our pending PharmacoSurgery patent applications issue as patents, October 20, 2019 for OMS103HP, July 30, 2023 for OMS302 and March 17, 2026 for OMS201, not taking into account any extensions due to potential adjustment of patent terms resulting from USPTO delays. We cannot assure you that any of these patent applications will issue as patents or of the scope of any claims that may issue from these pending and future patent applications, or the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the United States or foreign jurisdictions, which could limit patent protection for our product candidates and materially harm our business.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

we might not have been the first to make the inventions covered by any of our patents, if issued, or our pending patent applications;

we might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or products or duplicate any of our technologies or products;

it is possible that none of our pending patent applications will result in issued patents or, if issued, these patents may not be sufficient to protect our technology or provide us with a basis for commercially viable products and may not provide us with any competitive advantages;

if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws;

if issued, the patents under which we hold rights may not be valid or enforceable; or

we may develop additional proprietary technologies or products that are not patentable and which are unlikely to be adequately protected through trade secrets if, for example, a competitor were to independently develop duplicative, similar or alternative technologies or products.

In addition, to the extent we are unable to obtain and maintain patent protection for one of our product candidates or in the event such patent protection expires, it may no longer be



**Table of Contents**

cost-effective to extend our portfolio by pursuing additional development of a product candidate for follow-on indications.

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

**We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.**

If we choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe the patents.

Further, a third party may claim that we or our contract manufacturers are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in the alleged infringing activity, including making, using or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our contract manufacturers are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our contract manufacturers to pay the other party's damages for having violated the other party's patents. We have indemnified our contract manufacturers against certain patent infringement claims and thus may be responsible for any of their costs associated with such claims and actions. The pharmaceutical, biotechnology and other life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Although we have conducted searches of third-party patents with respect to our OMS103HP, OMS302, OMS201, MASP-2, Addiction, PDE10, PDE7 and GPCR programs, these searches may not have identified all third-party patents relevant to these product candidates. Consequently, we cannot assure you that third-party patents containing claims covering our product candidates, programs, technologies or methods do not exist, have not been filed, or could not be filed or issued. For example, we are aware of a U.S. Patent that claims antibodies that bind MASP-2 and other patents and patent applications related to MASP-2 held by researchers at Aarhus Universitet that are described above in more detail in these Risk Factors. Our ability to commercialize any MASP-2 antibody product candidate depends on the exclusive licenses we hold from MRC and the University of Leicester to at least joint ownership interest in the patents and patent applications filed by researchers at Aarhus Universitet.

**Table of Contents**

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents, our licensors' patents, our pending applications or our licensors' pending applications, or that we or our licensors were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technologies similar to ours. Any such patent application may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the capital necessary to continue our operations.

**We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.**

Our research operations produce hazardous waste products, which include chemicals and radioactive and biological materials. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply with applicable legal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. We generally contract with third parties for the disposal of such substances and store our low-level radioactive waste at our facilities until the materials are no longer considered radioactive. We may be required to incur further costs to comply with current or future environmental and safety regulations. In addition, although we carry insurance, in the event of accidental contamination or injury from these materials, we could be held liable for any damages that result and any such liability could exceed our insurance coverage and other resources.

**The loss of members of our management team could substantially disrupt our business operations.**

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies except for on the life of Gregory Demopoulos, M.D., our president, chief executive officer, chief medical officer and chairman of the board of directors. We agreed to enter into a new employment agreement with Dr. Demopoulos by May 1, 2009. Although we have not yet entered into a new employment agreement with Dr. Demopoulos, we and Dr. Demopoulos intend to do so. Following completion of this offering, our compensation committee intends to review all components of his compensation, including his cash and equity compensation, in connection with the determination of the terms of his new employment agreement. If we are unable to enter into a new agreement with Dr. Demopoulos because of our actions or omissions, he could claim that we are in material breach of his current employment agreement, which may entitle Dr. Demopoulos to severance benefits described below in Management Executive Compensation Potential Payment upon Termination or Change in Control. Losing the services of any key member of our management team, whether from death or disability,

**Table of Contents**

retirement, competing offers or other causes, could delay execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

**We rely on highly skilled personnel and, if we are unable to retain or motivate key personnel or hire qualified personnel, we may not be able to maintain our operations or grow effectively.**

Our performance is largely dependent on the talents and efforts of highly skilled individuals. Our future success depends on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization. In this regard, in anticipation of increased development and commercialization activities, we plan to increase the total number of our full-time employees from 62 as of August 31, 2009 to approximately 75 to 85 by the end of 2009. If we are unable to hire and train a sufficient number of qualified employees for any reason, we may not be able to implement our current initiatives or grow effectively. We have in the past maintained a rigorous, highly selective and time-consuming hiring process. We believe that our approach to hiring has significantly contributed to our success to date. If we do not succeed in attracting qualified personnel and retaining and motivating existing personnel, our existing operations may suffer and we may be unable to grow effectively.

To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

**Our former chief financial officer has made allegations against us that may lead to litigation.**

In December 2008, our former chief financial officer, Richard J. Klein, used our Whistleblower Policy procedures to report to the chairman of our audit committee that we had submitted grant reimbursement claims to the National Institutes of Health, or NIH, for work that we had not performed. In accordance with the Whistleblower Policy and its charter, our audit committee, with special outside counsel, commenced an independent investigation of our NIH grant and claims procedures. The investigation concluded that we had not submitted claims to the NIH for work we had not performed. In January 2009, we terminated Mr. Klein's employment for reasons other than this incident. Mr. Klein alleged that he was wrongfully terminated and claimed it was retaliatory. We subsequently voluntarily reported to the NIH Mr. Klein's whistleblower report and the audit committee findings; the NIH confirmed to us in writing that it was satisfied with our handling of these grant matters.

