OSIRIS THERAPEUTICS, INC.
Form 10-K
March 26, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934:

For the fiscal year ended December 31, 2006

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934:

For the transition period from to

Commission file number 001-32966

Osiris Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**71-0881115**
(State or other jurisdiction of Incorporation or organization)	(I.R.S. employer identification no.)
2001 Aliceanna Street, Baltimore, Maryland 21231-3043	**410-522-5005**
(Address of principal executive offices, including zip code)	(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on with Registered**
Common Stock, $0.001 par value	**NASDAQ Global Market**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in *Rule 405* of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to *Item 405* of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

On June 30, 2006, the last business day of the registrant s most recently completed second fiscal quarter, the registrant s common equity was not publicly traded. Our Common Stock began trading on the NASDAQ Global Market on August 4, 2006. The aggregate market value of voting Common Stock held by non-affiliates of registrant, based upon the last sale price of the Common Stock reported on the NASDAQ Global Market as of the last business day of the registrant s most recently completed third fiscal quarter ended September 30, 2006 was approximately $156,124,000.

The number of shares of registrant s Common Stock outstanding as of March 9, 2007 is 27,429,341.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our definitive Proxy Statement for our 2007 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2006 fiscal year are incorporated by reference into Part III of this Annual Report on Form 10-K.

OSIRIS THERAPEUTICS, INC.

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PART I

Item 1. BUSINESS

Forward-Looking Information

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Forward-looking statements include statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, compensation arrangements, financing needs, plans or intentions relating to acquisitions, business trends and other information that is not historical information and, in particular, may appear under the headings Risk Factors in this Part I Item 1A, Part II Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and the other documents we file with the Securities and Exchange Commission, or SEC, including, among others, our quarterly reports on Form 10-Q and amendments thereto. When used in this Annual Report, the words *estimates, expects, anticipates, projects, plans, intends, believes, forecasts* and variations of such words or similar expressions are intended to identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements regarding the following: our product development efforts; our clinical trials and anticipated regulatory requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for MSCs and biologic drug candidates; our cash needs; patents and proprietary rights; ability of our potential products to treat disease; our plans for sales and marketing; our plans regarding facilities; types of regulatory frameworks we expect will be applicable to our potential products; and results of our scientific research. All forward-looking statements, including, without limitation, management s examination of historical operating trends, are based upon our current expectations and various assumptions. Our expectations, beliefs and projections are expressed in good faith and we believe there is a reasonable basis for them. However, there can be no assurance that management s expectations, beliefs and projections will result or be achieved.

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

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

When we use the terms Osiris, we, us, and our we mean Osiris Therapeutics, Inc., a Delaware corporation.

Company Overview

We are a leading stem cell therapeutic company headquartered in Baltimore, Maryland and focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. We were incorporated in Delaware in April 2002. Our predecessor company was organized in 1992. We currently market and sell Osteocel for regenerating bone in orthopedic indications. It is the only commercially available product in the U.S. containing viable stem cells. Our lead biologic drug candidate, Prochymal, for the treatment of inflammatory disease, is the only stem cell therapeutic for which patients are being enrolled in Phase III clinical trials and is the only stem cell therapeutic currently designated by the FDA as both an Orphan Drug and Fast Track product candidate. Our pipeline of internally developed biologic drug candidates also includes Chondrogen, for regenerating cartilage in the

knee, and Provacel, for repairing heart tissue following a heart attack. We are a fully integrated company, having developed stem cell capabilities in research and development, manufacturing, marketing and distribution. We have developed an extensive intellectual property portfolio to protect our technology in the United States and a number of foreign countries including 47 U.S. and 167 foreign patents owned or licensed.

Osteocel and our three biologic drug candidates utilize human mesenchymal stem cells, or MSCs. MSCs are progenitor cells that differentiate into various connective tissues when they receive appropriate biochemical and biomechanical signals. In addition, MSCs have anti-inflammatory properties and can prevent fibrosis or scarring. These characteristics give MSCs the potential to treat a wide variety of medical conditions. We believe that our biologic drug candidates have advantages over other stem cell therapeutics in development for the following reasons:

- **Stem Cell Source.** Our stem cells are obtained from adult bone marrow, a readily available source. The cells are drawn from the hips of volunteer donors between the ages of 18 and 30 years, using a simple needle and syringe aspiration. Because the cells are obtained from consenting adult donors, we are able to largely avoid the ethical controversy surrounding embryonic and fetal stem cell research.

- **Ability to Mass Produce.** Through our proprietary manufacturing methods, we can grow MSCs in a controlled fashion to produce up to 5,000 treatments of our biologic drug candidates from a single bone marrow donation. Our ability to produce a large quantity of treatments from one donation provides us with manufacturing efficiencies and product consistency that are essential to commercialization.

- **Universal Compatibility.** Many stem cell therapies under development can elicit a rejection response in the recipient and therefore require donor-to-recipient matching or potentially harmful immunosuppression. This greatly reduces manufacturing efficiencies and creates a risk of mismatch which can result in an acute inflammatory response and, potentially, in death. Based on our clinical experience, we believe that our biologic drug candidates are not rejected by the patient s immune system and so, like type O negative blood, do not require matching. This universal compatibility allows us to produce a standardized product available to all patients in almost any medical setting.

- **Treatment on Demand.** Our biologic drug candidates can be stored frozen at end-user medical facilities until they are needed. We anticipate that medical facilities will be able to prescribe and dispense this product in much the same way as conventional drugs. In contrast, other stem cell technologies under development require weeks to prepare after a patient s need is identified. This is a key feature of our technology, as many patients in the critical care setting require prompt treatment.

The following table summarizes key information about Osteocel and our biologic drug candidates.

Product/Candidate	**Indication**	**U.S. Commercialization Rights**	**Status**
Osteocel	Spinal Procedures	Osiris and Blackstone	Marketing
	Orthopedics	Osiris, AlloSource and Blackstone	Marketing
Prochymal	Steroid Refractory GvHD	Osiris	Phase III
	Acute GvHD	Osiris	Phase II
	Crohn s Disease	Osiris	Phase III
Chondrogen	Meniscus Regeneration	Osiris	Phase I/II
	Cartilage Protection		
Provacel	Heart Attack	Boston Scientific	Phase I

Osteocel consists of a matrix of cancellous bone containing mesenchymal stem cells and is used in spinal fusion and other orthopedic surgical procedures. Cancellous bone is the porous and spongy inner structure accounting for approximately 20% of total bone mass. Osteocel is the only commercially available product containing viable stem cells in the United States. We launched Osteocel in July 2005 and to date it has been used in over 5,000 surgical procedures. We produce Osteocel from the marrow-rich bone of organ and tissue donors, and we believe that it is properly characterized, and regulated by the FDA, as a human cell, tissue, and cellular and tissue-based product, or HCT/P, under section 361 of the Public Health Service Act. Unlike our biologic drug candidates, our ability to supply Osteocel is limited by the amount of marrow-rich bone that we are able to obtain from organ and tissue donors. Osteocel is currently distributed non-exclusively by us and by Blackstone Medical (recently acquired by Orthofix) for orthopedic indications, and jointly by us and Blackstone Medical for spinal procedures. In December 2006, we entered into a multi-year agreement with AlloSource, Inc., a non-profit tissue procurement organization for the supply by AlloSource to us of tissue for use in the manufacture of Osteocel. Under the terms of the agreement, AlloSource commits to provide bone matrix to us for use in the production of Osteocel, and to ensure that the technology is made available to the communities from which it is sourced, the agreement enables AlloSource also to act as a non-exclusive distributor of Osteocel in AlloSource s local donor communities.

Prochymal is our biologic drug candidate for the treatment of inflammatory disease. We are currently enrolling patients in a pivotal Phase III trial for the treatment of steroid refractory Graft versus Host Disease, or GvHD. GvHD is a life threatening immune system reaction that commonly affects the skin, gastrointestinal tract, and liver in patients who have received a bone marrow transplant. Although in the U.S. there are no drugs approved for treating GvHD, the disease is commonly treated off-label with steroids. GvHD that does not respond to this treatment is known as steroid refractory GvHD. A large majority of steroid refractory GvHD patients die within six months. In our Phase II trial for treatment refractory GvHD, we enrolled patients that did not respond to treatment with steroids and at least one other therapy. Of these patients, 59% responded to Prochymal. We have also completed a Phase II trial evaluating Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD. The study found that patients were twice as likely to have total clinical resolution of their disease when Prochymal was added to steroid therapy, compared to reported results for steroid only treatment. Twenty-nine of 31 patients, or 94% responded after receiving two infusions of Prochymal, with 23 patients, or 74% achieving a complete response, meaning the patients had experienced total clinical resolution of the disease. Six patients, or 19% had a partial response and 2 patients, or 6% did not respond. Furthermore, patients experiencing this complete response had a survival rate of 91% at Day 120.

Our Phase III trial to evaluate Prochymal as a treatment for steroid refractory GvHD is a randomized, double blind, placebo controlled study designed to enroll up to 240 patients. The trial will investigate patient response to 2.0 million cells per kilogram of body weight administered twice per week for four consecutive weeks. The primary trial endpoint is complete resolution of GvHD for at least a 28 day duration. Each patient will also be monitored for safety for up to 180 days after their first treatment with Prochymal. Six-month survival is a key secondary endpoint

Based on our clinical observations of the effects of Prochymal on the gastrointestinal symptoms of patients with GvHD, we are developing Prochymal for the treatment of Crohn s Disease. Crohn s Disease is a chronic condition that results in inflammation of the gastrointestinal tract. We have completed Crohn s disease patient enrollment in a Phase II trial under a separate Investigational New Drug application, and have clearance by the FDA to conduct a Phase III trial in biologic drug refractory Crohn s patients. We received Fast Track designation from the FDA, for the development of Prochymal for moderate to severe Crohn s Disease patients that are treatment refractory to standard therapies, including biologics.

Chondrogen is our biologic drug candidate for regeneration of meniscus, a type of cartilage that cushions the knee joint. According to a 2005 article in the *American Journal of Sports Medicine*,

approximately 1.0 million people have surgery to remove damaged or torn meniscus in the United States each year. As noted in a 1999 article in the journal *Sports Medicine*, patients who have had this procedure are ten to 15 times more likely to develop osteoarthritis, a highly debilitating orthopedic condition. There are currently no FDA approved products available to regenerate meniscal tissue. In several preclinical studies, Chondrogen regenerated meniscal tissue and prevented osteoarthritis in animal models. We recently completed enrollment in a Phase I/II clinical trial for Chondrogen to evaluate its safety and efficacy in patients following surgery to remove torn meniscus. A total of 55 patients were treated in the Phase I/II, double-blind study evaluating the safety and exploratory effectiveness of Chondrogen, a preparation of adult stem cells formulated for direct injection into the knee. At the six month time point, Chondrogen met its primary endpoint, demonstrating product safety. The trial did not demonstrate that Chondrogen resulted in a statistically significant increase in the volume of meniscus as compared to placebo; however, an improvement in baseline cartilage and joint condition was noted in patients treated with the stem cell drug that was not seen in patients that received placebo.

Provacel is our biologic drug candidate for the repair of heart muscle in patients who have suffered a heart attack. Based on statistics published in 2005 by the American Stroke Association and the American Heart Association, approximately 700,000 individuals in the United States each year experience their first heart attack. According to these same statistics, approximately 20% of these patients suffer extensive damage to their heart muscle leading to heart failure within six years. In preclinical studies in animal models, Provacel targeted the damaged area of the heart following a single treatment. These studies also indicate that Provacel prevents scar formation that typically occurs after a heart attack and improves cardiac function eight to ten weeks after its administration.

We recently completed enrollment in a Phase I clinical trial for Provacel to evaluate its safety and efficacy to restore heart function in patients experiencing a first time heart attack. In March 2007, we reported six-month results in this trial. In a 53-patient, double-blind, placebo-controlled study evaluating the safety and preliminary efficacy of the intravenous administration of Provacel, heart attack patients receiving the therapy had significantly lower rates of adverse events, such as cardiac arrhythmias, as well as significant improvements in heart, lung and global function. Administration of Provacel was found to be well tolerated at all dose levels. Patients in the Provacel group were four times less likely to experience an arrhythmic event compared to those receiving placebo (9% vs. 37%, p=0.025). Fewer patients experienced clinically significant premature ventricular contractions after receiving Provacel as compared to placebo at the one month (6% vs. 32%, $p < 0.05$) and two month (9% vs. 38%, $p < 0.05$) time points. Patients with anterior wall MIs had a statistically significant 7.0 point (24%) improvement in ejection fraction at three months and a 7.3 point (25%) improvement at six months over baseline ($p<0.05$). In comparison, placebo patients in this group did not have a significant increase. Patients receiving Provacel had significantly improved pulmonary function as measured by improvement in FEV1% predicted values (17 point Provacel vs. 6 point placebo, $p<0.05$). Significantly more patients who received Provacel experienced improvement in their overall condition at six months as compared to those receiving placebo (42% vs. 11%, p=0.027).

We expended approximately $37.6 million in fiscal 2006, $16.9 million in fiscal 2005, and $11.9 million in fiscal 2004, on research and development. For more detailed financial information, including information regarding our revenues, profit and loss, and total assets and research and development costs and expenses for the past three fiscal years, see our Financial Statements included in Item 8 to this Annual Report on Form 10-K for fiscal year 2006.

Scientific Background

Stem cells are a special class of cells that can self-replicate and differentiate into multiple tissue types. Different populations of stem cells, also called progenitor or precursor cells, reside within the body. These cells are generally classified according to their differentiation potential, or ability to become distinct cell

types. Embryonic stem cells are recognized as being totipotent, or unlimited, in terms of the number of different cell types they can become. Other stem cells are either multipotent, meaning capable of becoming two or more cell types, or unipotent, meaning preprogrammed for a single final cell type. Multipotent stem cells include the hematopoietic stem cells responsible for generating cells associated with the circulatory and immune systems, mesenchymal stem cells responsible for the formation of connective tissue cells, and neuronal stem cells dedicated to producing the different nervous system cell types. Stem cells participate in embryological and fetal development and orchestrate tissue repair following disease or injury in the adult. Though the precise mechanism of their activity has not yet been determined, experimental work has provided empirical evidence of the therapeutic benefit of various types of stem cells administered to animal and human subjects.

The embryonic stem cell, or ESC, has the greatest differentiation potential and is capable of developing into all cell types found within the human body. ESCs must be harvested from human embryos, giving rise to ethical controversies surrounding the procurement of ESCs, which have hindered progress in ESC research. The United States government has significantly restricted the funding of ESC research. Also, technical difficulties in purifying and growing ESCs have prevented widespread experimental work capable of withstanding academic or regulatory scrutiny.

In the adult, two major classes of stem cells exist in bone marrow, hematopoietic stem cells and mesenchymal stem cells. Throughout life, hematopoietic stem cells, or HSCs, located within the bone marrow give rise to most types of blood cells. HSC transplantation has served as the basis for a number of aggressive treatments for various types of cancer. However, therapies based on HSCs are largely limited to hematological disorders because HSCs can only differentiate into blood cells.

In contrast to HSCs, mesenchymal stem cells, or MSCs, are progenitor cells that differentiate into various connective tissues, such as bone, muscle, fat, tendon, ligament, cartilage and bone marrow stroma when they receive appropriate biochemical and biomechanical signals. Other biochemical stimuli cause MSCs to mobilize to areas of injury or inflammatory disease. Once there, MSCs coordinate tissue regeneration at a local level by producing tissue growth factors and by interacting with local cells to reduce inflammation and scarring. Importantly, MSCs do not express markers on the surface of cells, known as HLA class II antigens, which are responsible for recognition of the cells by the immune system. Also, the cell surface markers, CD40, CD80 and CD86, which are essential for activation of immune cells, are not present on MSCs. These characteristics allow MSCs to:

- be transplanted into an unrelated patient without giving rise to an immune response;
- regenerate connective tissues like bone and cartilage;
- act as a potent anti-inflammatory agent; and
- exhibit anti-fibrotic activity to limit tissue damage.

MSCs and HSCs are most readily isolated from bone marrow. Because MSCs represent a small fraction of bone marrow cells, they require amplification to be clinically useful. We have developed and optimized a proprietary process for isolating and expanding these cells using standardized cell culture methodologies. We can grow MSCs in a controlled fashion to produce up to 5,000 treatments of our biologic drug candidates from a single bone marrow donation.

Stem cells can be derived from either the patient, referred to as an autologous source, or from a donor, referred to as an allogeneic source. For many cell therapies, allogeneic sourcing is not possible due to the immune response that typically occurs following the injection of unrelated cells. The non-immunogenic nature of MSCs permits allogeneic cell sourcing and carries significant advantages over autologous sourcing. Allogeneic cell sourcing from a healthy donor population allows for specific quality control measures to select therapeutically optimal stem cells. For example, if a patient s cells are of poor

quality due to advanced age, disease or metabolic state, the product to be re-infused will likely be of similar poor quality. We believe that allogeneic sources used in large scale production will enable us to utilize quality control practices to ensure that product potency is reproducible from treatment to treatment. We have developed and continue to develop quality standards for our biologic drug candidates, including potency assays directed to the specific indications for use. To our knowledge, no patients participating in our clinical trials or who have used Osteocel to date have experienced an immunogenic response.