Although we have been advised by outside employment and corporate counsel that we have meritorious defenses to Mr. Klein's allegations, and we intend to defend ourselves vigorously should he file a lawsuit, the outcome of any litigation is inherently uncertain. We cannot predict with certainty whether we will prevail. Further, if Mr. Klein files a lawsuit against us and our current and former directors as he has threatened, it may consume our time and resources to defend ourselves, harm our reputation and those of our current and former directors, materially negatively affect our financial position and cause our stock price to decline.

**We will incur increased costs and demands on management as a result of complying with the laws and regulations affecting public companies, which could affect our operating results.**

As a public company we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company



## **Table of Contents**

reporting requirements. We also have incurred and will continue to incur costs associated with recently adopted corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new rules implemented by the SEC and the NASDAQ Stock Market. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these new rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage than used to be available. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

We are not currently required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, and are therefore not required to make an assessment of the effectiveness of our internal controls over financial reporting. Further, our independent registered public accounting firm has not been engaged to express, nor has it expressed, an opinion on the effectiveness of our internal controls over financial reporting. As a public company, we will be required under Section 404 to perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting for fiscal years ending after December 31, 2009. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses.

If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, management may not be able to assess whether our internal controls over financial reporting are effective, which may subject us to adverse regulatory consequences and could result in a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we fail to develop and maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner or otherwise comply with the standards applicable to us as a public company. Any failure by us to provide the required financial information in a timely manner could materially and adversely impact our financial condition and the market value of our securities.

## **Risks Related to Our Industry**

**Our competitors may develop products that are less expensive, safer or more effective, or which may otherwise diminish or eliminate the commercial success of any potential products that we may commercialize.**

If our competitors market products that are less expensive, safer or more effective than our future products developed from our product candidates, that reach the market before our product candidates, or that otherwise negatively affect the market, we may not achieve commercial success. For example, we are developing PDE10 inhibitors to identify a product candidate for use in the treatment of schizophrenia. Other pharmaceutical companies, many with significantly greater resources than we have, are also developing PDE10 inhibitors for the treatment of schizophrenia and these companies may be further along in development. The failure of a PDE10 inhibitor product candidate from any of our competitors to demonstrate safety or efficacy in clinical trials may negatively reflect on the ability of our PDE10 inhibitor product candidates under development to demonstrate safety and efficacy. Further, the failure of any future products developed from our product candidates to effectively compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition and results of operations.

## **Table of Contents**

We expect to compete with other biopharmaceutical and biotechnology companies, and our competitors may:

develop and market products that are less expensive or more effective than any future products developed from our product candidates;

commercialize competing products before we can launch any products developed from our product candidates;

operate larger research and development programs, possess commercial-scale manufacturing operations or have substantially greater financial resources than we do;

initiate or withstand substantial price competition more successfully than we can;

have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;

more effectively negotiate third-party licenses and strategic relationships; and

take advantage of acquisition or other opportunities more readily than we can.

We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to remain current with rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our product discovery process that we believe we derive from our research approach and proprietary technologies and programs. In addition, physicians may continue with their respective current treatment practices, including the use of current preoperative and postoperative treatments, rather than adopt our PharmacoSurgery product candidates.

**Our product candidates could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our product candidates, if and when any of them are approved.**

Any product candidate for which we obtain marketing approval, together with the manufacturing processes, post-approval clinical data, and advertising and promotional activities for such product candidate, will be subject to continued regulation by the FDA and other regulatory agencies. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product candidate. Later discovery of previously unknown problems with our product candidates or their manufacture, or failure to comply with regulatory requirements, may result in:

restrictions on such product candidates or manufacturing processes;

withdrawal of the product candidates from the market;

voluntary or mandatory recalls;

finer;

suspension of regulatory approvals;

product seizures; or

injunctions or the imposition of civil or criminal penalties.

**Table of Contents**

If we are slow to adapt, or unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we may lose marketing approval for our product candidates when and if any of them are approved.

**Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.**

We intend to have our product candidates marketed outside the United States. In order to market our products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may be unable to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The approval procedure varies among countries and can involve additional testing and data review. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these Risk Factors. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. The failure to obtain these approvals could harm our business.

**If we are unable to obtain adequate reimbursement from governments or third-party payors for any products that we may develop or if we are unable to obtain acceptable prices for those products, they may not be purchased or used and, as a result, our revenue and prospects for profitability could suffer.**

Our future revenue and profit will depend heavily upon the availability of adequate reimbursement for the use of our approved product candidates from governmental and other third-party payors, both in the United States and in other countries. Even if we are successful in bringing one or more product candidates to market, these products may not be considered cost-effective, and the amount reimbursed for any product candidates may be insufficient to allow us to sell our product candidates profitably. Reimbursement by a third-party payor may depend on a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each government or third-party payor is a time-consuming and costly process that will require the build-out of a sufficient staff and could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. Because none of our product candidates have been approved for marketing, we can provide you no assurances at this time regarding their cost-effectiveness and the amount, if any, or method of reimbursement. There may be significant delays in obtaining reimbursement coverage for newly approved product candidates and we may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payor determines that a product is eligible for reimbursement, coverage may be more limited than the purposes for which the product candidate is approved by the FDA or foreign regulatory agencies. Increasingly, third-party payors who reimburse healthcare costs, such as government and private payors, are



requiring that companies provide them with predetermined discounts from list prices, and are challenging the prices charged for medical products. Moreover, eligibility for coverage does not mean that any product candidate will be

## **Table of Contents**

reimbursed at a rate that allows us to make a profit in all cases, or at a rate that covers our costs, including research, development, manufacturing, sale and distribution. In non-U.S. jurisdictions, we must obtain separate reimbursement approvals and comply with related foreign legal and regulatory requirements. In some countries, including those in the European Union, our product candidates may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time after the receipt of marketing approval for a product candidate. If the reimbursement we are able to obtain for any product candidate we develop is inadequate in light of our development and other costs or is significantly delayed, our business could be materially harmed.

### **Product liability claims may damage our reputation and, if insurance proves inadequate, these claims may harm our business.**

We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product candidate's safety and efficacy and could limit our ability to sell one or more product candidates, if approved, by preventing or interfering with commercialization of our product candidates. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain and maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the commercialization of our product candidates progresses, or that future claims against us will be covered by our product liability insurance. Although we currently have product liability insurance coverage for our clinical trials, our insurance coverage may not reimburse us or may be insufficient to reimburse us for any or all expenses or losses we may suffer. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

## **Risks Related to the Offering**

### **An active, liquid and orderly trading market for our common stock may not develop.**

Prior to this offering, there has been no public market for shares of our common stock. We and the representative of the underwriters will determine the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, the trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

results from our clinical trial programs, including our ongoing Phase 3 clinical trials for OMS103HP for use in ACL reconstruction surgery, our Phase 2 clinical trial for OMS103HP for use in meniscectomy surgery, our ongoing Phase 2 clinical trial for OMS302, and our ongoing Phase 1/Phase 2 clinical trial for OMS201;

FDA or international regulatory actions, including failure to receive regulatory approval for any of our product candidates;

failure of any of our product candidates, if approved, to achieve commercial success;

quarterly variations in our results of operations or those of our competitors;

our ability to develop and market new and enhanced product candidates on a timely basis;

announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;

third-party coverage and reimbursement policies;

**Table of Contents**

additions or departures of key personnel;

commencement of, or our involvement in, litigation;

our ability to meet our repayment and other obligations under our debt facility with BlueCrest, pursuant to which we have borrowed \$17.0 million;

changes in governmental regulations or in the status of our regulatory approvals;

changes in earnings estimates or recommendations by securities analysts;

any major change in our board or management;

general economic conditions and slow or negative growth of our markets; and

political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the commercialization of our product and product candidates may be delayed.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

**Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.**

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock immediately after this offering. Therefore, if you purchase our common stock in this offering, you will incur an immediate dilution of \$8.20 in net tangible book value per share from the price you paid, based on an assumed initial public offering price of \$11.00 per share (the mid-point of the range set forth on the cover page of this prospectus). In addition, investors who purchase shares in this offering will contribute approximately 45% of the total amount of equity capital raised through the date of this offering, but will only own approximately 32% of the outstanding share capital and voting rights. The exercise of outstanding options and warrants will result in further dilution. For a further description of the dilution that you will experience immediately after this offering, see Dilution.

**Future sales of shares by existing shareholders could cause our stock price to decline.**

If our existing shareholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on shares outstanding as of June 30, 2009, upon completion of this offering, we will have outstanding a total of 21,287,580 shares of common stock, assuming no exercise of the underwriters over-allotment option. Of these shares, only the shares of common stock sold in

**Table of Contents**

this offering by us will be freely tradable, without restriction, in the public market. The representative of the underwriters may, in its sole discretion, release our officers, directors and other current shareholders from these contractual lock-up agreements prior to the expiration of these agreements.

We expect that the lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus, although some of those lock-up agreements may be extended for up to an additional 34 days under certain circumstances. After the lock-up agreements expire, up to an additional 14,467,580 shares of common stock will be eligible for sale in the public market, 2,667,722 of which shares of common stock are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act. In addition, 4,067,822 shares of common stock that are either subject to outstanding warrants or subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act, as applicable. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

**Anti-takeover provisions in our charter documents and under Washington law could make an acquisition of us, which may be beneficial to our shareholders, more difficult and prevent attempts by our shareholders to replace or remove our current management.**

Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of shareholders to fill board vacancies and the ability of our board of directors to issue preferred stock without shareholder approval. In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of shareholders owning ten percent or more of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

**We have broad discretion in the use of the net proceeds from this offering and may not use the net proceeds effectively.**

We will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

**Table of Contents**

**We have never declared or paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.**

Our business requires significant funding, and we have not generated any material revenue. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Therefore, we currently do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a rise in the market price of our common stock, which is uncertain and unpredictable, will be your sole source of potential gain in the foreseeable future, and you should not rely on an investment in our common stock for dividend income.

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus includes forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words believe, may, will, estimate, continue, anticipate, intend, expect and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Risk Factors. In light of these risks, uncertainties and assumptions, the forward-looking events and trends discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Forward-looking statements in the prospectus include statements about:

assuming that we receive positive results from our ongoing Phase 3 clinical trials of OMS103HP in patients undergoing ACL reconstruction surgery, our ability to submit a related NDA to the FDA during the second half of 2010;

our ability to review the data from our first Phase 2 trial of OMS103HP in patients undergoing arthroscopic meniscectomy surgery in the second half of 2009;

our ability to market OMS103HP by 2011;

our ability to complete the ongoing Phase 2 clinical trial, and initiate a second Phase 2 clinical trial, for OMS302 in patients undergoing cataract surgery in the second half of 2009;

our ability to complete the Phase 1/Phase 2 clinical trial of OMS201 in patients undergoing ureteroscopic removal or ureteral or renal stones in the first half of 2010;

our ability to achieve the expected near-term milestones in our pipeline of preclinical development programs, including the selection of a clinical product candidate for our MASP-2 program in the second half of 2009, submission of an IND to the FDA for our Addiction program in the second half of 2009, the selection of one or more clinical candidates for our PDE10 program in the second half of 2009 and the selection of a clinical candidate for our PDE7 program in the first half of 2010, and the size of target markets;

our expectations regarding the growth in the number of arthroscopic, cataract and uroendoscopic operations, the rates at which each of our PharmacoSurgery product candidates will be reimbursed to the surgical facility for its utilization and to the surgeon for its use, the size of the markets for our PharmacoSurgery product candidates, in particular, the market opportunity for OMS103HP, and the rate and degree of adoption and market penetration of our PharmacoSurgery product candidates;

our ability to obtain commercial supplies of our PharmacoSurgery product candidates, our competition and, if approved, our ability to successfully commercialize our PharmacoSurgery product candidates with a limited, hospital-based marketing and sales force;



our expectations regarding the clinical benefits of our PharmacoSurgery product candidates;

the extent of protection that our patents provide and our pending patent applications may provide, if patents issue from such applications, to our technologies and programs;