Strategy

We are striving to be the first company to receive FDA marketing approval and to commercialize a stem cell drug therapy.

Successfully commercialize our lead stem cell therapy, Prochymal. We are currently enrolling patients in a pivotal Phase III clinical trial for Prochymal. Assuming marketing approval, we plan to develop a sales and marketing force to promote Prochymal initially for the treatment of steroid refractory GvHD. Based on the small number of bone marrow transplantation hospitals in the United States and the lack of effective treatments for this population, we believe we can successfully market Prochymal with a specialized sales force.

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

Expand our pipeline of biologic drug candidates where our stem cell technology has a therapeutic potential. We intend to continue investing in our biologic drug candidate pipeline by pursuing additional diseases and disorders where we believe MSCs have potential therapeutic benefit.

Exploit our MSC technology, manufacturing ability and proprietary know-how to advance our pipeline. We intend to leverage our preclinical research, safety data and manufacturing ability to rapidly and efficiently grow our biologic drug candidate pipeline. Because we utilize MSCs as the active agent for all of our biologic drug candidates, we believe the accumulated safety data will reduce the time and cost associated with early stage clinical trials for new indications.

Internally develop and commercialize future biologic drug candidates. We believe that we have the requisite experience to develop and commercialize our unpartnered biologic drug candidates and any future biologic drug candidates without the help of a strategic partner. Due to our experience with Osteocel and our current pipeline candidates, we believe we have gained the clinical, regulatory, manufacturing and commercial capabilities to successfully develop and commercialize biologic drug candidates.

Marketed Product

Osteocel

Osteocel consists of a matrix of cancellous bone containing mesenchymal stem cells and is used in spinal fusion and other orthopedic surgical procedures. It is the only commercially available product in the United States containing viable stem cells. We launched Osteocel in July 2005 and to date it has been used in over 5,000 surgical procedures. Osteocel is currently distributed non-exclusively by us, Blackstone and AlloSource for orthopedic indications, and by us jointly with Blackstone Medical for spinal procedures.

According to data published by the Centers for Medicare and Medicaid Services, over 900,000 surgeries are performed in the United States each year that require the reconstruction or replacement of bone. The standard of care is a procedure known as autograft, in which bone is harvested from another site within the same patient and transferred to the site of injury. The harvested bone contains stem cells and is often an effective agent for regenerating bone. However, this procedure has significant disadvantages. An additional surgery is required to obtain the autograft bone, resulting in increased time under anesthesia, additional blood loss, and the costs associated with an additional surgery. These patients also face an increased risk of infection and may experience chronic post-operative pain from the harvest procedure. As noted in an article published by the UCLA Department of Orthopaedic Surgery, complications from the autograft harvest occur in up to 35% of patients having the procedure. As such, we believe there is a significant medical need for a product that can provide reliable bone forming characteristics and eliminate the need for autograft.

Spinal fusion is used to treat damage to the intervertebral disc, including herniated discs, and is one of the most common and expensive surgeries in orthopedics. Based on data published by the Centers for Medicare and Medicaid Services, there were 450,000 spine fusion surgeries in 2003, associated with multi-billion dollar health care costs. All spinal fusion surgeries require autograft or other material to support bone formation. Non-viable bone sourced from cadavers, synthetic materials, and recombinant growth factors are used as alternatives to autograft. Each has significant limitations and none has the same regenerative characteristics of autograft. While Osteocel contains the same bone forming properties as autograft, it has several distinct advantages:

- Osteocel avoids the potential complications and expense of an additional surgical procedure.

- The availability of Osteocel during surgery is limited only by the in-house supply, while autograft availability is limited to the amount harvested from the patient in the prior surgical procedure.

- Every lot of Osteocel is tested to ensure consistent quality, while the quality of the autograft is dependent upon the health of the patient.

- Ease of use, storage characteristics, and shelf life allow Osteocel to be used in virtually any surgical setting where bone formation is needed.

Osteocel works in three ways. The cancellous bone matrix of Osteocel is osteoconductive, meaning it encourages new bone growth by providing a scaffold to support bone formation. Osteocel is also inductive. Osteoinduction is the indirect promotion of bone formation by recruiting the patient s cells to the site through signaling mechanisms. Lastly, the stem cells contained in Osteocel make it osteogenic. Osteogenesis is the ability of certain cells to form bone directly. Only two current treatments contain all three of these necessary components for new bone growth: autograft and Osteocel. Over the past 10 years our scientists have published over 20 peer reviewed journal articles demonstrating the consistent osteogenic capabilities of the MSCs in Osteocel.

We produce Osteocel from the marrow-rich bone of organ and tissue donors. Since its introduction in July 2005, we have been unable to produce quantities of Osteocel sufficient to meet surgeon demand. During 2006, we were constrained by our manufacturing facility and limitations on the supply of marrow-rich bone obtainable from adult organ and tissue donors. To increase our ability to supply our customers, we are currently expanding our manufacturing capacity and increasing the number of organ and tissue agencies that supply us with tissue. In December 2006, we entered into a multi-year agreement with AlloSource, Inc., a non-profit tissue procurement organization, for the supply by AlloSource to us of tissue for use in the manufacture of Osteocel. Under the terms of the agreement, AlloSource commits to provide bone matrix to us for use in the production of Osteocel, and to ensure that the technology is made available to the communities from which it is sourced, the agreement enables AlloSource to act as a non-exclusive distributor of Osteocel in AlloSource s local donor communities.

We believe that Osteocel is properly characterized, and regulated by the FDA, as a HCT/P under section 361 of the Public Health Service Act.

We are in the process of developing a second generation MSC product for bone repair, Osteocel-XC, as a long-term strategy to relieve supply constraints. Unlike Osteocel, Osteocel-XC will utilize culture-expanded MSCs like our other biologic drug candidates. Based on our clinical and preclinical experience with Osteocel and MSCs, we are preparing to submit an Investigational New Drug application to FDA to study Osteocel-XC.

Revenues from sales of Osteocel were $8.3 million in fiscal 2006 and $1.0 million in fiscal 2005. There were no Osteocel sales or revenues in fiscal 2004.

Clinical Programs

Prochymal

Prochymal is our biologic drug candidate for the treatment of inflammatory disease. We are currently enrolling patients in a pivotal Phase III trial for the treatment of steroid refractory GvHD. GvHD is a life threatening immune system reaction that commonly affects the skin, gastrointestinal tract, and liver in patients who have received a bone marrow transplant. We estimate that there are approximately 3,000 instances of GvHD in the United States each year. We are also evaluating Prochymal in a Phase III trial for Crohn s Disease for patients refractory to biologics.

Bone marrow transplantation is a treatment of last resort for patients with certain cancers and some genetic diseases. This procedure can result in a particularly serious type of rejection referred to as Graft versus Host Disease. This condition gets its name because the bone marrow transplant, or the graft, begins to attack the recipient, or the host. As noted in an article published in the journal *Biology of Blood and Marrow Transplantation* in 2005, acute GvHD is one of the most common complications of allogeneic bone marrow or hematopoietic stem cell transplantation, affecting approximately 50% of transplant patients. Acute GvHD is graded for prognostic and treatment purposes on a four grade scale, with Grade I considered mild, Grade II moderate, and Grades III-IV considered severe and life-threatening. The onset of GvHD in patients who have received a bone marrow transplant leads to a poor prognosis because of the already weakened state of such patients. According to a 2002 article published in *Biology of Blood and Marrow Transplantation*, the estimated one year survival rate for patients with acute GvHD decreases drastically with increasing disease severity, as illustrated below:

Acute GvHD	Estimated One Year Survival
Grade I	65 %
Grade II	60 %
Grade III	39 %
Grade IV	22 %

Typically, patients are treated aggressively with steroids when their GvHD reaches Grade II. A 2001 article published in the journal *Blood* noted that approximately 50% of these patients will not respond to treatment with steroids and approximately 50-80% of steroid refractory GvHD patients die of the disease.

The current treatments available for acute GvHD are inadequate in several ways. First, mortality in patients with acute GvHD is unacceptably high. Second, most treatments for acute GvHD work by suppressing or destroying the immune system. This leads to a number of debilitating side effects, including severe and life threatening infection. Unlike steroids or other immunosuppressant drugs, which have a systemic effect, Prochymal s mechanism of action is designed to specifically target areas of inflammation. Therefore, we believe the use of Prochymal will result in a lower rate of life threatening infection.

We completed a Phase II trial to evaluate Prochymal as a first-line treatment in combination with steroids, for patients diagnosed with Grade II through Grade IV acute GvHD. Patients were treated with doses of 2.0 or 8.0 million cells per kilogram of body weight administered in two infusions of Prochymal 72 hours apart. The treatment commenced within 48 hours of GvHD diagnosis. In this study, we are evaluating safety, dose, and response to treatment by day 28. Patients will be followed for safety for two years after trial enrollment. A total of 32 patients have been treated under this protocol. The study found that patients were twice as likely to have total clinical resolution of their disease when Prochymal was added to steroid therapy, compared to reported results for steroid only treatment. Twenty-nine of 31 patients, or 94% responded after receiving two infusions of Prochymal, with 23 patients, or 74% achieving a complete response, meaning the patients had experienced total clinical resolution of the disease. Six patients, or 19% had a partial response and 2 patients, or 6% did not respond. Furthermore, patients experiencing this complete response had a survival rate of 91% at Day 120.

Starting in 2004, several requests were made by physicians to use Prochymal in a compassionate use setting for patients with acute severe treatment refractory GvHD and no remaining treatment options. A total of seven pediatric patients that had failed to respond to steroids and other immunosuppressive agents were treated on an emergency-use basis, and clinical improvements were seen in gastrointestinal and skin GvHD.

As a result of the compassionate use requests, we initiated a second Phase II trial to investigate the use of Prochymal in patients diagnosed with Grade III or Grade IV GvHD that did not respond to treatment with steroids and at least one other therapy. This was an open label study in which we evaluated safety, dose, and response to treatment by day 28. Patients were treated with 8.0 million cells per kilogram every 72 hours as needed for response, for a maximum of eight treatments. Fourteen patients were treated under this protocol. The subjects enrolled in this trial had failed to respond to an average of 4.4 other drug therapies prior to enrollment. A 59% Prochymal response rate was observed in this treatment refractory population, defined as an improvement in at least one affected organ by at least one full GvHD stage without disease progression in any other organ. Because the patients in this trial had previously not responded to multiple lines of therapy and their condition was immediately life threatening, for ethical reasons the use of a placebo control was not possible. Therefore, further analysis of the statistical significance of our results was not performed. We are following patients for safety for one year after trial enrollment.

In 2003 we completed a Phase I trial to determine the safety of Prochymal in patients who received hematopoietic stem cell transplants. The trial investigated patient response to doses of 1.0, 2.5, and 5.0 million cells per kilogram of body weight. No safety concerns related to the use of Prochymal were observed in the 46 subjects who were evaluated.

We obtained both Fast Track and Orphan Drug designation in 2005 for the use of Prochymal in GvHD patients. The FDA grants Fast Track designation to investigational drugs that have the potential to treat life-threatening diseases with unmet medical needs. Our Biologic License Application will be eligible for an expedited review process by the FDA as a result of this designation. Orphan Drug designation offers several benefits including eligibility for grants to fund studies, seven years of marketing exclusivity and a waiver of the Biologic License Application fee of approximately $900,000. Prochymal is the only stem cell therapeutic currently designated by the FDA as both an Orphan Drug and Fast Track product candidate.

Based on our clinical observations of the effects of Prochymal on the gastrointestinal symptoms of patients with GvHD, we are developing Prochymal for the treatment of Crohn s Disease. Crohn s Disease is a chronic, life-long condition that features relapsing inflammation of the gastrointestinal tract. Severe Crohn s Disease can cause intractable diarrhea and abdominal pain, undesirable changes in lifestyle, hospitalization, and unwanted side effects from required medications. Approximately 60% of Crohn s Disease patients require at least one surgery to remove an affected portion of their intestine at some time

during their lifetime, according to a 2002 article in the journal *Alimentary Pharmacology & Therapeutics*. This article further notes that there are over 500,000 cases of diagnosed Crohn s Disease in the United States, and at any given time approximately 10% of these have a severe exacerbation or relapse that does not respond to traditional immunosuppressive treatments. Standard treatments of steroids and other immune suppressants often cause secondary health problems. According to a 2003 article in the *British Journal of Clinical Pharmacology*, with current medical therapies about 50% of patients with severe Crohn s Disease will relapse within a year. Also, one year post-surgical recurrence rates of over 85% have been reported in such patients in a 1990 article published by *The Medical Clinics of North America*.

We completed a Phase II trial studying Prochymal as a treatment for moderate to severe Crohn s Disease that is refractory to steroids and other immune suppressants. We enrolled ten patients in this study and communicated the results during the October 2006 annual meeting of the American College of Gastroenterology. The trial was a prospective, randomized, open label trial, conducted at 4 leading centers in the US. Patients with moderate to severe Crohn s disease, defined as having a CDAI (Crohn s Disease Activity Index) of at least 220, who had previously failed treatment with steroids and other immunosuppressive agents, were given two infusions of Prochymal seven days apart. A total of 10 patients were treated, with 9 patients evaluated through the 28 day follow-up. One patient elected to exit the trial prior to completion. Patients were divided into two groups and received either low dose (2 million cells per kilogram) or high dose (8 million cells per kilogram) of Prochymal on an outpatient basis. In addition to safety parameters, patients were evaluated for changes in CDAI and improvement in the Inflammatory Bowel Disease Questionnaire or IBDQ. Prior to entering the trial, patients who had been treated with infliximab or other biological agents were required to complete a washout period of 90 days to preclude the possibility that response was the result of a previous treatment.

Entering the trial, the average CDAI score at baseline was 341. Patients entering this study had suffered from Crohn s Disease for an average of 14.2 years, and 80% of the patients required prior surgical intervention to treat their Crohn s Disease. In the study, one-third of the patients had a reduction of CDAI of greater than 100 points within 14 days of treatment. Each of these responders had failed previous treatment with infliximab (Remicade(R)). Mean IBDQ scores improved significantly from baseline to day 28 (113 to 146, p=0.008). One-third of the patients reported IBDQ scores of at least 170, indicating they had achieved clinical remission of their disease. Although not reaching statistical significance, there appeared to be correlation between dose and response. Patients receiving the high dose had a 72 point greater reduction in CDAI than those receiving low dose (CDAI reduction of 137 vs. 65). There were no infusional toxicities, nor were there any treatment related severe adverse event.

As the result of the encouraging data, we initiated a Phase III program for moderate to severe Crohn s Disease patients who are refractory to standard therapy, including biologics. We have received Fast Track designation from the FDA, which makes us eligible for expedited FDA review of Prochymal for this indication. We have also received clearance from the FDA to conduct a Phase III clinical trial using Prochymal to treat this resistant form of Crohn s Disease.

Chondrogen

Chondrogen is our biologic drug candidate for regeneration of meniscus, a type of cartilage that cushions the knee joint. There are currently no FDA approved products available to regenerate meniscal tissue. In several preclinical studies, Chondrogen, a preparation of adult stem cells formulated for direct injection into the knee, regenerated meniscus and prevented osteoarthritis in animal models. As described further below, at the end of the first quarter of 2006 we completed enrollment in a Phase I/II clinical trial for Chondrogen, designed to evaluate the safety and preliminary efficacy in patients following surgery to remove torn meniscus.

The meniscus is a crescent-shaped cushion in the knee joint that protects cartilage and enables the knee to move smoothly. Injury and tears to the meniscus are common and can be traumatic, arising from sports injury for example, or degenerative, due to daily wear and tear. An injured or torn meniscus is painful and typically requires surgical intervention. The current standard of care for significant injuries is partial meniscectomy surgery, in which the damaged portion of the meniscus is permanently removed. According to a 2005 article in the *American Journal of Sports Medicine*, approximately 1.0 million people have surgery to remove damaged or torn meniscus in the United States each year. As noted in a 1999 article in the journal *Sports Medicine*, patients who have had this procedure are ten to 15 times more likely to develop osteoarthritis, a highly debilitating orthopedic condition. As a result, a significant medical need exists for a product that can regenerate the meniscal tissue removed during surgery and prevent cartilage degeneration.

At the end of the first quarter of 2006, we completed enrolling patients in a randomized double-blind, placebo controlled Phase I/II clinical trial evaluating Chondrogen for safety and preliminary efficacy based upon regeneration of meniscus at six-months. We plan on evaluating each patient for safety two years after the patient enrolled in the trial. Participants in the trial received doses of either 50 million cells, 150 million cells, or placebo and a total of 55 patients were treated. At the six month time point, Chondrogen met its primary endpoint, demonstrating product safety. An initial review of the data showed that Chondrogen was well tolerated, was not associated with serious adverse events, did not result in any adverse hematological events, and did not result in the formation of any unwanted or ectopic tissue. There was no significant change in the volume of meniscus on MRI at six-months in patients that received Chondrogen compared to those patients receiving placebo. However, about 30% of patients treated with Chondrogen demonstrated an improvement in their baseline cartilage or joint condition, while no patients in the placebo group demonstrated similar improvement. Patients will be followed for safety and additional preliminary efficacy, such as cartilage damage and changes in the meniscus for two years under the current study protocol.