**Table of Contents**

our estimate regarding how long our existing cash, cash equivalents and short-term investments, along with the net proceeds from this offering, will be sufficient to fund our anticipated operating expenses and capital expenditures, the factors impacting our future capital expenditures and our expected number of full-time employees by the end of 2009;

our expectations regarding our ability to de-orphanize orphan GPCRs and the number of druggable targets among the orphan GPCRs;

our ability to meet our repayment and other obligations under our debt facility with BlueCrest, pursuant to which we have borrowed \$17.0 million; and

our estimates regarding the use of the net proceeds from this offering and our future net losses, revenues, expenses and net operating loss carryforwards and research and development tax credit carryforwards.

You should read this prospectus and the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. These forward-looking statements represent our estimates and assumptions only as of the date of this prospectus and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended.

**Table of Contents**

**USE OF PROCEEDS**

We estimate that we will receive net proceeds of approximately \$68.4 million from our sale of 6,820,000 shares of common stock in this offering, or approximately \$78.9 million if the underwriters exercise their over-allotment option in full, based upon an assumed initial public offering price of \$11.00 per share (the mid-point of the range set forth on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share would increase (decrease) the net proceeds to us from this offering by \$6.3 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We anticipate that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will allow us to complete our Phase 3 clinical trials and to submit the related NDA(s) for our lead PharmacoSurgery product candidate, OMS103HP. We currently expect to use the net proceeds from this offering as follows:

approximately \$5.5 million to fund the completion of our clinical trials and our submission of the related NDA(s) to the FDA for our lead PharmacoSurgery product candidate, OMS103HP;

approximately \$30.5 million to fund the launch and commercialization of OMS103HP;

approximately \$11.0 million to fund the clinical development of our other PharmacoSurgery product candidates, OMS302 and OMS201, through Phase 2 clinical trials; and

the remainder to continue to fund our pipeline of preclinical product development programs focused on inflammation and CNS disorders, and to fund working capital, capital expenditures, potential acquisitions of products or technologies and general corporate purposes.

We may use a portion of the net proceeds for the repayment of a \$17.0 million loan and related interest pursuant to the terms of a Loan and Security Agreement with BlueCrest Venture Finance Master Fund Limited, assignee of BlueCrest Capital Finance, L.P., dated as of September 12, 2008. We borrowed the \$17.0 million in three tranches, one \$5.0 million tranche in September 2008 and two \$6.0 million tranches in December 2008. The proceeds of this borrowing have been used for working capital and general corporate activities. Our obligations under the agreement are secured by a first priority security interest in our assets excluding intellectual property. We are required to pay only interest on amounts borrowed during the first three months, and thereafter the amount borrowed is amortized over 36 months with equal monthly principal and interest payments. The interest rate of the debt is 12.50%. We have the right to prepay the principal amount of the loan in whole, but not in part, upon 30 days advance written notice to BlueCrest. If we prepay the loan, we will be required to pay BlueCrest a prepayment premium equal to two percent of the principal amount of any part of the loan that has been outstanding for 18 months or less and one percent for any amount that has been outstanding for more than 18 months. In connection with this financing arrangement, we are obligated to pay a one-time fee to BlueCrest in the amount of \$340,000 upon closing of this offering.

We may also use a portion of the net proceeds from this offering to purchase assets for our GPCR program pursuant to the terms of an Exclusive Technology Option Agreement with Patobios Limited. Under this agreement, we have the right to purchase Patobios' assets related to a GPCR assay technology, comprised of patents and other intellectual property rights, for approximately \$10.8 million Canadian dollars, or CAD, of which \$7.8 million CAD is payable in cash and \$3.0 million CAD is payable in our common stock, subject to adjustment as described below. Upon signing

the agreement, we paid Patobios a \$200,000 CAD cash option fee

**Table of Contents**

(\$188,000 USD) for the right to test and exclusive option to purchase the assets during the nine-month period ending June 4, 2009. On June 12, 2009 we paid Patobios an additional \$522,000 CAD cash option fee (\$471,000 USD) to extend the option period until December 4, 2009. We have the option to extend this period for one additional six-month period ending June 4, 2010 by paying Patobios a cash option fee of \$650,000 CAD. If during any option period we purchase these assets, the cash portion of the purchase price will be reduced by a portion of the related option fee we paid for such period based on the number of days remaining in the period. In addition, if during an option period we identify a set of molecules, or ligands, that binds to an orphan GPCR using the assay technology, Patobios will have the option to require us to purchase these assets for the same price we would be required to pay if we elected to purchase them. While we are currently evaluating the utility of these assets for our GPCR program, we are not required to and are not currently attempting to identify any ligands that bind to an orphan GPCR using the assay technology.

The expected uses of the net proceeds from this offering represents our current intentions based on our present plans and business conditions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received from this offering. The amounts and timing of our actual expenditures will depend on numerous factors including the progress in, and costs of, our clinical trials and other preclinical development programs. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgement of management regarding the application of the net proceeds from the offering. We may find it necessary or advisable to use the net proceeds for other purposes. Pending such uses set forth above, we plan to invest the net proceeds in highly liquid, investment grade securities.

**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock, we do not currently intend to pay any cash dividends on our common stock in the foreseeable future and under our Loan and Security Agreement with BlueCrest Venture Finance Master Fund Limited we have agreed not to pay any dividends so long as we have any outstanding obligations under the agreement. We expect to retain all available funds and future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends, if any, on our common stock will be at the discretion of our board of directors and will depend on, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

**Table of Contents****CAPITALIZATION**

The following table sets forth our cash, cash equivalents and short-term investments and our capitalization as of June 30, 2009, as follows:

on an actual basis;

on a pro forma basis reflecting (a) the automatic conversion of all outstanding shares of our convertible preferred stock into 11,514,506 shares of our common stock upon the closing of this offering and (b) the automatic conversion of all outstanding warrants to purchase convertible preferred stock into warrants to purchase 208,983 shares of our common stock upon the closing of this offering, resulting in the reclassification of \$1.8 million from preferred stock warrant liability to additional paid-in capital;

on a pro forma as adjusted basis to give effect to the issuance and sale by us of 6,820,000 shares of common stock in this offering and the receipt of the net proceeds from our sale of these shares at an assumed initial public offering price of \$11.00 per share (the mid-point of the range set forth on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the sections of this prospectus entitled "Selected Consolidated Financial Data and Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	<b>As of June 30, 2009</b>		
	<b>Actual</b>	<b>Pro Forma</b>	<b>Pro Forma As Adjusted</b>
	<b>(in thousands, except share and per share data)</b>		
Cash, cash equivalents and short-term investments	\$ 10,363	\$ 10,363	\$ 79,353
Total notes payable	\$ 15,192	\$ 15,192	\$ 15,192
Preferred stock warrant liability	1,820		
Convertible preferred stock; Issued and outstanding shares 11,514,506 (0 pro forma and pro forma as adjusted)	91,019		
Shareholders' equity (deficit):			
Preferred stock, par value \$0.01 per share; Authorized shares 13,425,919 (20,000,000 pro forma and pro forma as adjusted; issued and outstanding shares 0 pro forma and pro forma as adjusted)			
Common stock, par value \$0.01 per share; Authorized shares 20,410,000 (150,000,000 pro forma and pro forma as adjusted); issued and outstanding shares 2,953,074 (14,467,580 pro forma and 21,287,580 pro forma as adjusted)	30	145	213
Additional paid-in capital	7,104	99,828	168,193
Accumulated other comprehensive income	56	56	56

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Deficit accumulated during the development stage	(108,838)	(108,838)	(108,838)
Total shareholders' equity (deficit)	(101,648)	(8,809)	59,624
Total capitalization	\$ 6,383	\$ 6,383	\$ 74,816

A \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share would increase (decrease) each of cash, cash equivalents and short-term investments, additional paid-in capital, total shareholders' equity (deficit) and total capitalization by \$6.3 million, assuming that the number of shares offered by us, as set forth on the cover page

**Table of Contents**

of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The outstanding share information set forth in the table above excludes the following shares:

2,819,594 shares of common stock issuable upon the exercise of options outstanding at June 30, 2009 at a weighted-average exercise price of \$1.82 per share;

209,017 shares of common stock issuable upon exercise of warrants outstanding at June 30, 2009 at a weighted-average exercise price of \$12.08 per share; and

1,039,211 shares of common stock available for future issuance under our 2008 Equity Incentive Plan.



Table of Contents**DILUTION**

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

Our historical net tangible book value as of June 30, 2009 was \$(101.7) million, or \$(34.42) per share of common stock. Our pro forma net tangible book value as of June 30, 2009 was \$(8.8) million, or \$(0.61) per share of common stock. Our pro forma net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of June 30, 2009, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into common stock upon the closing of this offering and to the automatic conversion of all outstanding warrants to purchase convertible preferred stock into warrants to purchase common stock upon the closing of this offering.

After giving effect to our issuance and sale in this offering of 6,820,000 shares of common stock at an assumed initial public offering price of \$11.00 per share (the midpoint of the range set forth on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma net tangible book value as of June 30, 2009 would have been approximately \$59.6 million, or \$2.80 per share of common stock. This represents an immediate increase in pro forma net tangible book value of \$3.41 per share to our existing shareholders and an immediate dilution of \$8.20 per share to investors purchasing shares in this offering. The following table illustrates this per share dilution:

Assumed initial public offering price per share		\$ 11.00
Historical net tangible book value per common share at June 30, 2009	\$ (34.42)	
Pro forma increase in net tangible book value per common share attributable to conversion of all outstanding convertible preferred stock into common stock and the reclassification of the preferred stock warrant liability to additional paid-in capital	33.81	
Pro forma net tangible book value per share as of June 30, 2009	(0.61)	
Pro forma increase in net tangible book value per share attributable to investors participating in this offering	3.41	
Pro forma net tangible book value per share after this offering		2.80
Dilution in pro forma net tangible book value per share to investors purchasing shares in this offering		\$ 8.20

A \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share would increase (decrease) our pro forma net tangible book value per share after this offering by \$6.3 million and the dilution in pro forma net tangible book value per share to investors purchasing shares in this offering by \$0.30, 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 and estimated offering expenses payable by us.

If the underwriters exercise their over-allotment option in full, at an assumed initial public offering price of \$11.00 per share, the pro forma net tangible book value per share after this offering would be approximately \$3.14 per share, and the dilution in pro forma net tangible book value per share to investors purchasing shares in this offering would be

approximately \$7.86 per share.

**Table of Contents**

The following table sets forth on an as adjusted basis, as of June 30, 2009, the number of shares of common stock purchased or to be purchased from us, the total consideration paid or to be paid and the average price per share paid or to be paid by existing holders of common stock and by the new investors purchasing shares in this offering, before deducting estimated underwriting discounts and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing shareholders	14,467,580	68%	\$ 92,051,000	55%	\$ 6.36
New investors	6,820,000	32	75,020,000	45	11.00
Total	21,287,580	100%	\$ 167,071,000	100%	\$ 7.85

A \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share would increase (decrease) total consideration paid by new investors by \$6.3 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 and estimated offering expenses payable by us.