Provacel

Provacel is our biologic drug candidate for the repair of heart muscle in patients who have suffered a heart attack. Preclinical studies indicate that Provacel prevents scar formation that typically occurs after a heart attack and improves cardiac function eight to ten weeks after its administration. As discussed further below, in March 2006 we completed enrollment in a Phase I clinical trial for Provacel. This trial is designed to evaluate the safety and efficacy of Provacel to restore heart function in patients experiencing a first time heart attack.

A heart attack, or acute myocardial infarction (AMI), occurs when coronary arteries become blocked with fatty deposits, depriving the heart muscle of oxygen and nutrients. Based on statistics published in 2005 by the American Stroke Association and the American Heart Association, in the United States approximately 700,000 individuals each year experience their first heart attack. According to these same statistics, approximately 20% of patients experiencing their first heart attack suffer extensive damage to their heart muscle, leading to heart failure within six years. Furthermore, we believe the statistics indicate that despite improvements in the standard of care, this progression from myocardial infarction to heart failure remains largely unavoidable in patients with AMIs.

Provacel is being developed for the treatment of heart muscle damage following AMI. Its primary indication is to treat post-AMI complications and prevent the formation of scar tissue and associated cardiac dysfunction. Our preclinical studies indicate that the mechanism by which Provacel improves myocardial function includes preventing pathological scarring of the heart muscle and growing new blood vessels. We are developing Provacel as a therapy to be delivered through a standard intravenous line up to 10 days post-myocardial infarction.

In preclinical studies, Provacel selectively targeted the damaged area of the heart when a single infusion was administered. These studies also indicated that Provacel has the effect of retarding or

stopping the progress of further cardiac tissue deterioration and limiting the damage caused by an AMI. Significant improvements in cardiac function as demonstrated by increased ejection fraction, reduced end diastolic pressures, and reduced wall stress were observed eight to ten weeks after administration of Provacel. A preclinical study was performed to determine if an intravenous infusion of MSCs following myocardial infarction would result in an improvement in cardiac function. Significant improvement in cardiac function as indicated by left ventricular ejection fraction was observed three months after infarct in those animals receiving intravenous delivery of MSCs compared to control animals. MSCs were detected in the damaged area of the heart muscle of Provacel treated animals, but not in the remote, undamaged regions.

In March 2006, we completed enrollment of a 53 patient Phase I randomized, double blind, placebo controlled clinical study to evaluate Provacel in patients following AMI. The trial is designed to investigate patient response to doses of 0.5, 1.6, and 5.0 million cells per kilogram of body weight or placebo. Exploratory efficacy endpoints include overall improvement in the function and remodeling of the heart muscle six months after treatment. A safety evaluation for each subject will be conducted two years after the subject is enrolled in the trial.

In March 2007, we reported six-month results in this trial. Heart attack patients receiving Provacel had significantly lower rates of adverse events, such as cardiac arrhythmias, as well as significant improvements in heart, lung and global function. Administration of Provacel was found to be well tolerated at all dose levels. Patients in the Provacel group were four times less likely to experience an arrhythmic event compared to those receiving placebo (9% vs. 37%, p=0.025). Fewer patients experienced clinically significant premature ventricular contractions after receiving Provacel as compared to placebo at the one month (6% vs. 32%, $p < 0.05$) and two month (9% vs. 38%, $p < 0.05$) time points. Patients with anterior wall MIs had a statistically significant 7.0 point (24%) improvement in ejection fraction at three months and a 7.3 point (25%) improvement at six months over baseline ($p<0.05$). In comparison, placebo patients in this group did not have a significant increase. Patients receiving Provacel had significantly improved pulmonary function as measured by improvement in FEV1 % predicted values (17 point Provacel vs. 6 point placebo, $p<0.05$). Significantly more patients who received Provacel experienced improvement in their overall condition at six months as compared to those receiving placebo (42% vs. 11%, p=0.027).

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

Other

In addition to the indications described above, we intend to investigate alternative uses for MSCs and our biologic drug candidates. We may also evaluate the use of Provacel for additional cardiovascular indications and Chondrogen for the regeneration of cartilage in other areas of the body.

Collaborations

Boston Scientific Corporation Research, Development and Commercialization Collaboration

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

Under the terms of the collaboration, we are responsible for the preclinical development of an MSC biologic drug candidate having application in the covered field, and for associated regulatory filings, and Boston Scientific is responsible for the research and development activities performed following completion of preclinical development of a biologic drug candidate, including, without limitation, development of the clinical protocols, clinical trial management and Phase II efficacy research testing. The collaboration provides for us to manufacture the MSC clinical trial materials, and provides that, upon

regulatory approval for commercial sale, we will manufacture and Boston Scientific will have exclusive rights to distribute and sell the product globally. Boston Scientific may also assume the manufacturing rights and responsibilities from us and if it does so the royalty rate payable to us is subject to increase. This collaboration may be terminated at any time upon mutual agreement of the parties. Also, Boston Scientific can terminate the collaboration prior to obtaining FDA approval of a product, provided that it gives us at least 120 days notice of such termination.

In connection with this collaboration, we granted to Boston Scientific a worldwide, exclusive license to develop, market and distribute MSC products in the covered field. Unless earlier terminated, the license terminates on the expiration of the last to expire licensed patent covering the product, and with regard to member states of the European Economic Area, or EEA, on the later of the tenth anniversary of the commercial launch of a product in the EEA or the expiration of the last to expire patent. This license automatically terminates upon termination of the collaboration prior to FDA approval of a product as described above.

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

We have a $50.0 million line of credit with Boston Scientific, of which we have drawn $5.0 million to date. Borrowings can only be used by us in connection with Provacel development efforts. Advances under the loan agreement are secured by an interest granted to Boston Scientific in the license agreement, including the right to develop, market and distribute MSC products in the covered field and our right to receive payments under the license; all equipment, books and records relating to the manufacture of Provacel; and all future proceeds or payments received in connection with such collateral. We must commence quarterly repayment of the advance during the first fiscal quarter following commercialization of Provacel up to a maximum of 2.5% of sales of Provacel per quarter. If commercialization has not occurred prior to December 31, 2008, we must issue shares of our common stock in repayment of the loan at a rate of 20% per year up to a maximum repayment term of five years. Alternatively, upon any termination of the collaboration with Boston Scientific or any default under the loan agreement, Boston Scientific may require us to satisfy the full balance of the outstanding loan through an issuance of shares of our common stock. We can elect to repay the amounts borrowed from Boston Scientific at any time.

In conjunction with this collaboration, Boston Scientific made a $10.0 million investment in our preferred stock, which was converted into 500,000 shares of our common stock. Upon the enrollment of the first patient in a Phase III clinical trial for Provacel, Boston Scientific is obligated to purchase from us and we are obligated to sell, 166,667 shares of common stock for an aggregate purchase price of $10.0 million, or $60.00 per share. Upon FDA approval of Provacel, Boston Scientific is obligated to purchase from us and we are obligated to sell, 89,286 shares of common stock for an aggregate purchase price of $10.0 million, or $112.00 per share. Boston Scientific was granted registration rights in respect of the shares of our common stock received by it, which rights have been waived to the extent that they related to our initial public offering. Boston Scientific was also granted a preemptive right to purchase its pro rata share of securities issued and sold by us, which right has been permanently waived.

JCR Pharmaceuticals Co., Ltd. License Agreement

In August 2003, we entered into a license agreement with JCR Pharmaceuticals Co., Ltd., or JCR, pursuant to which we granted to JCR an exclusive right in Japan to our MSC technology for use in connection with the use of hematopoietic stem cells derived from peripheral blood, cord blood or bone marrow in the treatment of hematological malignancies including the treatment of GvHD with Prochymal.

The license agreement provided for a payment by JCR to us of an up-front license fee of $3.0 million and payment of an additional $500,000 upon certain technology transfer. In addition, if and when marketing approval is obtained in Japan, JCR is required to pay up to $7.0 million in pre-commercialization milestones per product and certain amounts for pre-determined thresholds of cumulative net sales. Lastly, JCR has an obligation to pay royalties to us, with such amount dependent upon the cumulative net sales.

Under the terms of the collaborative arrangement, JCR is obligated to use its reasonable best efforts to develop and commercialize in Japan products covered under the terms of the license, including conducting clinical trials and procuring regulatory and other approvals. The license expires with respect to specific products on the later of 15 years from the date of the first sale of the product in Japan or the date on which our last patent in Japan covering that product expires. Also, the license and the collaboration can be terminated unilaterally by JCR upon 180 days notice to us or by mutual agreement between us and JCR.

In conjunction with this collaboration, JCR made a $3.0 million investment in our preferred stock, which converted at the closing of our initial public offering into 136,363 shares of our common stock. JCR was granted registration rights in respect of the shares of our capital stock received by it, which rights have been waived to the extent that they related to our initial public offering. JCR was also granted a preemptive right to purchase its pro rata share of securities issued and sold by us, which right has been permanently waived.

Blackstone Medical, Inc. Distribution Agreement

In November 2005, we entered into a distribution and supply arrangement for Osteocel with Blackstone Medical, Inc., or Blackstone. Blackstone has since been acquired and now operates as a division of Orthofix International, N.V. Blackstone has the right to distribute Osteocel in the United States for the treatment of spinal injuries or diseases. In addition, we granted Blackstone an exclusive distribution right with regard to spinal implant manufacturers provided that it commits to purchase at least 80% of the quarterly production forecast of Osteocel at a stipulated price per unit.

Blackstone markets Osteocel under the Trinity name. We have also retained the right to directly market and distribute Osteocel under the Osteocel brand.

Blackstone is required to use its best efforts to distribute Osteocel. Unless earlier terminated, the agreement terminates on December 31, 2008; however, it can be renewed for one-year periods so long as Blackstone achieves certain predetermined performance objectives.

Either party may terminate the agreement immediately upon written notice to the other party of the occurrence of certain bankruptcy events or failure to remedy a material breach that continues for more than 30 days.

Intellectual Property

We have established a considerable patent position in adult stem cell technology. We currently own or have exclusive licenses to 47 issued U.S. patents. Foreign counterparts to these patents, including composition of matter claims, have been filed, and we own or hold licenses to 167 issued patents in Europe, Canada, Australia and other countries. The patents and patent licenses included in our portfolio address the composition and therapeutic use of mesenchymal stem cells. We are committed to protecting our intellectual property position and to aggressively pursue our patent portfolio, and have 13 additional U.S. patent applications pending and 59 foreign patent applications on file but not yet allowed.

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

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

Through our experience with MSCs and MSC-based product development, we have developed expertise and know-how in this field. We manufacture clinical grade MSCs in-house and contract for the production through contract manufacturers. To protect this non-patentable know-how, our policies require confidentiality agreements with our employees, consultants, contractors, manufacturers, outside collaborators, sponsored researchers, and advisors. These agreements generally provide for protection of confidential information, restrictions on the use of materials and assignment of inventions conceived during the course of performance for us. These agreements might not effectively prevent disclosure of our confidential information.

We were founded on the basis of MSC technology obtained from Case Western Reserve University, or CWRU. In January 1993, we entered into a Technology Transfer and License Agreement with CWRU, which was subsequently amended in October 1999 and twice in October 2003. Pursuant to this license agreement certain patents were assigned to us and others were exclusively licensed to us, with the right to grant sublicenses.

The exclusive license is subject to any rights of a governmental agency based on research funding by such an agency, and to CWRU s retained rights under the patents for non-clinical research, testing or educational purposes of CWRU.

With respect to the patents licensed to us, we are obligated to pay royalties to CWRU based on sales of products covered by granted licensed patents, and such royalties commence with respect to each such product on the third anniversary of the initial sale thereof. We are also obligated to pay minimum royalties under the agreement with CWRU. We are responsible for patent costs and along with CWRU have the right to enforce licensed patents. The license is terminable by CWRU in the event that there is a material breach by us. Otherwise the license is for the life of the patents. Under certain circumstances, we are obligated to negotiate in good faith with a third party a sublicense under patents licensed from CWRU and under patents and know-how owned by us that are reasonably required by the third party to exercise the granted sublicense. We are not obligated to grant such a sublicense where it would have a potential adverse effect on a product being researched, developed or commercialized by us or by a licensee or sublicensee of ours.

Under terms of a Marketing, Collaboration and License Agreement with BioWhittaker, Inc., (recently acquired by Lonza), we have licensed our MSC technology to BioWhittaker to sell MSCs, MSC descendants, cells produced from MSCs and materials used with MSCs for commercial and non-commercial research purposes. Under the terms of this agreement, BioWhittaker is specifically precluded from selling the licensed products for use in humans. We receive royalties on any sales under this agreement.

Patent life determination depends on the date of filing of the application or the date of patent issuance and other factors as promulgated under patent law. The United States Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, permits a patent extension of up to five years as compensation for patent term lost during the FDA regulatory review process. The patent term restoration period is generally one-half the time between the effective date of an Investigational New Drug Application or IND and the submission date of a New Drug Application or NDA, plus the time between the submission date of an NDA and the approval of the drug. Only the earliest patent applicable to an approved drug is eligible for the extension. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves applications for patent term extension. We expect to apply for patent term extensions for eligible patents to add patent life beyond the expiration date, depending on the expected length of clinical trials and other factors involved in the filing of a new drug application.

Manufacturing

Production of Biologic Drug Candidates

We believe that we have differentiated ourselves from other stem cell companies through proprietary manufacturing methods that allow for the controlled growth of MSCs to produce up to 5,000 treatments of our biologic drug candidates from a single bone marrow donation. This is in contrast to most other stem cell technologies that are able to make only a single treatment from each donation.

We have been manufacturing mesenchymal stem cells for over eight years. The first material manufactured in-house was released in 1999. Since that time manufacturing has continued to improve in support of clinical trials. The current manufacturing process utilizes cell factories, a closed system of surfaces on which the cells adhere, for stem cell expansion. We have developed this technology into a reproducible process that we believe can be scaled up at additional sites. A second manufacturing site was successfully qualified in 2003. In addition, JCR Pharmaceuticals, our partner in Japan, has successfully implemented our manufacturing technology in Japan. We believe that we perform all of our manufacturing activities in compliance with FDA current Good Manufacturing Practice requirements.

Our manufacturing process begins with the collection of bone marrow aspirate from qualified volunteer donors, 18-30 years of age. Prior to donation, these individuals are screened and tested for a battery of diseases including HIV and hepatitis according to FDA donor suitability guidance. We purchase bone marrow aspirate from commercial sources. Since the mesenchymal stem cell is extremely rare, accounting for only one in every 100,000 cells in bone marrow, an initial purification process is required. Upon arrival at our facilities, MSCs are isolated and selectively removed from the bone marrow by an adherent culture process. Our stem cells adhere to the surface of the cell factory and the other remaining cell populations do not adhere and are washed away throughout the process. Our stem cells are then expanded over the course of a month. Once expanded, the cells are harvested, packaged and cryopreserved as an in-process intermediate, and we conduct a second battery of quality testing. Each packaged intermediate is further expanded and formulated to produce the final product. Sterility and quality testing completes the process. This well-defined process has allowed for the development of a supply chain where material specifications have been established and vendors have been qualified.

The final product will be configured to allow for ease of storage, distribution and use in the clinic. We expect the product will be provided in ready to use patient dose quantities, shipped from the distribution center on dry ice, and stored in the freezer at the pharmacy.

Production of Osteocel

Osteocel is a matrix of viable cancellous bone containing primary or unexpanded MSCs. Unlike our biologic drug candidates, the stem cells and cancellous bone used in Osteocel are obtained from organ and tissue donors. Additionally, the production of Osteocel is different from our biologic drug candidates in that it does not feature the expansion of MSCs.

Since its introduction into the marketplace in July 2005, we have been unable to produce Osteocel in quantities sufficient to meet our customer demand due to constraints in our manufacturing facility and the lack of sufficient quantities of marrow-rich bone. We contract with tissue recovery agencies for Osteocel source tissue. We currently have eight agencies under contract, including Allosource as discussed above. These agencies in turn have contracts with federally designated Organ Procurement Organizations who notify the agencies of donor candidates in their areas. Once an initial qualification of the donor is performed, a surgical team is deployed to remove the tissue and send it to our processing center via overnight delivery. The agencies also compile the donor s medical records, perform a medical and social history evaluation, collect serum samples for serological testing and perform other donor screening services. These agencies operate on a fee for service basis, which varies depending upon the tissue type and transplant suitability. We intend to enter into contracts with additional tissue recovery agencies in the future in order to fulfill product demand. We expect to continue to increase manufacturing capacities in line with tissue supply, and believe we will eventually be limited by available donor material regardless of manufacturing capacity.

The processing of Osteocel is in many ways more like the process of organ donation than standard tissue processing. This is because it is essential that the stem cells contained within Osteocel are kept in a living, healthy state. We overcome this challenge through a proprietary process that is designed to preserve the material, particularly the stem cells. Sterility cultures are performed on the final product from every lot according to United States Pharmacopeia standards. Following completion of quality control testing and quality assurance review, the product is released for distribution.

Sales, Marketing and Distribution

Our current sales network consists of approximately 45 independent sales representatives and a distribution agreement with Blackstone Medical, Inc., and its affiliates, for the distribution of Osteocel. In addition, to ensure that Osteocel is made available to the communities from which it is sourced, our agreement with AlloSource enables AlloSource to act as a non-exclusive distributor of Osteocel in AlloSource s local donor communities.

To increase Osteocel s market penetration, we intend to further expand our network of sales professionals in the United States. Except for Provacel, we intend to self commercialize all of our biologic drug candidates in the United States upon FDA approval through the creation of additional sales and marketing capabilities in existing and new indications and the leverage of Osteocel s sales and marketing infrastructure for orthopedic indications. We have entered into a collaborative arrangement with Boston Scientific Corporation to commercialize Provacel upon marketing approval. We also have a collaborative arrangement with JCR Pharmaceuticals Co. Ltd. for the distribution of Prochymal for GvHD in Japan following marketing approval.

Both our Osteocel product and our biologic drug candidates have long-term storage requirements within specific frozen temperature ranges, -80 degrees Centigrade and -140 degrees Centigrade, respectively. Generally, we do not believe this will pose a significant problem for end-users as most hospitals and medical centers have freezers with these storage capabilities readily available. However, some facilities may not have this type of storage available and this may limit product and biologic drug candidate distribution. In an effort to mitigate potential issues with product and biologic drug candidate storage, we are performing studies to develop less restrictive storage temperatures. For example, we have implemented temporary -50 degree Centigrade storage of Osteocel for up to two weeks, which opens distribution to a wider hospital base.

Osteocel

Our marketing of Osteocel is targeted to orthopedic surgeons and neurosurgeons practicing in the United States. The most rapid adoption rates to date have been for spinal fusion procedures. Osteocel is currently distributed by our corporate partner, Blackstone Medical, Inc., and its affiliates, and is also distributed by AlloSource and for us by an independent network of approximately 45 sales representatives. Blackstone is a designer and manufacturer of spinal instruments and implants located in Massachusetts. In the field of orthopedics, we intend to continue to develop a network of sales professionals for the distribution of Osteocel.

Prochymal

Upon FDA approval of Prochymal, we expect to focus our sales and marketing efforts on the approximately 210 transplantation hospitals in the United States that are registered with the International Bone Marrow Transplantation Registry. We expect to employ a number of sales representatives, initially targeting the most active transplantation centers in a region. An important component of the sales strategy will be to gain the support of key opinion leaders, facilitating the adoption of Prochymal as the treatment strategy for GvHD. We have entered into a license agreement with JCR Pharmaceuticals that grants it the exclusive right to distribute Prochymal for the treatment of GvHD in Japan when it has been approved for marketing in that country.

Chondrogen

According to a 2005 article in the *American Journal of Sports Medicine*, approximately 1.0 million people have surgery to remove damaged or torn meniscus in the United States each year. Given the similarity in call points between Osteocel and our biologic drug candidate Chondrogen, we intend to utilize our Osteocel sales force to penetrate this market if we successfully develop and obtain marketing approval for Chondrogen. Current Osteocel sales training includes modules on basic stem cell biology, immunology, and the preclinical and clinical data pertaining to Chondrogen. This cross-training will help the existing sales force in marketing Chondrogen to orthopedic surgeons.

Provacel

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

Competition

Our industry is subject to rapid and intense technological change. We face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery

activities or funding, both in the U.S. and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we target in our commercial, clinical and preclinical programs.

Many of the companies competing against us have financial and other resources substantially greater than our own. In addition, many of our competitors have significantly greater experience in testing pharmaceutical and other therapeutic products, obtaining FDA and other regulatory approvals of products, and marketing and selling those products. Accordingly, our competitors may succeed more rapidly than we will in obtaining FDA approval for products and achieving widespread market acceptance. If we obtain necessary regulatory approval and commence significant commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited or no commercial-scale experience.

Our commercialized product, Osteocel, currently competes with established treatment options such as autograft bone and Medtronic s InFuse and potentially may compete with other products currently in development for the same indications. Our three biologic drug candidates, if approved, would compete with several marketed products and other future biologic drug candidates. For our existing product and each of our clinical-stage biologic drug candidates, the primary competitors include:

- *Osteocel.* Our commercialized bone regeneration product competes with autograft bone, synthetic biomaterials, growth factors and allograft bone. Competing products include Medtronic s InFuse, Stryker s OP-1, numerous bone void filler products such as Zimmer s CopiOs and autologous bone marrow products such as DePuy Spine s CELLECT .

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

- *Chondrogen.* If approved, Chondrogen will compete with products such as allograft menisci from cadavers, Conmed Linvatec s meniscal fixation system of screws and arrows and if approved, Regen Biologics Collagen Meniscus Implant.

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

We may face competition in the future from other companies that are researching and developing stem cell therapies. We are aware of many companies working in this area, including: Aastrom Biosciences, Advanced Cell Technology, Athersys, Cellerant Therapeutics, Cognate Therapeutics, Cytori Therapeutics, Gamida Cell, Geron, Mesoblast, MultiCell Technologies, Neuronyx, Theradigm, ViaCell and StemCells.

We expect to compete based upon, among other things, our intellectual property portfolio and the efficacy of our products. Our ability to compete successfully will depend on our continued ability to attract and retain skilled and experienced scientific, clinical development and executive personnel, to identify and develop viable biologic drug candidates and to exploit these products and compounds commercially before others are able to develop competitive products.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in the development, manufacture, commercialization and reimbursement of our products and services. Virtually all of the products we develop will require marketing approval, or licensure, by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical testing and other approval procedures of the U.S. Food and Drug Administration, or FDA, and similar regulatory authorities in other countries. Various governmental statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage and record keeping related to such products and their marketing. State, local and other authorities may also regulate pharmaceutical manufacturing facilities. The process of obtaining these approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and money, and there can be no guarantee that approvals will be granted.

FDA Approval Process

We believe that Osteocel is appropriately characterized as a product regulated by the FDA as a human cells, tissues and cellular and tissue-based product, for which the FDA does not require premarket approval. See the discussion below under the caption Human Cellular and Tissue-Based Product. Our biologic drug candidates will require approval from the FDA and corresponding agencies in other countries before they can be marketed. The FDA regulates human therapeutic products in one of three broad categories: biologics, drugs, or medical devices. Our biologic drug candidates will be regulated as biological products. The FDA generally requires the following steps for premarket approval or licensure of a new biological product or new drug product:

- preclinical laboratory and animal tests conducted in compliance with FDA s Good Laboratory Practice, or GLP, requirements to assess a drug s biological activity and to identify potential safety problems, and to characterize and document the product s chemistry, manufacturing controls, formulation, and stability;

- submission to the FDA of an investigational new drug or IND application, which must become effective before clinical testing in humans can begin;

- obtaining approval of Institutional Review Boards, or IRBs, of research institutions or other clinical sites to introduce the biologic drug candidate into humans in clinical trials;

- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication conducted in compliance with FDA s Good Clinical Practice, or GCP, requirements;

- compliance with current Good Manufacturing Practices, or cGMP regulations and standards;

- submission to the FDA of a biologics license application, or BLA, or new drug application, or NDA, for marketing that includes adequate results of preclinical testing and clinical trials;

- FDA review of the marketing application in order to determine, among other things, whether the product is safe, effective and potent for its intended uses; and

- obtaining FDA approval of the BLA or NDA, including inspection and approval of the product manufacturing facility as compliant with cGMP requirements, prior to any commercial sale or shipment of the pharmaceutical agent.

Typically, clinical testing involves a three-phase process although the phases may overlap. In Phase I, clinical trials are conducted with a small number of healthy volunteers or patients and are designed to provide information about product safety and to evaluate the pattern of drug distribution and metabolism

within the body. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In some cases, an initial trial is conducted in diseased patients to assess both preliminary efficacy and preliminary safety and patterns of drug metabolism and distribution, in which case it is referred to as a Phase I/II trial. Phase III clinical trials are generally large-scale, multi-center, comparative trials conducted with patients afflicted with a target disease in order to provide statistically valid proof of efficacy, as well as safety and potency. In some circumstances, the FDA may require Phase IV or post-marketing trials if it feels that additional information needs to be collected about the drug after it is on the market. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. An agency may, at its discretion, re-evaluate, alter, suspend, or terminate the testing based upon the data which have been accumulated to that point and its assessment of the risk/benefit ratio to the patient. Monitoring all aspects of the study to minimize risks is a continuing process. All adverse events must be reported to the FDA.

The results of the preclinical and clinical testing on a non-biologic drug and certain diagnostic drugs are submitted to the FDA in the NDA or BLA. In the case of vaccines or gene and cell therapies, the results of clinical trials are submitted as a BLA. In responding to the submission of a BLA or NDA, the FDA may grant marketing authority, request additional clinical data or deny approval if the FDA determines that the application does not satisfy its regulatory approval criteria. FDA review of a BLA or NDA typically takes one to three years, but may last longer, especially if the FDA asks for more information or clarification of information already provided. Further clinical trials may be required to gain approval to promote the use of the product for any additional indications. Such additional indications are obtained through the approval of a supplemental BLA or NDA.

The process of obtaining regulatory approval is lengthy, uncertain, and requires the expenditure of substantial resources. Each NDA or BLA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA s fee schedule, effective through September 30, 2007, the user fee for an application requiring clinical data, such as an NDA or BLA, is $896,200. PDUFA also imposes an annual product fee for prescription drugs and biologics ($49,750), and an annual establishment fee ($313,100) on facilities used to manufacture prescription drugs and biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the drug also includes a non-orphan indication, and if a contract manufacturer is used, the contract manufacturer is responsible for the establishment fee.

Before approving an NDA or BLA, all facilities and manufacturing techniques used for the manufacture of products must comply with applicable FDA regulations governing cGMP. A local field division of the FDA is responsible for completing this inspection and providing recommendation for or against approval. This effort is intended to assure appropriate facility and process design to avoid potentially lengthy delays in product approvals due to inspection deficiencies. Similarly, before approving a new drug or biologics application, the FDA may also conduct pre-licensing inspections of a company, its contract research organizations and/or its clinical trial sites to ensure that clinical, safety, quality control and other regulated activities are compliant with GCP. To assure such cGMP and GCP compliance, the applicants must incur significant time, money and effort in the area of training, record keeping, production, and quality control. Following approval, the manufacture, holding, and distribution of a product must continue to devote significant resources to maintain full compliance in these areas.

After FDA approval has been obtained, the FDA will require post-marketing reporting to monitor the side effects of the drug. Further studies may be required to provide additional data on the product s risks, benefits, and optimal use, and will be required to gain approval for the use of the product as a treatment for clinical indications other than those for which the product was initially tested. Results of post-

marketing programs may limit or expand the further marketing of the product. Further, if there are any modifications to the drug, including changes in indication, labeling, or a change in the manufacturing process or manufacturing facility, an NDA or BLA supplement may be required to be submitted to the FDA.

Additionally, after the FDA has authorized a drug product to enter commercial distribution, numerous regulatory requirements apply. These include, among others, the cGMPs, which require manufacturers to follow extensive design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA s general prohibition against promoting drug products for unapproved or off-label uses; and adverse event reporting regulations, which require that manufacturers report to the FDA if their drug may have caused or contributed to a death or serious injury. The FDA has broad post-market and regulatory and enforcement powers. Failure to comply with the applicable U.S. drug regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, refunds, recalls or seizures of products (which would result in the cessation or reduction of production volume), total or partial suspension of production, withdrawals or suspensions of current product applications, and criminal prosecution. Adverse events related to a drug product in any existing or future markets could cause regulatory authorities to withdraw market approval for such product.

Fast Track and Orphan Drug Designations

Congress enacted the Food and Drug Administration Modernization Act of 1997 in part to ensure the availability of safe and effective drugs, biologics, and medical devices by expediting the FDA review process for new products. The Modernization Act establishes a statutory program for the approval of Fast Track products, including biologics. A Fast Track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Under the Fast Track program, the sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. This designation assures access to FDA personnel for consultation throughout the development process and provides an opportunity to request priority review of a marketing application providing a six-month review timeline for the designated product. If a preliminary review of the clinical data suggests that a Fast Track product may be effective, the FDA may initiate review of sections of a marketing application for a Fast Track product before the sponsor completes the application. This rolling review is available if the applicant provides a schedule for submission of remaining information and pays applicable user fees. However, the time periods specified under PDUFA concerning timing goals to which the FDA has committed in reviewing an application do not begin until the sponsor submits the complete application. During the first quarter of 2005 the FDA designated Prochymal as a Fast Track product for the treatment of GvHD. Prochymal also received Fast Track designation from the FDA in January 2007 for treatment refractory Crohn s Disease. We cannot predict whether this designation will impact the timing or likelihood of FDA approval of Prochymal.

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for Orphan Drug designation. The first developer to receive FDA marketing approval for an Orphan Drug is entitled to a seven year exclusive marketing period in the United States for that product as well as a waiver of the BLA user fee. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven year exclusive marketing period. The FDA granted Orphan Drug designation for Prochymal during the last quarter of 2005.

Legislation similar to the Orphan Drug Act has been enacted in countries other than the United States, including the European Union. The orphan legislation in the European Union is available for therapies addressing conditions that affect five or fewer out of 10,000 persons. The marketing exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Human Cellular and Tissue-Based Product

Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient is regulated by the FDA as human cells, tissues, and cellular and tissue-based product, or HCT/Ps. We believe that Osteocel is appropriately characterized as an HCT/P and not as a biologic or drug. HCT/Ps are regulated differently from drug or biologic products due to the fact they are minimally manipulated tissues intended for homologous use in the patient s body, are not combined with a drug, device or biologic, and do not have systemic or metabolic effects on the body. The FDA does not require premarket approval for HCT/Ps, however, it does require strict adherence to federally mandated current Good Tissue Practice, or cGTP, regulations. These regulations are analogous to the GMP regulations described above in terms of manufacturing standards. In addition, FDA s regulations include other requirements to prevent the introduction, transmission and spread of communicable disease. Specifically, FDA s regulations require tissue establishments to register and list their HCT/Ps with the FDA and to evaluate donors through screening and testing.

We maintain state licensure as a human tissue bank in Maryland, California, Florida, Illinois and New York. These are the only states in which such licensure is required for us.

Privacy Law

Federal and state laws govern our ability to obtain and, in some cases, to use and disclose data we need to conduct research activities. Through the Health Insurance Portability and Accountability Act of 1996, or HIPAA, Congress required the Department of Health and Human Services to issue a series of regulations establishing standards for the electronic transmission of certain health information. Among these regulations were standards for the privacy of individually identifiable health information. Most health care providers were required to comply with the Privacy Rule as of April 14, 2003.

HIPAA does not preempt, or override, state privacy laws that provide even more protection for individuals health information. These laws requirements could further complicate our ability to obtain necessary research data from our collaborators. In addition, certain state privacy and genetic testing laws may directly regulate our research activities, affecting the manner in which we use and disclose individuals health information, potentially increasing our cost of doing business, and exposing us to liability claims. In addition, patients and research collaborators may have contractual rights that further limit our ability to use and disclose individually identifiable health information. Claims that we have violated individuals privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Other Regulations

In addition to privacy law requirements and regulations enforced by the FDA, we also are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. These laws include, but are not limited to, the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the

Resource Conservation and Recovery Act. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, we cannot assure you that accidental contamination or injury to employees and third parties from these materials will not occur. We may not have adequate insurance to cover claims arising from our use and disposal of these hazardous substances.

Foreign Regulation

We will most likely have to obtain approval for the manufacturing and marketing of each of our products from regulatory authorities in foreign countries prior to the commencement of marketing of the product in those countries. The approval procedure varies among countries, may involve additional preclinical testing and clinical trials, and the time required may differ from that required for FDA approval or licensure. Although there is now a centralized European Union approval mechanism in place, this applies only to certain specific medicinal product categories. In respect of all other medicinal products each European country may impose certain of its own procedures and requirements in addition to those requirements set out in the appropriate legislation, many of which could be time-consuming and expensive. Although data requirements presently exist for gene therapy and somatic cell therapy medicinal products, additional European approval standards for cellular therapy are still under development, and consequently approval of cell therapy products in Europe may require additional data that we may not be able to satisfy.

Employees

As of December 31, 2006, our headcount was 113 individuals, comprising 73 full-time employees and 40 full-time contract employees. Of this total, 68 were engaged in manufacturing and operations, 32 were engaged in research and development and clinical trials and 13 were engaged in administration, facilities and finance. All of our employees have entered into non-disclosure agreements with us regarding our intellectual property, trade secrets and other confidential information. None of our employees are represented by a labor union or covered under a collective bargaining agreement, nor have we experienced any work stoppages.