If the underwriters exercise their over-allotment option in full, our existing shareholders would own 65% and our new investors would own 35% of the total number of shares of our common stock outstanding after this offering.

The discussion and tables above are based on the number of shares of common stock outstanding at June 30, 2009. The discussion and tables above exclude the following shares:

2,819,594 shares of common stock issuable upon the exercise of options outstanding at June 30, 2009 at a weighted-average exercise price of \$1.82 per share;

209,017 shares of common stock issuable upon exercise of warrants outstanding at June 30, 2009 at a weighted-average exercise price of \$12.08 per share; and

1,039,211 shares of common stock available for future issuance under our 2008 Equity Incentive Plan.

To the extent outstanding options or warrants are exercised, new investors will experience further dilution.

**Table of Contents****SELECTED CONSOLIDATED FINANCIAL DATA**

The following selected consolidated financial data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the accompanying notes included elsewhere in this prospectus. The consolidated statements of operations data for the years ended December 31, 2008, 2007 and 2006 and for the period from June 16, 1994 (inception) to December 31, 2008, and the consolidated balance sheet data as of December 31, 2008 and 2007 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations data for the years ended December 31, 2005 and 2004, and the consolidated balance sheet data as of December 31, 2006, 2005 and 2004 are derived from our consolidated financial statements not included in this prospectus. The consolidated statements of operations data for the six months ended June 30, 2009 and 2008 and for the period from June 16, 1994 (inception) to June 30, 2009, and the consolidated balance sheet data as of June 30, 2009 are derived from our unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements included in this prospectus and include, in the opinion of management, all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results to be expected in any future period, and the results for the six months ended June 30, 2009 are not necessarily indicative of the results to be expected for the full year ending December 31, 2009. We acquired nura on August 11, 2006, and the results of nura are included in the consolidated financial statements from that date. The pro forma basic and diluted net loss per common share data are computed using the weighted-average number of shares of common stock outstanding, after giving effect to the conversion (using the as if-converted method) of all shares of our convertible preferred stock into common stock.

Six Months		Period from June 16, 1994 (inception) to June 30, 2009		Years Ended December 31,			
2009	2008	2009	2008	2007	2006	2005	2004
(in thousands, except share and per share data)							
\$ 568	\$ 488	\$ 3,961	\$ 1,170	\$ 1,923	\$ 200	\$	\$
8,599	8,018	70,833	17,850	15,922	9,637	5,803	2,670
		10,891			10,891		
2,885	2,899	35,368	7,845	10,398	3,625	1,904	2,079
11,484	10,917	117,092	25,695	26,320	24,153	7,707	4,749

ations	(10,916)	(10,429)	(113,131)	(24,525)	(24,397)	(23,953)	(7,707)	(4,749)
me	142	460	5,305	661	1,582	1,088	333	171
e	(1,165)	(38)	(1,794)	(335)	(151)	(91)		
	348	(57)	782	372	(125)	179	8	
\$	(11,591)	\$ (10,064)	\$ (108,838)	\$ (23,827)	\$ (23,091)	\$ (22,777)	\$ (7,366)	\$ (4,578)
ed net								
n	\$ (3.96)	\$ (3.53)		\$ (8.26)	\$ (10.65)	\$ (12.08)	\$ (4.16)	\$ (2.63)
ge								
nd								
per	2,929,397	2,852,616		2,883,522	2,167,500	1,884,925	1,769,830	1,742,958
and								
per	\$ (0.80)			\$ (1.65)				
ge								
s								
e								
and								
per	14,411,430			14,275,579				

**Table of Contents**

	<b>As of June 30, 2009</b>	<b>2008</b>	<b>As of December 31,</b>				<b>2004</b>
			<b>2007</b>	<b>2006</b>	<b>2005</b>		
			<b>(in thousands)</b>				
<b>Consolidated Balance Sheet</b>							
<b>Data:</b>							
Cash, cash equivalents and short-term investments	\$ 10,363	\$ 19,982	\$ 24,082	\$ 35,885	\$ 12,372	\$ 14,008	
Working capital (deficit)	(12,101)	(3,083)	16,526	32,277	10,672	13,664	
Total assets	12,682	21,681	27,162	38,432	13,109	14,600	
Total notes payable	15,192	16,674	1,010	2,015			
Preferred stock warrant liability	1,820	1,780	1,562	1,037	483		
Convertible preferred stock	91,019	89,168	89,168	85,742	40,888	35,203	
Deficit accumulated in the development stage	(108,838)	(97,247)	(73,420)	(50,329)	(27,553)	(20,187)	
Total shareholders deficit	(101,648)	(91,166)	(69,941)	(53,363)	(29,743)	(21,114)	
		42					

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**Table of Contents**

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

*The following discussion and analysis should be read in conjunction with our audited annual and unaudited interim consolidated financial statements and the related notes that appear elsewhere in this prospectus. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this prospectus.*

**Overview**

*Background*

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products focused on inflammation and disorders of the central nervous system. Our most clinically advanced product candidates are derived from our proprietary PharmacoSurgery™ platform designed to improve clinical outcomes of patients undergoing arthroscopic, ophthalmological, urological and other surgical and medical procedures. Our PharmacoSurgery platform is based on low-dose combinations of therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to preemptively inhibit inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. We currently have four ongoing PharmacoSurgery clinical development programs, the most advanced of which is in Phase 3 clinical trials. In addition to our PharmacoSurgery platform, we have leveraged our expertise in inflammation and the central nervous system, or CNS, to build a deep and diverse pipeline of preclinical programs targeting large markets. For each of our product candidates and programs, we have retained all manufacturing, marketing and distribution rights.