Executive Officers of the Registrant

Executive officers are appointed annually by the Board of Directors and, subject to the terms of any applicable employment agreement, serve at the discretion of the Board of Directors. Information regarding our executive officers is as follows:

Name	Age	Position	Other Offices or Positions Held During the Past Five Years
C. Randal Mills, Ph.D.	35	President and Chief Executive Officer (since July 2004)	Dr. Mills is also a member of the Board of Directors. Prior to joining Osiris, Dr. Mills was an executive officer of Regeneration Technologies, Inc. (NASDAQ RTIX). Dr. Mills served in several leadership positions at RTI from its formation in 1998 until 2004, including Vice President of Business Development and Vice President of Operation and R&D and is credited with several key initiatives including the development and commercialization of RTI s core technology, BioCleanse®.

Name	Age	Position	Other Offices or Positions Held During the Past Five Years
Cary J. Claiborne	46	Chief Financial Officer and Corporate Secretary (since December 2004)	Mr. Claiborne previously was Vice President, Financial Planning and Analysis at Constellation Energy, a diversified energy company from December 2001 to June 2004. At Constellation, he oversaw a budget consisting of $12 billion in revenue and over $500 million in net income. Prior to Constellation Energy, he served as Vice President, Financial Planning and Analysis for Home Depot from April 2000 to July 2001. Mr. Claiborne spent the first 15 years at GE Capital Business Services and served as President of New Enterprise Wholesale Services.
Harry E. Carmitchel	56	Chief Operating Officer (since September 2004)	Mr. Carmitchel has over 20 years of general management and operations experience in the medical field. Prior to joining Osiris, Mr. Carmitchel was a Principal with the Pacific Consulting Group for four years, where he specialized in corporate turnarounds. Prior to this time, Mr. Carmitchel was a General Manager with McQuay International, running a $410 million group, and spent eight years as President of the Medical Division for Stryker Corporation.
Earl R. Fender	59	Vice President and General Manager of Orthopedics (since June 2006)	Prior to joining Osiris, Mr Fender served for over ten years with DePuy Spine, a Johnson & Johnson company, holding positions as Vice President, Sales, U.S. President, and finally as Worldwide President. Under his direction, DePuy Spine became the second largest spinal implant manufacturer in the world.
Lode Debrabandere Ph.D.	42	Vice President and General Manager, Inflammatory Diseases (since July 2006)	Prior to joining Osiris, Dr. Debrabandere served for over four years with Bristol-Myers Squibb as Vice President for Strategic Marketing for Neuroscience and Infectious Diseases. He led the Neuroscience Unit and was the Global Brand Leader for Abilify . Previously, Dr. Debrabandere led the Marketing department of UCB Pharma Inc., focusing in the areas of allergy/respiratory (Zyrtec) and neurology (Keppra).

Item 1A. RISK FACTORS

Risks Related To Our Business

We have a history of operating losses and may not achieve or sustain profitability.

We have incurred losses in each year since our inception and expect to experience losses over the next several years. As of December 31, 2006, we had an accumulated deficit of $188 million. These losses resulted principally from costs incurred in our research and development programs and from our general and administrative expenses. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets and working capital.

We expect to continue to incur significant operating expenses and anticipate that our expenses and losses will increase in the foreseeable future as we seek to:

- complete our Phase II and III clinical trials for Prochymal;
- complete our Phase I/II clinical trial for Chondrogen and, if supported by the Phase I/II clinical trial, initiate additional clinical trials;
- complete our Phase I clinical trial for Provacel and, if supported by the Phase I clinical trial, initiate Phase II clinical trials;
- maintain and expand our network of sales professionals for the distribution of Osteocel, and further expand and train our sales network in anticipation of the approval of our biologic drug candidates for commercial sale;
- expand our manufacturing capacity, which will require that we obtain additional administrative and manufacturing space and build-out a portion of that space as a Food and Drug Administration, or FDA, compliant and validated product manufacturing facility;
- continue the relocation of some or all of our business operations to a newly leased facility;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific and management personnel; and
- add operational, financial, accounting, facilities engineering and information systems personnel, consistent with expanding our operations and our status as a public company.

In addition, Osteocel is our only commercially available product. While revenue from Osteocel has increased since its commercial introduction in July 2005, our ability to scale up our production capabilities for commercial quantities of this product are limited, and our costs in marketing and distributing this product will also increase as production increases.

The extent of our future operating losses or profits is highly uncertain, and we may not achieve or sustain profitability. If we are unable to achieve and then maintain profitability, the market value of our common stock will decline and you could lose part or all of your investment.

If we are not able to recruit and retain qualified management and scientific personnel, we may fail in developing our technologies and biologic drug candidates.

Our future success depends to a significant extent on the skills, experience and efforts of the principal members of our scientific, management and sales personnel. These members include C. Randal Mills, Ph.D., Harry E. Carmitchel, Cary J. Claiborne, Earl R. Fender and Lode Debrabandere Ph.D. The loss of any or all of these individuals could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. We have entered into employment agreements with Dr. Mills, Messrs. Carmitchel, Claiborne, Fender and Dr. Debrabandere for an initial

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term of three years. The existence of an employment agreement does not, however, guarantee retention of these employees, and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. Except for Dr. Mills, Messrs. Claiborne, Carmitchel, Fender and Dr. Debrabandere, none of our employees is employed for a specified term. Competition for personnel is intense. We may be unable to retain our current personnel or attract or integrate other qualified management and scientific personnel in the future.

We may not be able to raise additional capital necessary to fund our operations.

Our future capital requirements will depend on many factors, including:

- the level of cash flows from Osteocel sales;
- the scope and results of our research and preclinical development programs;
- the scope and results of our clinical trials, particularly regarding the number of patients required for our Phase III trial for Prochymal;
- the timing of and the costs involved in obtaining regulatory approvals for our biologic drug candidates, which could be more lengthy or complex than obtaining approval for a new conventional drug, given the FDA s limited experience with late-stage clinical trials and marketing approval for stem cell therapeutics;
- the costs of building and operating our manufacturing facilities, both in the near term to support Osteocel sales and our clinical activities and also in anticipation of expanding our commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- our debt repayment obligations; and
- the costs of enlarging our work force consistent with expanding our business and operations and status as a public company, and as necessary to enhance and train our sales network in anticipation of the approval of our biologic drug candidates for commercial sale.

As a result of these factors, we may need or choose to seek additional funding prior to our becoming cash flow positive on an operational basis. We would likely seek such funding through public or private financings or some combination of them. Although not our current focus, we might also seek funding through collaborative arrangements if determined to be necessary or appropriate. Additional funding may not be available to us on acceptable terms, or at all. If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our technologies or biologic drug candidates. If we raise capital through the sale of equity, or securities convertible into equity, dilution to our then existing stockholders would result. In October 2006, we issued approximately $20.0 million in convertible promissory notes that are convertible under certain circumstances into shares of our common stock at $18.00 per share. The holders of these notes also are afforded registration rights in respect to the shares of common stock issuable upon conversion. If we raise additional capital through the incurrence of debt, we would likely become subject to covenants restricting our business activities, and holders of debt instruments would have rights and privileges senior to those of our equity investors. In addition, servicing the interest and repayment obligations under these borrowings would divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we are unable to obtain adequate financing on a timely basis, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our business, financial condition and results of operations.

If the potential of our stem cell therapies to treat diseases is not realized, the value of our technology and our development programs could be significantly reduced.

The potential of our stem cell therapies to treat diseases is currently being explored by us. We have not proven in clinical trials that our stem cell therapy will be a safe and effective treatment for any disease. Our stem cell therapies are susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their marketing approval or commercial use. We have not treated a sufficient number of patients to allow us to make a determination that serious unintended consequences will not occur. If the potential of our stem cell therapies to treat disease is not realized, the value of our technology and our development programs could be significantly reduced. Because our biologic drug candidates are based on MSCs, any negative developments regarding the therapeutic potential or side effects of MSCs could have a material adverse effect on our business, financial condition and results of operations. At the six month time point of our randomized, double blind, placebo controlled Phase I/II clinical trial evaluating Chondrogen s ability to regenerate meniscus in patients who have had a significant portion of their meniscus surgically removed, the trial did not demonstrate that Chondrogen resulted in a statistically significant increase in the volume of meniscus as compared to placebo; however, Chondrogen met its primary endpoint, demonstrating product safety, and an improvement in baseline cartilage and joint condition was noted in patients treated with the stem cell drug but was not seen in patients that received placebo.

Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our therapeutics creates significant challenges in regards to product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, the FDA has relatively limited experience with stem cell therapies. None has been approved by the FDA for commercial sale, and the pathway to regulatory approval for our biologic drug candidates may accordingly be more complex and lengthy. Additionally, stem cells are subject to donor-to-donor variability, which can make standardization more difficult. As a result, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

There are no FDA approved treatments for some of the disease indications we are pursuing. This could complicate and delay FDA approval of our biologic drug candidates.

There are no drugs or therapies currently approved with stated indications for the first-line treatment of acute GvHD or the treatment of steroid refractory GvHD. As a result, the clinical efficacy endpoints, or the criteria to measure the intended results of treatment, for our biologic drug candidate Prochymal for the treatment of GvHD may be difficult to determine. In addition, patients battling GvHD and who, therefore, are candidates for treatment with Prochymal, are typically very ill as a result of an underlying genetic or oncologic condition. Due to the graveness of their underlying disease and the very serious complications and disorders that often accompany acute GvHD, many of these patients will die from causes other than GvHD prior to the completion of the study even if their GvHD responds favorably to treatment with Prochymal. The resulting reduction in the number of patients available for evaluation at the end of the study may make it more difficult for us to demonstrate efficacy, as necessary to obtain FDA approval to market Prochymal for commercial sale.

There are also no drugs or therapies currently approved with stated indications for the regeneration of meniscal tissue or the repair of heart muscle following heart attack. As a result, the clinical endpoints for our biologic drug candidates Chondrogen and Provacel may be difficult to determine. In the case of Prochymal for the treatment of Crohn s Disease, there are other products approved for the treatment of this disease, so it is expected that the clinical efficacy endpoints for Prochymal for this indication will be

established by comparison with these already approved treatments. In order to obtain FDA approval for this indication, we will have to demonstrate, among other things, that our biologic drug candidate is safe and effective. The results of our clinical trials must be statistically significant, meaning that there must be sufficient data to indicate that it is unlikely the outcome occurred by chance. These challenges may prevent us from developing and commercializing products on a timely or profitable basis, or at all.

Our biologic drug candidates represent new classes of therapy that the marketplace may not understand or accept.

Even if we successfully develop and obtain regulatory approval for our biologic drug candidates, the market may not understand or accept them. We are developing biologic drug candidates that represent novel treatments and will compete with a number of more conventional products and therapies manufactured and marketed by others, including major pharmaceutical companies. The degree of market acceptance of any of our developed and potential products will depend on a number of factors, including:

- the clinical safety and effectiveness of Osteocel and our biologic drug candidates and their perceived advantage over alternative treatment methods;

- our ability to demonstrate that Prochymal can have a clinically significant effect on steroid refractory GvHD;

- our ability to separate ourselves from the ethical controversies associated with stem cell drug candidates derived from human embryonic or fetal tissue;

- ethical controversies that may arise regarding the use of stem cells or human tissue of any kind, including adult stem cells, adult bone marrow and other adult tissues derived from donors, in the manufacture and sale for profit of Osteocel and our biologic drug candidates;

- adverse events involving our biologic drug candidates or the products or product candidates of others that are stem cell based;

- our ability to supply a sufficient amount of our product to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our products; and

- the cost of our products and the reimbursement policies of government and third-party payors.

If the health care community does not accept Osteocel or our potential products for any of the foregoing reasons, or for any other reason, it could affect our sales, having a material adverse effect on our business, financial condition and results of operations.

The successful commercialization of our biologic drug candidates, or any of our other potential stem cell therapeutics, will depend on obtaining reimbursement from third-party payors.

If we successfully develop and obtain necessary regulatory approvals, we intend to sell our biologic drug candidates initially in the United States and Europe. In the United States, the market for any pharmaceutical product is affected by the availability of reimbursement from third-party payors, such as government health administration authorities, private health insurers, health maintenance organizations and pharmacy benefit management companies. Stem cell therapies like Prochymal, Chondrogen and Provacel may be expensive compared with standard pharmaceuticals, due to the higher cost and complexity associated with the research, development and production of stem cell therapies, the small size and large geographic diversity of the target patient population for some indications, and the complexity associated with distribution of stem cell therapies which require special handling and shipment procedures and protocols. This, in turn, may make it more difficult for us to obtain adequate reimbursement from third-party payors, particularly if we cannot demonstrate a favorable cost-benefit relationship. Third-party

payors may also deny coverage or offer inadequate levels of reimbursement for our potential products if they determine that the product has not received appropriate clearances from the FDA or other government regulators or is experimental, unnecessary or inappropriate. For example, patients battling GvHD and who, therefore, are candidates for treatment with Prochymal, are typically very ill as a result of an underlying genetic or oncologic condition. Because these patients have a low probability of survival (whether or not their GvHD is successfully treated), third-party payors may resist reimbursing the cost of treatment.

In the countries of Europe and in some other countries, the pricing of prescription pharmaceutical products and services and the level of government reimbursement are subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct one or more clinical trials that compares the cost effectiveness of our biologic drug candidates or products to other available therapies. Conducting one or more clinical trials would be expensive and result in delays in commercialization of our products.

Managing and reducing health care costs has been a general concern of federal and state governments in the United States and of foreign governments. Although we do not believe that any recently enacted or presently proposed legislation should impact our business, we might be subject to future regulations or other cost-control initiatives that materially restrict the price we receive for our products. In addition, third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and many limit reimbursement for newly approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price for products that we may develop, which would result in lower product revenues to us.

Our dependence upon a limited supply of adult marrow-rich bone necessary to produce Osteocel may impact our ability to produce Osteocel on a large scale.

The production of Osteocel does not involve an expansion of MSCs and is therefore limited by the amount of adult human marrow-rich bone donations that are available to us. Since the introduction of Osteocel into the marketplace in July 2005, we have been unable to obtain quantities of adult human marrow-rich bone sufficient to meet the demand for Osteocel. Osteocel consists of primary, or unexpanded, MSCs in a matrix of viable cancellous bone. Cancellous bone is the porous and spongy inner structure of bones accounting for approximately 20% of total bone mass. The bone and cells are derived from human organ and tissue donors. We rely on the efforts of not-for-profit donor procurement agencies to educate the public and foster an increased willingness to donate bone tissue. These organizations may not be able to provide us with sufficient amounts of viable cancellous bone to meet present or future demand for Osteocel. Our inability to secure enough viable cancellous bone to meet our Osteocel demands could limit our ability to successfully market and drive market acceptance of Osteocel and may limit our potential revenues from Osteocel.

Our dependence upon a limited supply of bone marrow donors may impact our ability to produce sufficient quantities of our biologic drug candidates as necessary to complete our clinical trials, and if our trials are successful, to meet product demand.

The population of acceptable bone marrow donors is limited to volunteers between the ages of 18 and 30. In addition, potential donors are prescreened for a variety of health conditions and are only allowed to donate bone marrow a total of six times in their lifetime, further limiting the total number of potential donors. The amount of bone marrow donated may be insufficient for us to mass produce our biologic drug candidates. Future government regulation or health concerns may also reduce the number of donors or otherwise limit the amount of bone marrow available to us. If we cannot secure quantities of bone marrow

sufficient to meet the manufacturing demands for our clinical trials, we might not be able to complete our clinical trials and obtain marketing approval for our biologic drug candidates. Moreover, even if our clinical trials are successful and we obtain marketing approval for our biologic drug candidates, our inability to secure enough bone marrow to meet product demand would limit our potential revenues.

Osteocel and our biologic drug candidates are derived from human tissue and bone marrow sources and therefore have the potential for disease transmission.

The utilization of donated adult human cancellous bone and bone marrow creates the potential for transmission of communicable disease, including but not limited to human immunodeficiency virus, or HIV, viral hepatitis, syphilis, Creutzfeldt-Jakob disease, or the human form of mad cow disease, and other viral, fungal or bacterial pathogens. Although we are required to comply with federal and state regulations intended to prevent communicable disease transmission, and our suppliers of adult human bone and bone marrow are also required to comply with such regulations in connection with their collection, storage and supply to us:

- we or our suppliers may fail to comply with such regulations;
- even with compliance, our products might nevertheless be viewed by the public as being associated with transmission of disease; and
- a patient that contracts an infectious disease might assert that the use of our products resulted in disease transmission, even if the patient became infected through another source.

Any actual or alleged transmission of communicable disease could result in patient claims, litigation, distraction of management s attention and potentially increased expenses. Further, any failure in screening, whether by us or other manufacturers of similar products, could adversely affect our reputation, the support we receive from the medical community and overall demand for our products. As a result, such actions or claims, whether or not directed at us, could have a material adverse effect on our reputation with our customers and our ability to market our products, which could have a material adverse effect on our business, financial condition and results of operations.

We have only limited experience manufacturing Osteocel and our biologic drug candidates. We may not be able to manufacture Osteocel in quantities sufficient to expand our market for the product and may not be able to manufacture our biologic drug candidates in quantities sufficient for later stage clinical studies or for commercial sale.

We may encounter difficulties in the production of Osteocel and our biologic drug candidates due to our manufacturing capabilities. We have not built commercial-scale manufacturing facilities, and we have limited manufacturing experience with Osteocel and our biologic drug candidates. These difficulties could reduce sales of our products, increase our costs or cause production delays, any of which could damage our reputation and hurt our profitability. Even if we were to obtain access to quantities of adult marrow-rich bone sufficient to allow us otherwise to expand our Osteocel manufacturing capabilities, we may not be able to produce sufficient quantities of the product at an acceptable cost, or at all.

If we successfully obtain marketing approval for one of our biologic drug candidates, we may not be able to produce sufficient quantities of the product at an acceptable cost. Commercial-scale production of therapies made from live human mesenchymal stem cells involves production in small batches and strict adherence to complex manufacturing and storage protocols and procedures. Our biologic drug candidates are inherently more difficult to manufacture at commercial-scale than chemical pharmaceuticals, which are manufactured using precise chemical formulations and operational methods.

We use third-party collaborators to help us develop and commercialize our products, and our ability to commercialize such products may be impaired or delayed if collaborations are unsuccessful.

We have arrangements in place with third-party collaborators as a means to help us with research and development efforts or marketing and distribution. For example:

- we currently sell a large majority of our Osteocel product through a distribution arrangement with Blackstone Medical, Inc., which sells this product under the Blackstone brand Trinity ;

- we have a collaboration with Boston Scientific Corporation for cardiovascular applications of our MSC technology; and

- we have a collaboration with JCR Pharmaceuticals Co., Ltd. granting to JCR an exclusive right to Prochymal for the treatment of GvHD in Japan.

Although we have no current intention to do so, we may enter into additional collaborations in the future. We are dependent upon the success of our current and any future collaborators in performing their responsibilities and their continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development and commercialization of our potential products will be delayed if collaborators fail to conduct their responsibilities in a timely manner or if they breach or terminate their collaboration agreements with us. Disputes with our collaborators could result in product development delays, decreased revenues and litigation expenses. In addition, because our products may be marketed under a different brand name by our collaborators, as is the case in our relationship with Blackstone, should the relationship be terminated for any reason, our product recognition could be adversely impacted, affecting our product and potentially causing brand confusion in the market.

We are dependent upon third-party suppliers for services and raw materials needed for the manufacture, and we are dependent upon third parties for the distribution, of Osteocel and our biologic drug candidates. If any of these third parties fail or are unable to perform in a timely manner, our ability to manufacture and deliver will be compromised.

In order to produce our biologic drug candidates for use in clinical studies, and to produce Osteocel and any other of our biologic drug candidates that may be approved for commercial sale, we require biological media, reagents and other highly specialized materials. This is in addition to the adult marrow-rich bone donations used in the manufacture of Osteocel, and the bone marrow aspirate used in the manufacture of our biologic drug candidates. These items must be manufactured and supplied to us in sufficient quantities and in compliance with current Good Manufacturing Practices, or cGMP. To meet these requirements, we have entered into supply agreements with firms that manufacture these components to cGMP standards. Our requirements for these items are expected to increase if and when we transition to the manufacture of commercial quantities of our biologic drug candidates.

In addition, as we proceed with our clinical trial efforts, we must be able to demonstrate to the FDA that we can manufacture our biologic drug candidates with consistent characteristics. Accordingly, we are materially dependent on these suppliers for supply of cGMP-grade components of consistent quality. Our ability to complete ongoing clinical trials may be negatively affected in the event that we are forced to seek and validate a replacement source for any of these critical components. If we are not able to obtain adequate supplies of these items of consistent quality from our third-party suppliers, it will also be more difficult to manufacture commercial quantities of Osteocel or any of our current biologic drug candidates that may subsequently be approved for commercial sale.

In addition, we rely on third parties to distribute Osteocel and, if approved, our biologic drug candidates. Proper shipping and distribution requires compliance with specific storage and shipment procedures. For example, our products must be placed in a freezer within 72 hours of shipment. Failure to comply with these procedures or the occurrence of inadvertent damage to the shipping container will necessitate return and replacement, potentially resulting in additional cost and causing us to fail to meet supply requirements.

Use of third-party manufacturers may increase the risk that we will not have adequate quantities of our biologic drug candidates.

We have used third-party manufacturers to supply our biologic drug candidates for clinical trials. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured such components ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Our contract manufacturers are subject to all of the risks and uncertainties that we have when we manufacture on our own. Similar to us, they are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP regulations and other governmental regulations and corresponding foreign standards. However, we do not control compliance by our contract manufacturers with these regulations and standards. Our present or future manufacturers might not be able to comply with these regulatory requirements. If our third-party manufacturers fail to comply with applicable regulations, the FDA or other regulatory authorities could impose sanctions on us, including fines, injunctions, civil penalties, denial of marketing approval of our biologic drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of biologic drug candidates or our other products, operating restrictions and criminal prosecutions. Any of these actions could significantly and adversely affect supplies of our biologic drug candidates or other products and could have a material adverse effect on our business, financial condition and results of operations.

We have contracted with BioWhittaker (recently acquired by Lonza) to manufacture quantities of our stem cell drug candidates for our clinical trials. In addition, we are negotiating with a second contract manufacturing company, to supply us with biologic drug product. If we are unable to successfully negotiate this agreement or if these contract manufacturers are unable to supply sufficient product in a timely manner, we could experience shortages of clinical trial materials which would negatively impact our ability to complete our clinical trials and obtain marketing approval for the commercial sale of our biologic drug candidates. If one or both of these contract manufacturers is unable to ramp up production sufficiently, we may also not be able to meet anticipated market demand in the future.

If our processing and storage facility or our clinical manufacturing facilities are damaged or destroyed, our business and prospects would be negatively affected.

If our processing and storage facility or the equipment in the facility were to be significantly damaged or destroyed, we could suffer a loss of some or all of the stored units of our biologic drug candidates and it would force us to halt our clinical trial processes.

We have a manufacturing facility located in Baltimore, Maryland at which we produce and store stem cells for our clinical trials and Osteocel prior to sale. If this facility or the equipment in it is significantly damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity.

This facility is located on the Baltimore harbor, and in September 2003 it was flooded by Hurricane Isabel. This event resulted in a temporary suspension of our manufacturing operations. In the event of another temporary or protracted loss of this facility or equipment, we may be able to transfer manufacturing to a third party, but the shift would likely be expensive, and the timing would depend on availability of third-party resources and the speed with which we could have a new facility comply with the necessary regulatory requirements. Such an event could halt our clinical trials and distribution of Osteocel due to a lack of available product.

We entered into an agreement to sublease approximately 61,203 square feet of space in Columbia, Maryland beginning August 2006, and plan to begin manufacturing our biologic drug candidates in this facility in the fourth quarter of 2007.

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

Ethical and other concerns surrounding the use of stem cell therapy or human tissue may negatively affect public perception of us or our products or biologic drug candidates, or may negatively affect regulatory approval of our products or biologic drug candidates, thereby reducing demand for our products and adversely affecting the market price for our common stock.

The commercial success of Osteocel and our biologic drug candidates will depend in part on general public acceptance of the use of stem cell therapy and donated human tissue for the prevention or treatment of human diseases. The use of embryonic stem cells and fetal tissue for research and stem cell therapy has been the subject of substantial national and international debate regarding related ethical, legal and social issues. In the U.S., for example, federal government funding of embryonic stem cell research has been limited to specifically identified cell lines and is not otherwise available. We do not use embryonic stem cells or fetal tissue, but the public may not be able to, or may fail to, differentiate our use of adult stem cells from the use by others of embryonic stem cells or fetal tissue. This could result in a negative perception of our company or our products or biologic drug candidates.

We obtain our stem cells from volunteer adult bone marrow donors and we obtain cancellous human bone for the production of Osteocel from non-profit organizations that collect and process human organ and tissue donations. Bone marrow donors receive payment, but payment is not received by either human organ and tissue donors or their surviving family members. Ethical concerns have been raised by some about the use of donated human tissue in a for-profit setting, as we are doing.

Future adverse events in the field of stem cell therapy or changes in public policy could also result in greater governmental regulation of our products and biologic drug candidates and potential regulatory delays relating to the testing or approval of our biologic drug candidates.

We compete with other companies for funding and product sales. Many of our competitors have greater resources or capabilities than we have, or may already have or succeed in developing better products or in developing products more quickly than we do, and we may not compete successfully with them.

The pharmaceutical and biotechnology industries are highly competitive. We compete for funding and, if our products become available for commercial sale, we will compete in the market place. For funding, we compete primarily with other companies which, like us, are focused on developing novel products or therapies for the treatment of human disease based on stem cells or other novel scientific principles. These include Aastrom Biosciences, Advanced Cell Technology, Athersys, Cellerant Therapeutics, Cognate Therapeutics, Cytori Therapeutics, Gamida Cell, Geron, Mesoblast, MultiCell Technologies, Neuronyx, Theradigm, ViaCell, and StemCells.

In the marketplace, we compete or may eventually compete with other companies and organizations that are marketing or developing therapies for our targeted disease indications, based on traditional pharmaceutical, medical device or other, non-cellular therapy and technologies. These include: Johnson & Johnson, the manufacturer of CELLECT for the repair of bone, which competes with Osteocel; Medtronic and Stryker, the manufacturers of InFuse and OP-1, respectively, which compete with Osteocel; Novartis, the manufacturer of Neoral® for the prevention of organ rejection in transplant patients, which would compete with Prochymal for the treatment of GvHD; and Johnson & Johnson, the manufacturer of Remicade®, and Abbott, the manufacturer of Humira, which would compete with Prochymal for the treatment of Crohn s Disease. In addition to those listed above, we have other potential competitors developing a variety of therapeutics.

We also face competition in the cell therapy field from academic institutions and governmental agencies. Many of our current and potential competitors have greater financial and human resources than we have, including more experience in research and development and more established sales, marketing and distribution capabilities.

We anticipate that competition in our industry will increase. In addition, the health care industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render our current product or any future product non-competitive or otherwise obsolete.

The use of our stem cell therapies in human subjects may expose us to product liability claims, and we may not be able to obtain adequate insurance.

We face an inherent risk of product liability claims. Neither Osteocel nor any of our biologic drug candidates has been widely used over an extended period of time, and therefore our safety data are limited. We derive the raw materials for manufacturing Osteocel and our biologic drug candidates from human donor sources, the manufacturing process is complex, and the handling requirements are specific, all of which increase the likelihood of quality failures and subsequent product liability claims. We will need to increase our insurance coverage if and when we begin commercializing our biologic drug candidates. We may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all. If we are unable to obtain insurance, or if claims against us substantially exceed our coverage, then our business could be adversely impacted. Whether or not we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in:

- significant awards against us;
- substantial litigation costs;
- recall of the product;
- injury to our reputation;
- withdrawal of clinical trial participants; and
- adverse regulatory action.

Any of these results could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Intellectual Property

If our patent position does not adequately protect Osteocel, our biologic drug candidates or any future products, others could compete against us more directly, which would harm our business and have a material adverse effect on our financial condition and results of operations.

Our success depends, in large part, on our ability to obtain and maintain intellectual property protection for our biologic drug candidates. The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions and has been the subject of much litigation. Neither the U.S. Patent and Trademark Office nor the courts has a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology patents.

The claims of our existing U.S. patents and those that may issue in the future, or those licensed to us, may not confer on us significant commercial protection against competing products. Third parties may challenge, narrow, invalidate or circumvent any patents we own or may obtain in the future. Our patents on MSC technology, in particular, are quite broad in that they cover mesenchymal stem cells and the therapeutic use thereof. Patents with broad claims tend to be more vulnerable to challenge by other parties than patents with more narrowly written claims. Also, our pending patent applications may not issue, and we may not receive any additional patents. Further, the laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. We have filed a patent application covering the composition of matter and methods of manufacture of our commercially available product, Osteocel. This patent has not yet issued and there can be no assurances that it will ever issue. Osteocel is different from our other biologic drug candidates in that it contains primary, or unexpanded, MSCs in a matrix of cancellous bone. Because we do not have a granted patent specifically directed to Osteocel, and because FDA approval is generally not required for tissue based products like Osteocel, competitors might choose to enter this market and produce a substantially similar product that is not covered by a granted patent, whereby we may not be able to prevent the marketing and sale of any such similar products by others. Should others produce a substantially similar product, we will be subject to increased competition and our potential revenues from Osteocel sales may be limited.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. For instance, one of our base patents on MSC technology will expire in 2013. To the extent our biologic drug candidates based on that technology are not commercialized significantly ahead of this date, or to the extent we have no other patent protection on such products, those products would not be protected by patents beyond 2013. The background technologies used in the development of our biologic drug candidates are known in the scientific community, and it is possible to duplicate the methods we use to create our biologic drug candidates.

If we are unable to protect the confidentiality of our proprietary information and know-how, our competitive position would be impaired and our business, financial condition and results of operations could be adversely affected.

A significant amount of our technology, especially regarding manufacturing processes, is unpatented and is maintained by us as trade secrets. In an effort to protect these trade secrets, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual s

relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. For example, a portion of the manufacture of Osteocel is protected by trade secrets. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and could have a material adverse effect on our business, financial condition and results of operations.

If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business, financial condition and results of operations.

Our research, development and commercialization activities, including any biologic drug candidates or products resulting from these activities, may infringe or be claimed to infringe patents owned by third parties and to which we do not hold licenses or other rights. There may be applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or biologic drug candidate that is the subject of the suit.

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

As a result of patent infringement claims, or in order to avoid potential claims, we may choose or be required to seek a license from the third party. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also impact our collaborators, which would also impact the success of the collaboration and therefore us.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the United States Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. For example, the patent that was granted to us in Europe for human mesenchymal stem cells has been opposed in the European Patent Office by two different companies. A hearing date for the opposition has not been set, and the losing party has the right to appeal the initial decision. If we do not prevail in the opposition proceedings, we will not have broad patent protection with respect to mesenchymal stem cells in Europe. The outcome of the proceedings is uncertain at this time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their

substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace and, as a result, on our business, financial condition and results of operations.

We may become involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, which could be expensive and time consuming.

Competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. We are aware of several companies that are employing mesenchymal stem cell technology in their research and product development efforts. If such companies commercialize such products, there is no assurance that we would have a basis for initiating patent infringement proceedings or that if initiated we would prevail in such proceedings.

Interference proceedings brought by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Risks Related to Regulatory Approval and Other Government Regulations

If we are not able to successfully develop and commercialize our biologic drug candidates and obtain the necessary regulatory approvals, we may not generate sufficient revenues to continue our business operations.

In order to generate sales revenue from our biologic drug candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate that our biologic drug candidates are safe and effective and obtain required regulatory approvals. Our early stage biologic drug candidates may fail to perform as we expect. Moreover, our biologic drug candidates in later stages of development may fail to show the desired safety and efficacy traits despite having progressed successfully through preclinical or initial clinical testing. We will need to devote significant additional research and development, financial resources and personnel to develop commercially viable products and obtain the necessary regulatory approvals.

If our biologic drug candidates do not prove to be safe and efficacious in clinical trials, we will not obtain the required regulatory approvals. If we fail to obtain such approvals, we may not generate sufficient revenues to continue our business operations.

Even if we obtain regulatory approval of a product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities, which may create additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer or facility, may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, regulatory agencies may establish additional regulations that could prevent or delay regulatory approval of our products.

We cannot market and sell our biologic drug candidates in the United States or in other countries if we fail to obtain the necessary regulatory approvals or licensure.

We cannot sell our biologic drug candidates until regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain. It is likely to take two to three years or more to obtain the required regulatory approvals for our lead stem cell biologic drug candidate, Prochymal, or we may never gain the necessary approvals. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our operations and cause our stock price to decline significantly. Moreover, because our biologic drug candidates are all based on a single platform technology, MSCs, any adverse events in our clinical trials for one of our biologic drug candidates could negatively impact the clinical trials and approval process for our other biologic drug candidates.

To obtain marketing approvals in the United States for MSC products, for instance, we must, among other requirements, complete carefully controlled and well-designed clinical trials sufficient to demonstrate to the FDA that the biologic drug candidate is safe and effective for each disease for which we seek approval. Several factors could prevent completion or cause significant delay of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that MSCs are safe, effective and potent for use in humans. Negative or inconclusive results from or adverse medical events during a clinical trial could cause the clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful. The FDA can place a clinical trial on hold if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury. If safety concerns develop, we or the FDA could stop our trials before completion. Some participants in our MSC clinical trial have experienced serious adverse events, four of which have been determined to be possibly related to MSCs and one of which has been determined to be probably related. A serious adverse event is an event that results in significant medical consequences, such as hospitalization, disability or death, and must be reported to the FDA. We cannot assure you that safety concerns regarding MSCs will not develop.

The pathway to regulatory approval for MSCs may be more complex and lengthy than for approval of a new conventional drug. Similarly, to obtain approval to market our stem cell products outside of the United States, we will need to submit clinical data concerning our products and receive regulatory approval from governmental agencies, which in certain countries includes approval of the price we intend to charge for our product. We may encounter delays or rejections if changes occur in regulatory agency policies during the period in which we develop a biologic drug candidate or during the period required for review of any application for regulatory agency approval. If we are not able to obtain regulatory approvals for use of our biologic drug candidates under development, we will not be able to commercialize such products, and therefore may not be able to generate sufficient revenues to support our business.