OMS103HP, our lead PharmacoSurgery product candidate, is in two clinical programs. The first is a Phase 3 clinical program, expected to include a total of approximately 1,040 patients, evaluating OMS103HP's safety and ability to improve postoperative joint function and reduce pain following arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery. The second program is evaluating OMS103HP's safety and ability to reduce pain and improve postoperative joint function following arthroscopic meniscectomy surgery. Assuming that we receive positive results from our ongoing Phase 3 clinical program for ACL reconstruction surgery, we intend to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, under the Section 505(b)(2) NDA process during the second half of 2010. We believe that OMS103HP will, if approved, be the first commercially available drug product for the improvement of function following arthroscopic surgery. In the second half of 2009, we expect to review the data from our first Phase 2 clinical trial in patients undergoing meniscectomy surgery.

Our other current PharmacoSurgery product candidates are OMS302, being developed for use during ophthalmological procedures, including cataract and other lens replacement surgery, and OMS201, being developed for use during urological surgery, including uroendoscopic procedures. We recently completed a Phase 1/Phase 2 clinical trial that evaluated the efficacy and safety of OMS302 added to standard irrigation solution and delivered to patients undergoing cataract surgery, and we are currently conducting a Phase 2 concentration-ranging clinical trial of the mydriatic API contained in OMS302 as a mydriasis induction agent in patients undergoing cataract surgery and a Phase 1/Phase 2 clinical trial of OMS201 in patients undergoing ureteroscopic removal of ureteral or renal stones. We own and exclusively control a U.S. and international portfolio of issued patents and pending patent applications that we believe protects our PharmacoSurgery platform.





**Table of Contents**

In addition to our PharmacoSurgery platform, we have a deep and diverse pipeline of preclinical product development programs targeting large market opportunities in inflammation and the CNS covered by a broad intellectual property portfolio. In our mannan-binding lectin-associated serine protease-2, or MASP-2, program, we are developing proprietary MASP-2 antibody therapies to treat disorders caused by complement-activated inflammation. Our CNS pipeline includes our Addiction program, our Phosphodiesterase 10, or PDE10, program, our PDE7 program and our G protein-coupled receptors, or GPCR, program. In our Addiction program, we are developing proprietary compositions that include peroxisome proliferator-activated receptor gamma agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine, alcohol and amphetamines, as well as other compulsive behaviors. In our PDE10 program, we are developing proprietary compounds to treat schizophrenia. Our PDE7 program is based on our demonstration of a previously unknown link between PDE7 and any movement disorder, such as Parkinson's disease and Restless Legs Syndrome, and we are developing proprietary compounds for the treatment of these and other movement disorders. In our GPCR program, we believe that we have the capability to complete high-throughput de-orphanization of orphan GPCRs, or the identification of synthetic molecules that bind the receptors, and to develop product candidates that act at these new potential drug targets.

We have incurred significant losses since our inception. As of June 30, 2009, our accumulated deficit was \$108.8 million and total shareholders' deficit was \$101.6 million. We recognized net losses of \$11.6 million, \$23.8 million, \$23.1 million and \$22.8 million for the six months ended June 30, 2009 and the years ended December 31, 2008, 2007 and 2006, respectively. These losses have resulted principally from expenses incurred in connection with research and development activities, consisting primarily of preclinical studies, manufacturing services, and clinical trials associated with our current product candidates. We expect our net losses to increase as we continue to advance our clinical trials, expand our research and development efforts, and add personnel as well as laboratory and office space for our anticipated growth. We plan to increase the total number of our full-time employees from 62 as of August 31, 2009 to approximately 75 to 85 by the end of 2009.

*Revenue*

We have recognized \$4.0 million of revenue from inception through June 30, 2009, consisting of grant funding from third parties. Other than grant funding, we do not expect to receive any revenue from our product candidates until we receive regulatory approval and commercialize the products or until we potentially enter into collaborative agreements with third parties for the development and commercialization of our product candidates. We continue to pursue government and private grant funding for our product candidates and research programs. If our development efforts for any of our product candidates result in clinical success and regulatory approval or collaboration agreements with third parties, we could generate revenue from those product candidates.

*Research and Development Expenses*

The majority of our operating expenses to date have been for research and development activities. Research and development expenses consist of costs associated with research activities, as well as costs associated with our product development efforts, which include clinical trials and third party manufacturing services. Internal research and development costs are recognized as incurred. Third-party research and development costs are expensed at the

**Table of Contents**

earlier of when the contracted work has been performed or as upfront and milestone payments are made. Research and development expenses include:

employee and consultant-related expenses, which include salaries and benefits;

external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, contract research organizations and clinical trial sites;

facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and depreciation of leasehold improvements and equipment; and

third-party supplier expenses including laboratory and other supplies.

At any time, we have many ongoing research and development projects.

The following table identifies our current major research and development projects:

<b>Project</b>	<b>Development Status</b>	<b>Expected Near-Term Milestone (1)</b>
OMS103HP Arthroscopic ACL reconstruction	Phase 3	Complete Phase 3 trials; submit NDA in second half of 2010
OMS103HP Arthroscopic meniscectomy	Phase 2	Review data from Phase 2 trial in second half of 2009
OMS302 Cataract surgery	Phase 2	Complete first/initiate second Phase 2 trial in second half of 2009
OMS201 Ureteroscopy	Phase 1/ Phase 2	Complete Phase 1/ Phase 2 trial in first half of 2010
MASP-2 Macular degeneration, ischemia-reperfusion injury, transplant surgery	Preclinical	Select clinical candidate in second half of 2009
Addiction Addiction and other compulsive behaviors	Preclinical	File IND in second half of 2009
PDE10 Schizophrenia	Preclinical	Select clinical candidate in second half of 2009
PDE7 Parkinson's disease, Restless Legs Syndrome	Preclinical	Select clinical candidate in first half of 2010
GPCR Multiple CNS Disorders	Preclinical	Surrogate de-orphanization of orphan GPCR(s)

- (1) Following selection of a clinical candidate, we must conduct additional studies, including in vivo toxicity studies of the clinical candidate. We must submit the results of these studies, together with manufacturing information and analytical results related to the clinical candidate, to the FDA as part of an IND, which must become effective before we may commence clinical trials. Submission of an IND does not always result in the FDA allowing clinical trials to commence. Depending on the nature of information that we must obtain and include in an IND, it may take from 12 to 24 months from selection of the clinical candidate to IND submission, if it occurs at all. All of these expected near-term milestones are subject to a number of risks, uncertainties and assumptions, including those described in Risk Factors, and may not occur in the timelines set forth above or at all.