If we are not able to conduct our clinical trials properly and on schedule, marketing approval by FDA and other regulatory authorities may be delayed or denied.

The completion of our clinical trials may be delayed or terminated for many reasons, including, but not limited to, if:

- the FDA does not grant permission to proceed and places the trial on clinical hold;
- subjects do not enroll in our trials at the rate we expect;
- subjects experience an unacceptable rate or severity of adverse side effects;
- third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice and regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or Institutional Review Boards (IRBs) of research institutions participating in our clinical trials, find regulatory violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit us from using some or all of the data in support of our marketing applications; or
- one or more IRBs suspends or terminates the trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial.

Our development costs will increase if we have material delays in our clinical trials, or if we are required to modify, suspend, terminate or repeat a clinical trial. If we are unable to conduct our clinical trials properly and on schedule, marketing approval may be delayed or denied by FDA.

We may not be able to secure and maintain research institutions to conduct our clinical trials.

We rely on research institutions to conduct our clinical trials. Specifically, the limited number of bone marrow transplant centers further heightens our dependence on such research institutions for the Phase III Prochymal trial. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreement with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. We may not be able to secure and maintain suitable research institutions to conduct our clinical trials.

Final marketing approval of our biologic drug candidates by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

Any of the following factors may cause final marketing approval for our biologic drug candidates to be delayed, limited or denied:

- our biologic drug candidates require significant clinical testing to demonstrate safety and effectiveness before applications for marketing approval can be filed with the FDA;
- data obtained from preclinical and nonclinical animal testing and clinical trials can be interpreted in different ways, and the FDA may not agree with our interpretations;
- it may take many years to complete the testing of our biologic drug candidates, and failure can occur at any stage of the process;
- negative or inconclusive results or adverse side effects during a clinical trial could cause us to delay or terminate development efforts for a biologic drug candidate; and

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- commercialization may be delayed if the FDA requires us to expand the size and scope of the clinical trials.

If marketing approval for our biologic drug candidates is delayed, limited or denied, our ability to market products, and our ability to generate product sales, would be adversely affected.

Should the FDA decide that Osteocel does not meet the appropriate regulatory requirements, we will be required to stop production, which will have a material adverse effect on our business, financial condition and results of operations.

The FDA has developed a tiered, risk-based regulatory framework, which includes criteria for facility management, quality assurance, donor selection, and processing of human cells, tissues, and cellular and tissue based products. We believe that commercial sale of Osteocel does not require pre-market approval by the FDA because we believe that it meets the regulatory definition of human cells, tissue, and cellular and tissue-based products, or HCT/Ps. However, should the FDA decide that Osteocel does not meet the regulatory definition of HCT/Ps, we will not be able to produce and sell Osteocel until we obtain FDA approval, which could take years to obtain and which could have a material adverse effect on our business, financial condition and results of operations.

Producing and marketing an approved drug or other medical product is subject to significant and costly post-approval regulation.

It is likely that Prochymal, if approved based on our currently contemplated Phase III trial, will receive conditional approval by the FDA, and we will be required to conduct Phase IV clinical trials to obtain full approval. Even if we obtain full approval of a product, that approval is subject to limitations on the indicated uses for which we can market it. After granting marketing approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities, creating additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, regulatory agencies may establish additional regulations that could prevent or delay marketing approval of our products.

Our business involves the use of hazardous materials that could expose us to environmental and other liability.

We have facilities in Maryland that are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. In the United States, these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. We cannot assure you that accidental contamination or injury to our employees and third parties from hazardous materials will not occur. We do not have insurance to cover claims arising from our use and disposal of these hazardous substances other than limited clean-up expense coverage for environmental contamination due to an otherwise insured peril, such as fire.

We may not be able to obtain or maintain Orphan Drug designation for our biologic drug candidates.

Some jurisdictions, including Europe and the United States, may designate drugs for relatively small patient populations as orphan drugs. Although the FDA and it s European counterpart, EMFA have designated Prochymal for the treatment of steroid refractory GvHD as an orphan drug, none of our other biologic drug candidates have received such designation. Orphan Drug designation does not convey any

advantage in, or shorten the duration of, the regulatory review and approval process, but does make the product eligible for orphan drug exclusivity, reduced filing fees and specific tax credits. Generally, if a company receives the first marketing approval for a product with an Orphan Drug designation in the clinical indication for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that the health authorities will not approve another application to market the same drug for the same indication, except in limited circumstances, for a period of seven years in the United States and ten years in Europe. This exclusivity, however, could block the approval of our biologic drug candidates if a competitor obtains marketing approval before us. Even if we obtain orphan drug exclusivity for any of our biologic drug candidates, we may not be able to maintain it. For example, if a competitive product is shown to be clinically superior to our product, any orphan drug exclusivity we have will not block the approval of such competitive product.

The Fast Track designation for development of any of our products may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood the biologic drug candidate will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification. Although we have obtained a Fast Track designation from the FDA for Prochymal for the treatment of GvHD and treatment refractory Crohn s Disease, receipt of Fast Track designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw our Fast Track designation at any time. If we lose our Fast Track designation, the approval process may be delayed. In addition, our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that Prochymal will receive regulatory approval for the treatments of steroid refractory GvHD or Crohn s Disease.

Risks Related to Our Common Stock

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

Our stock price is volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price they paid for it. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of our biologic drug candidates or those of our competitors;
- regulatory developments in the United States and foreign countries;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts reports or recommendations;

- sales of substantial amounts of our stock by existing stockholders;
- sales of our stock by insiders and 5% stockholders;
- general economic, industry and market conditions;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- expiration or termination of our relationships with our collaborators; and
- the other factors described in this Risk Factors section.

In addition, in the past, stockholders have initiated class action lawsuits against biotechnology and pharmaceutical companies following periods of volatility in the market prices of these companies stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and beneficial owners of 5% or more of our common stock and their affiliates, in aggregate, beneficially own approximately 50% of our outstanding common stock as of December 31, 2006. These persons, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with our interests or the interests of other stockholders.

In addition, Peter Friedli, our Chairman of the Board of Directors, and certain entities with which he is affiliated, beneficially own approximately 47% of our outstanding common stock as of December 31, 2006. Accordingly, Mr. Friedli currently has, and will continue to have, a significant influence over the outcome of all corporate actions requiring stockholder approval.

Certain provisions of Delaware law and of our charter documents contain provisions that could delay and discourage takeover attempts and any attempts to replace our current management by stockholders.

Certain provisions of our certificate of incorporation and bylaws, and applicable provisions of Delaware corporate law, may make it more difficult for or prevent a third party from acquiring control of us or changing our Board of Directors and management. These provisions include:

- the ability of our Board of Directors to issue preferred stock with voting or other rights or preferences;
- the inability of stockholders to act by written consent;
- a classified Board of Directors with staggered three-year terms;
- requirements that special meetings of our stockholders may only be called by the chairman of our Board of Directors, upon request of stockholders holding at least 20% of our capital stock issued and outstanding, or upon a resolution adopted by, or an affirmative vote of, a majority of our Board of Directors; and
- requirements that our stockholders comply with advance notice procedures in order to nominate candidates for election to our Board of Directors or to place stockholders proposals on the agenda for consideration at meetings of stockholders.

We will also be afforded the protections of Section 203 of the Delaware General Corporation Law, which will prevent us from engaging in a business combination with a person who acquires at least 15% of our common stock for a period of three years from the date such person acquired such common stock, unless advance board or stockholder approval was obtained.

Any delay or prevention of a change of control transaction or changes in our Board of Directors or management could deter potential acquirors or prevent the completion of a transaction in which our stockholders could receive a substantial premium over the then current market price for their shares.

Item 1B. UNRESOLVED STAFF COMMENTS

Not Applicable

Item 2. PROPERTIES

Our corporate headquarters are currently located in Baltimore, Maryland, where we lease approximately 118,000 square feet, currently at a rent of approximately $1.1 million per annum. This lease expires in September 2008. We have an option to renew this lease through 2023 and have not made a decision regarding the exercise of our renewal options. Since August 2006, we have subleased approximately 61,000 square feet of space in Columbia, Maryland at a rent of approximately $0.8 million per annum. This sublease expires in May 2009. We have also entered into a direct lease with the owner of the facility that will become effective upon expiration of the sublease. This direct lease terminates in July 2016 and includes options to extend the term of the lease for two additional five-year periods. We moved our administrative offices to the Columbia facility in March 2007, and during the fourth quarter of 2007 we expect to move our manufacturing facilities for our biologic drug candidates to the Columbia building. Our tissue manufacturing facilities will remain in Baltimore.

Item 3. LEGAL PROCEEDINGS

Lawsuits and claims are filed against us from time to time in the ordinary course of our business, including without limitation, challenges to our intellectual property positions. We do not believe that any lawsuits or claims, or proceedings, currently pending against us, individually or in the aggregate, are material, or will have a material adverse effect on our financial condition or business.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our security holders during the fourth quarter of the year ended December 31, 2006.

Item 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our Common Stock began trading on the NASDAQ Global Market on August 4, 2006 under the symbol OSIR . The following table sets forth, the high and low sales prices for the Common Stock, as reported by the NASDAQ Global Market, during the periods indicated.

	High	Low
Fiscal Year Ended December 31, 2006		
Fourth Quarter	$ 27.93	$ 10.00

Stockholders

As of March 7, 2007, there were approximately 1,023 stockholders of record or our Common Stock and, according to our estimates, approximately 1,726 beneficial owners of the Common Stock.

Dividends

We have not paid dividends to our stockholders since our inception and we do not plan to pay cash dividends in the foreseeable future. We currently intend to retain earnings, if any, to finance our growth.

Unregistered Sales of Securities

On October 30, 2006, the Company issued an aggregate of $20 million in convertible promissory notes, placed by Friedli Corporate Finance, Inc., as further described in Item 2.03 of our Current Report on Form 8-K filed with the United States Securities and Exchange Commission on October 30, 2006, which is incorporated herein by reference.

From January 1, 2006 through December 31, 2006, we sold and issued the following unregistered securities without the involvement of underwriters or placement agents:

(a) In April 2006, we issued 6,250 restricted shares of our common stock to our non-employee medical director as compensation. Twenty-five percent of these shares vest immediately and the balance vest ratably over the following three years.

(b) In January 2006, we issued 12,500 shares of our common stock to a non-management director in connection with his successful fundraising activities during 2005.

(c) In April 2006, we issued 10,000 shares of our common stock to non-management directors as compensation.

(d) In June 2006, we issued 307 shares of our common stock to a former non-management director as compensation.

(e) In May 2006, we issued warrants to purchase 1,000,000 shares of our common stock, with an exercise price equal to the initial public offering price of $11.00 per share, to a non-management director. These warrants expire five years after grant.

(f) In September 2006, options to purchase an aggregate of 95,000 shares of our common stock were exercised by two of our executive officers under our Amended and Restated 1994 Stock Incentive Plan.

The sale and issuance of the securities described in paragraphs (a) through (e) above were issued in reliance upon the exemption from the registration requirements of the Securities Act as set forth in Section 4(2) under the Securities Act and Rule 506 of Registration D promulgated there under relating to sales by an issuer not involving any public offering, to the extent an exemption from such registration was required. The purchasers of our securities described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. The sales of these securities were made without general solicitation or advertising.

The sale and issuance of the securities described in paragraph (f) above were issued were issued in reliance upon the exemption from the registration requirements of the Securities Act as set forth in

Section 4(2) under the Securities Act, and as set forth in Rule 701 promulgated thereunder in that they were offered and sold pursuant to a written compensatory benefit plan, as provided in Rule 701.

Issuer Purchase of Equity Securities and Use of Proceeds

There were no repurchases by us of our securities during fiscal 2006.

On August 4, 2006, we sold 3,500,000 shares of our common stock in our initial public offering at the price to the public of $11.00 per share. The offer and sale of all of the shares in the offering were registered under the Securities Act of 1933, as amended, pursuant to a registration statement on Form S-1 (File No. 333-13407), which was declared effective by the Securities and Exchange Commission on August 3, 2006. The underwriters of the offering were Jefferies & Company, Inc., Lazard Capital Markets, LLC and Leerink Swann & Co., Inc. There were no selling stockholders in the offering.

We registered 3,500,000 shares of our common stock in connection with the initial public offering and the aggregate offering amount was $38.5 million. We paid approximately $2.7 million in underwriting discounts and commissions to the underwriter. We also incurred other expenses in connection with the offering of approximately $1.4 million, including registration fees, accounting and legal, printing and engraving and other expenses.

None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates, to persons owning 10 percent or more of our common stock or to any affiliates or ours.

After deducting the underwriting discounts and commissions and these other estimated offering expenses, our net proceeds from the offering were approximately $34.4 million. We deposited the net proceeds in two highly rated financial institutions in the United States.

There has been no material change in our planned use of proceeds from our initial public offering as described in our final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b). Between August 3, 2006 and December 31, 2006, we used approximately $10.5 million of the net proceeds to fund our operating activities, including activities relating to the development of our biologic drug candidates and for working capital, capital expenditures, repayment of debt and other general corporate purposes. During this period, our research and development expenses comprised approximately 94% of our operating expenses. The remaining approximately $23.9 million in net proceeds remains on deposit in two highly rated financial institutions in the United States. At December 31, 2006, we had $39.2 million in cash and short-term investments.

Stock Performance Graph

The following graph shows the cumulative total return, assuming the investment of $100 on August 4, 2006 (based upon the closing price of our common stock on August 4, 2006, the first day of trading on the NASDAQ Global Market), on an investment in each of the Company s common stock, the NASDAQ Composite Index (U.S. and Foreign) and the NASDAQ Biotechnology Index. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of the Company s common stock.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 201(d) of Regulation S-K, pursuant to paragraph (a) of this Item 5, is incorporated by reference to the information set forth under the caption Equity Compensation Plan Information in the Company s Proxy Statement for the 2007 Annual Meeting of Stockholders, which is anticipated to be filed pursuant to Regulation 14A no later than one hundred twenty (120) days following the end of the fiscal year reported on.

Item 6. SELECTED FINANCIAL DATA

We derived the selected financial data presented below for the periods or dates indicated from our financial statements. Our financial statements for these periods were audited by Stegman & Company, an independent registered public accounting firm. You should read the data below in conjunction with our financial statements, related notes and other financial information appearing in Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Year Ended December 31,				
	2002	2003	2004	2005	2006
	(in thousands, except per share data)				
Statement of Operations Data:					
Product sales	$	$	$	$ 957	$ 8,291
Cost of goods sold				444	3,697
Gross profit				513	4.594
Revenue from collaborative research licenses and grants	1,217	3,981	3,911	3,013	1,181
Operating expenses:					
Research and development	11,206	18,639	11,888	16,927	37,590
General and administrative and other expenses	4,096	4,467	1,704	2,294	8,459
Total operating expenses	15,302	23,106	13,592	19,221	46,049
Loss from operations	(14,085)	(19,125)	(9,681)	(15,695)	(40,274)
Interest expense, net	(5,033)	(605)	(847)	(4,300)	(4,685)
Net loss	$ (19,118)	$ (19,730)	$ (10,528)	$ (19,995)	$ (44,959)
Basic and diluted net loss per share	$ (8.69)	$ (3.60)	$ (1.19)	$ (2.23)	$ (2.70)
Weighted average shares of common stock used in computing basic and diluted net loss per share	2,201	5,475	8,814	8,959	16,663

	At December 31,				
	2002	2003	2004	2005	2006
Balance Sheet Data:					
Cash and short-term investments	$ 394	$ 1,339	$ 488	$ 43,371	$ 39,181
Working capital	(34,495)	(5,314)	(7,893)	38,103	33,166
Total assets	8,525	9,748	5,972	51,014	49,168
Notes payable, less current portion	245	179	7,519	47,411	25,000
Mandatorily redeemable convertible preferred stock				64,267	
Convertible preferred stock		13,000	15,243	32,746	
Accumulated deficit	(92,291)	(112,021)	(122,549)	(142,544)	(187,503)
Total stockholders equity (deficit)	(26,476)	(5,563)	(13,004)	(73,662)	11,287

Quarterly Financial Data (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
2006				
Total revenues	$ 1,400	$ 1,987	$ 2,841	$ 3,244
Product sales	1,105	1,689	2,539	2,958
Cost of goods sold	489	762	1,113	1,333
Research and development expenses	4,368	10,922	9,242	13,058
General and administrative expenses and fees	1,138	1,209	5,300	812
Net loss	(5,121)	(11,605)	(15,565)	(12,668)
**Net loss per common share, basic and diluted	(0.56)	(1.27)	(0.75)	(0.46)
2005				
Total revenues	$ 385	$ 1,339	$ 1,285	$ 961
Product sales			284	673
Cost of goods sold			220	224
Research and development expenses	2,657	3,592	3,464	7,214
General and administrative expenses and fees	752	487	554	501
Net loss	(3,868)	(2,740)	(4,678)	(8,055)
**Net loss per common share, basicand diluted	(0.43)	(0.38)	(0.52)	(0.88)

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

Item 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a leading stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Our marketed product, Osteocel, and our biologic drug candidates utilize mesenchymal stem cells, or MSCs. In July 2005, we launched Osteocel for regenerating bone in orthopedic indications. We currently have five clinical trials ongoing. We are currently enrolling patients in a Phase III clinical trial for Prochymal, our lead biologic drug candidate, for the treatment of steroid refractory Graft versus Host Disease, or GvHD. We were recently given clearance to conduct a Phase III trial using Prochymal to treat Crohn s Disease. In addition, we have two other clinical stage biologic drug candidates, Chondrogen for regenerating cartilage in the knee, and Provacel for repairing heart tissue following a heart attack. We have developed stem cell capabilities in research and development, manufacturing, marketing and distribution. We manufacture Osteocel and clinical batches of our biologic drug candidates. We, together with AlloSource, distribute Osteocel in orthopedic indications and jointly distribute Osteocel with Blackstone Medical, Inc., a division of Orthofix International, N.V., for spinal procedures.