Our internal resources, employees and infrastructure are not directly tied to any individual research project and are typically deployed across multiple projects. Through our clinical development programs, we are advancing our product candidates in parallel for multiple therapeutic indications and, through our preclinical development programs, we are seeking to develop potential product candidates for additional disease indications. Due to the number of ongoing projects and our ability to utilize resources across several projects, we do not record or maintain information regarding the costs incurred for our research and development programs on a program-specific basis. In addition, we believe that allocating costs on the basis of time incurred by our employees does not reflect the actual costs of a project.

**Table of Contents**

Research and development expenses since inception to June 30, 2009 were \$70.8 million. Our research and development expenses can be divided into clinical research and development and preclinical research and development activities. The following table illustrates our expenses associated with these activities:

	<b>Six Months Ended</b>		<b>Years Ended December 31,</b>		
	<b>June 30,</b>		<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>2009</b>	<b>2008</b>	<b>(In thousands)</b>		
<b>Clinical Research and Development</b>					
Salaries, benefits, and related costs	\$ 1,911	\$ 1,796	\$ 3,521	\$ 2,944	\$ 1,849
Clinical trials	1,162	1,584	3,525	3,630	2,116
Manufacturing services, consulting, laboratory supplies, and other costs	712	920	2,080	1,943	825
Other costs	576	486	1,049	633	152
Stock-based compensation	259	301	590	280	181
<b>Total Clinical Research and Development Expenses</b>	<b>4,620</b>	<b>5,087</b>	<b>10,765</b>	<b>9,430</b>	<b>5,123</b>
<b>Preclinical Research and Development</b>					
Salaries, benefits, and related costs	1,331	1,236	2,572	2,315	1,848
Research and preclinical studies, consulting, laboratory supplies, and other costs	1,711	868	2,774	2,566	1,604
Other costs	759	643	1,346	1,412	934
Stock-based compensation	178	184	393	199	128
<b>Total Preclinical Research and Development Expenses</b>	<b>3,979</b>	<b>2,931</b>	<b>7,085</b>	<b>6,492</b>	<b>4,514</b>
<b>Total Research and Development Expenses</b>	<b>\$ 8,599</b>	<b>\$ 8,018</b>	<b>\$ 17,850</b>	<b>\$ 15,922</b>	<b>\$ 9,637</b>
<b>Total Acquired In-process Research and Development Expense</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$ 10,891</b>

Clinical research and development costs consist of clinical trials, manufacturing services, regulatory activities and related personnel costs, and other costs such as rent, utilities, depreciation and stock-based compensation. Preclinical research and development costs consist of our research activities, preclinical studies, related personnel costs and laboratory supplies, and other costs such as rent, utilities, depreciation and stock-based compensation. Acquired in-process research and development was recorded in 2006 as an operating expense as a result of our acquisition of the PDE10 program, which we obtained in connection with our purchase of nura, and was determined using the income approach to estimate the present value of future cash flows from the program.

At this time, due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

While we are currently focused on advancing each of our product development programs, our future research and development expenses will depend on the clinical success of each product candidate, as well as ongoing assessments of each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

We expect our research and development expenses to increase in the future as we continue the advancement of our clinical trials and preclinical product development programs. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in

## **Table of Contents**

generating product revenue and cause our research and development expense to increase and, in turn, have a material adverse effect on our operations. We do not expect any of our current product candidates to be commercially available before 2011, if at all. Because of the factors above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

### *General and Administrative Expenses*

General and administrative expenses consist principally of salaries and related costs for personnel in executive, legal, finance, accounting, information technology and human resource functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent costs and professional fees for legal, consulting and audit services.

### *Investment Income*

Investment income consists of interest earned on our cash, cash equivalents, and short-term investments.

### *Interest Expense*

Interest expense consists of interest paid on our notes payable.

### *Other Income (Expense)*

Other income (expense) consists primarily of rental income received under subleases for use of a portion of our vivarium and laboratory facility and changes in the fair value of our preferred stock warrant liability.

### *Income Taxes*

As of December 31, 2008, we had federal net operating loss carryforwards and research and development tax credit carryforwards of approximately \$72.5 million and \$2.3 million, respectively. Our net operating loss and research and development tax credit carryforwards will expire between 2009 and 2027 unless utilized prior to such dates. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event a change in ownership, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, has occurred or may occur in the future. In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statement of operations.

## **Critical Accounting Policies and Significant Judgments and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of any contingent assets and liabilities at the date of the financial statements, as well as reported revenue and expenses during the reporting periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. An accounting policy is considered critical if it is important to a company's financial condition and results of operations, and if it requires the exercise of significant judgment and the use of estimates on the part of management in its application. Although we believe that our judgments and estimates are appropriate, actual results may differ from our estimates.



**Table of Contents**

We believe the following to be our critical accounting policies because they are both important to the portrayal of our financial condition and results of operations and they require critical management judgment and estimates about matters that are uncertain:

revenue recognition;

research and development expenses, primarily clinical trial expenses;

stock-based compensation;

preferred stock warrant liability; and

fair value measurement of financial instruments.

If actual results or events differ materially from those contemplated by us in making these estimates, our reported financial condition and results of operations for future periods could be materially affected.

*Revenue Recognition*