We have incurred annual operating losses since inception and expect to incur substantial operating losses in the future in connection with the development of our core products. As of December 31, 2006, we had an accumulated deficit of $187.5 million.

Financial Operations Overview

Revenue

Osteocel is our only commercial product. Sales of Osteocel generated revenue of approximately $8.3 million for the year ended December 31, 2006. In prior years, we have entered into strategic agreements with other companies for the development and commercialization of select stem cell biologic drug candidates for specific indications and geographic markets. In 2003, we entered into an agreement with a major pharmaceutical company relating to the development of our cardiac biologic drug candidate, and we received a $5.0 million fee for licensing the use of our technology. This fee is being recognized as revenue over a 63-month period, $1.0 million of which was recognized in 2006 and 2005. Also in 2003, we entered into an agreement with a foreign pharmaceutical company granting it exclusive rights to Prochymal for the treatment of GvHD in Japan. We recognized $0.5 million of revenue during 2005 related to this agreement.

Historically, we have also recognized revenue from governmental grants for research and in 2005, we recorded $1.4 million in grant revenues from three separate grants. Revenue from research grants is recognized as the related research expenditures are incurred. During 2006, we did not have any active government grants and we presently do not expect to solicit governmental grants in the future.

Other than Osteocel, we have no commercial products for sale. A substantial portion of our revenue in the future will be dependent on the approval and sale of our biologic drug candidates. Our revenue may vary substantially from quarter to quarter and from year to year. We believe that period-to-period comparisons of our results of operations are not meaningful and should not be relied upon as indicative of our future performance.

Cost of Goods Sold

Our cost of goods sold relate to direct costs of producing Osteocel, which we launched in July 2005. Cost of goods sold consist primarily of the costs of obtaining tissue and other chemicals and supplies, direct labor and allocated costs of our facilities and overhead.

Research and Development Costs

Our research and development costs consist of expenses incurred in identifying, developing and testing biologic drug candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for independent monitoring and analysis of our clinical trials, costs of contract research and manufacturing, costs of facilities, and the costs of manufacturing clinical batches of biologic drug candidates, quality control supplies and material to expand biologic drug candidates.

Consistent with our focus on the development of biologic drug candidates with potential uses in multiple indications, many of our costs are not attributable to a specifically identified product. We use our employee and infrastructure resources across several projects. Accordingly, we do not account for internal research and development costs on a project-by-project basis. As a result, we cannot state precisely the total costs incurred for each of our clinical and preclinical projects on a project-by-project basis. From inception through December 31, 2006, we incurred aggregate research and development costs of approximately $183 million.

We expect our research and development expenses to increase substantially in the future, as we expand our clinical trial activity, as our biologic drug candidates advance through the development cycle and as we invest in additional product opportunities and research programs. Clinical trials and preclinical studies are time-consuming and expensive. Our expenditures on current and future preclinical and clinical development programs are subject to many uncertainties. We test our products in several preclinical

studies, and we then conduct clinical trials for those biologic drug candidates that we determine to be the most promising. As we obtain results from clinical trials, we may elect to discontinue or delay trials for some biologic drug candidates in order to focus our resources on more promising biologic drug candidates. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, size of trial and intended use of a biologic drug candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the length of time required to enroll trial participants;
- the duration of patient treatment and follow-up;
- the costs of producing supplies of the biologic drug candidates needed for clinical trials and regulatory submissions;
- the efficacy and safety profile of the biologic drug candidate; and
- the costs and timing of, and the ability to secure, regulatory approvals.

As a result of the uncertainties discussed above, we are unable to determine with any significant degree of certainty the duration and completion costs of our research and development projects or when and to what extent we will generate revenues from the commercialization and sale of any of our biologic drug candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of the costs associated with our general management, including salaries, allocations of facilities and related costs, and professional fees such as legal and accounting expenses. In anticipation of and since the closing of our initial public offering in August 2006, we began to incur increases in our general and administrative expense for legal and accounting compliance costs, investor relations and other activities associated with operating as a publicly traded company. Continued increases will also likely result from additional the hirings of operational, financial, accounting, facilities engineering and information systems personnel.

Interest and Other Income (Expense), Net

Interest income consists of interest earned on our cash and short-term investments. Interest expense consists of interest incurred on capital leases and other debt financings. We pay interest on our bank loan, capital leases and our convertible long-term debt.

Income Taxes

We have not recognized any deferred tax assets or liabilities in our financial statements since we cannot assure their future realization. Because realization of deferred tax assets is dependent upon future earnings, a full valuation allowance has been recorded on the net deferred tax assets, which relate primarily to net operating loss and research and development carry-forwards. In the event that we become profitable within the next several years, we have net deferred tax assets of approximately $70 million that may be utilized prior to us having to recognize any income tax expense or make payments to the taxing authorities. Utilization of our net operating loss carry-forwards in any one year may be limited however, and we could be subject to the alternative minimum tax.

Critical Accounting Policies

General

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, deferred tax assets, stock-based compensation, and contingencies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable. These results form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following critical accounting policies reflect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Our revenue recognition policies are governed by the Securities and Exchange Commission s, or SEC, Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*.

We have one commercial product on the market. We recognize revenue on sales when legal title to the product has passed to the customer, which is usually when the product is shipped from our Baltimore, Maryland facilities. We have agreements with our customers that specify the terms of sale, including price.

Revenues from collaborative agreements and grants are recognized as earned upon either the incurring of reimbursable expenses directly related to the particular research plan or the completion of certain development milestones as defined within the terms of the collaborative agreement. Payments received in advance of research performed are designated as deferred revenue. We recognize non-refundable upfront license fees and certain other related fees on a straight-line basis over the development period. Fees associated with substantive at risk, performance based milestones are recognized as revenue upon their completion, as defined in the respective agreements. Incidental assignment of technology rights is recognized as revenue at the time of receipt.

Milestone payments that are based on designated achievement points and that are considered at risk and substantive at the inception of the collaboration are recognized as earned when the corresponding payment is considered reasonably assured. We evaluate whether milestone payments are at risk and substantive based on the contingent nature of the milestone, specifically reviewing factors such as the technological and commercial risk that must be overcome and the level of the investment required. Milestone payments that are not considered at risk and substantive are recognized, when achieved, in proportion to the percentage of the collaboration completed through the date of achievement. The remainder of the milestone payment is recognized as services are performed over the remaining term of the collaboration.

Royalties for the use of our MSCs for clinical research purposes are recognized when earned, however, such amounts have not been material and are not expected to be material in the future. Additionally, we may receive royalty payments under our collaborative arrangements upon sales of product.

We evaluate all collaborative agreements on a quarterly basis to determine the appropriate revenue recognition for that period. The evaluation includes all of the potential revenue components from each specific collaborative agreement.

Accounts Receivable

Our accounts receivable are reported at their net realizable value. As of December 31, 2006 and 2005, there was no allowance for doubtful accounts as we believe the reported amounts are fully collectible. During the year ended December 31, 2006, we recognized $3 of bad debt expense. We did not recognize any bad debt expense for the years ended December 31, 2005 and 2004. Accounts receivable balances are not collateralized.

Stock-Based Compensation

Prior to January 1, 2006, as permitted by the provisions of Statement of Financial Accounting Standards, SFAS, No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure,* and SFAS No. 123, *Accounting for Stock-Based Compensation,* our employee stock option plan was accounted for under Accounting Principles Board Opinion No. 25, APB 25, *Accounting for Stock Issued to Employees.* We grant qualified stock options for a fixed number of shares to employees and directors with an exercise price equal to the fair market value of the shares at the date of grant. Prior to January 1, 2006, in these circumstances and in accordance with APB 25, we recognized no compensation expense for qualified stock option grants. We have issued some non-qualified stock options for a fixed number of shares to employees and directors with an exercise price less than the fair market value of the shares at the date of grant. As such options vest, we will recognize the difference between the exercise price and fair market value at date of grant as compensation expense in accordance with APB 25. For share-grants of common stock to directors, we record the intrinsic value of the shares granted based upon the estimated fair value on the date of grant.

In December 2004, FASB issued SFAS No. 123(R) (revised 2004), *Share-Based Payment.* This Statement is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation.* This Statement supersedes APB 25 and its related implementation guidance. We adopted SFAS No. 123(R) on January 1, 2006, and now expense stock options using a fair-value method in our statement of operations. Adoption of the expensing requirements has increased our net loss. See Stock-Based Compensation in Note 6 of our financial statements for disclosures regarding the effect on net earnings and earnings per share if we had applied the fair value recognition provisions of SFAS No. 123(R) prior to January 1, 2006. We use the modified prospective method. Under this method, compensation cost is recognized beginning with the effective date of adoption (a) based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date of adoption and (b) based on the requirements of SFAS 123(R) for all awards granted to employees prior to the effective date of adoption that remain unvested on the date of adoption. We currently utilize the Black-Scholes option pricing model to estimate the fair value. The Black-Scholes model meets the requirements of SFAS 123(R), but the fair values generated by the model may not be indicative of the actual fair values of our stock-based awards.

Significant New Accounting Pronouncements

In May 2005, the Financial Accounting Standards Board (FASB) issued SFAS No. 154, Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS No. 154 requires retrospective application to prior periods financial statements for changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS No. 154 also requires that a change in depreciation, amortization, or depletion method for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS No. 154 is effective for accounting

changes and corrections of errors made in fiscal years beginning after December 15, 2005. The implementation of SFAS No. 154 on January 1, 2006 did not have a material impact on the results of operations, financial position or cash flows.

In November 2005, FASB issued, FASB Staff Position (FSP) FAS 115-1 and FAS 124-1, The meaning of Other-than-Temporary Impairment and Its Application to Certain Investments (FSP 115-1) which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of an other-than temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP 115-1 is effective for reporting periods beginning after December 15, 2005. Our adoption of FSP 115-1 on January 1, 2006 did not have a material impact on our results of operations, financial position or cash flows.

In July 2006, FASB issued FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes, an interpretation of FASB No. 109 (FIN 48) that clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAF 109, Accounting for Income Taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement effects of a tax position when it is more likely than not of being sustained on examination, based on the technical merits of the position. In addition, FIN 48 indicates that the measurement of a tax position that meets the more likely than not threshold shall consider the amounts and probabilities of the outcomes that could be realized upon ultimate settlement. This interpretation is effective for fiscal years beginning after December 15, 2006. We expect the impact of adopting FIN 48 to be immaterial.

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year s financial statements are materially misstated. SAB 108 is effective for fiscal years ending after November 15, 2006. The implementation of SAB 108 did not have a material impact on the results of operations, financial position or cash flows.

Results Of Operations

Comparison of Years ended December 31, 2006 and 2005

Revenue

Total revenues increased 138% to $9.5 million for the twelve months ended December 31, 2006, compared to $4.0 million in the corresponding period in 2005. Our revenues in 2006 resulted primarily from $8.3 million generated from the sale of Osteocel and the recognition of $1.2 million in licensing fees and royalties. In the twelve months ended December 31, 2005, we recognized $1.0 million from the sale of Osteocel and $3.0 million in license fees and grants.

Cost of Goods Sold

Cost of goods sold were $3.7 million for the twelve months ended December 31, 2006 compared to $0.4 million in the prior year. The cost of goods sold associated with sales of Osteocel was comprised of payments to tissue banks, direct labor costs and the costs of processing, testing and preserving Osteocel, plus allocated costs of our facilities and overhead. The gross margin on Osteocel sales for the twelve months ended December 31, 2006 was 56%, compared with 54% for 2005.

Research and Development Expenses

Research and development expenses were approximately $37.5 million for the twelve months ended December 31, 2006 compared to $16.9 million in the prior year. The increase in research and development expenses in 2006 reflects the increased number of clinical trials in process versus the prior year. In 2006, we incurred costs associated with the enrollment of a Phase II trial for Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD, a Phase II trial for Prochymal for treatment of steroid refractory GvHD, a Phase II trial for Prochymal for treatment of Crohn s Disease, a Phase I/II clinical trial for Chondrogen, and a Phase I clinical trial for Provacel.

General and Administrative Expenses

General and administrative expenses were $4.4 million for the twelve months ended December 31, 2006 compared to $2.2 million in the prior year. The increase in 2006 includes $0.9 million of non-cash charges associated with the completion of our initial public offering. Exclusive of these charges, general and administrative expenses in 2006 were $3.5 million and the increase over the prior year was attributable to additional personnel and related costs to support the company s growth and costs incurred in connection with being a public company.

Related party expenses

Fees paid to related parties were $0.6 million for the twelve months ended December 31, 2006 compared to $0.1 million in the prior year. In 2006, we recorded $3.5 million in non-cash charges related to warrants issued to our chairman that were priced and vested upon completion of our initial public offering and $0.2 million in share-based compensation for stock awards for services of our board of directors

Interest Expense, Net

Interest expense, net was $4.7 million for the twelve months ended December 31, 2006 compared to $4.3 million in the prior year. The 2006 costs include $2.7 million of previously deferred debt financing costs and premiums associated with debt that was converted into common stock upon the completion of our initial public offering. Exclusive of these charges, net interest expense during 2006 was $2.0 million, a decrease of $2.3 million compared to 2005. This decrease is the result of higher interest income related to the investment of the proceeds of the initial public offering and the $21.8 million decrease in debt, which was converted into common stock upon the completion of the initial public offering in early August 2006.

Comparison of Years ended December 31, 2005 and 2004

Revenue

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

Cost of Goods Sold

Cost of goods sold were $0.4 million for the year ended December 31, 2005 compared to none in the prior year. We launched Osteocel in July 2005. The cost of goods sold associated with sales of Osteocel was comprised of payments to tissue banks and the costs of processing, testing and preserving Osteocel.

Research and Development Expenses

Research and development costs were approximately $16.9 million for the year ended December 31, 2005 compared to $11.9 million in the prior year. The increase in research and development expenses in 2005 reflects the costs we incurred in the initiation of a Phase II trial for Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD, a Phase II trial for Prochymal for treatment of steroid refractory GvHD, a Phase I/II clinical trial for Chondrogen, and a Phase I clinical trial for Provacel during the year. Of the $16.9 million in 2005 research and development costs, approximately $7.4 million is attributable to external research and clinical trials, $3.9 million to the cost of science supplies including research materials for cell manufacture, media and testing supplies, $3.4 million to payroll and related expenses for personnel, and $2.2 million to facilities and equipment costs.

General and Administrative Expenses

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

Interest Expense, Net

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

Liquidity and Capital Resources

Liquidity

At December 31, 2006, we had $0.7 million in cash and $38.5 million in short-term investments. In addition to the cash and short-term investments, at December 31, 2006, we had drawn only $5.0 million of the $50.0 million line of credit available for the development of Provacel under a loan agreement with a large pharmaceutical company. This $5.0 million draw occurred in March 2004. In connection with this line of credit, we have granted the pharmaceutical company a security interest in the intellectual property, equipment and books and records involved in the development, manufacture and distribution of Provacel. The pharmaceutical company is also obligated to make additional investments in our Company and pay licensing fees up to $45.0 million to us upon completion of certain milestones.

In addition to the $5.0 million balance on the line of credit, at December 31, 2006 our debt included approximately $20.0 million of convertible promissory notes due in 2009.

Cash Flows

Net cash used in operating activities was $35.3 million for the twelve months ended December 31, 2006 primarily reflecting our net loss of $45.0 million, partially offset by $5.7 million in non-cash interest $5.5 million in non-cash stock-based compensation expense and $1.5 million in depreciation and

amortization. Other long-term liabilities decreased by $1.9 million, reflecting the reclassification of the accrued interest and principal on the $20.6 million convertible note payable that was redeemed in October 2006. Net cash used for operating activities was $14.6 million for the twelve months ended December 31, 2005. Net cash used in operating activities for 2005 primarily reflects our net loss of $20.0 million, partially offset by $3.5 million in non-cash interest expense.

Net cash provided by investing activities was $2.6 million for the twelve months ended December 31, 2006. Net cash used in investing activity for the twelve months ended December 31, 2005 was $43.1 million. Net cash provided by investing activities in 2006 includes cash flows from the sale of $40.1 million of short-term investment, largely offset by the purchase of $35.8 million of short-term investments. In 2005, we purchased $45.0 million of short-term investments during the year. Purchases of property and equipment during 2006 were $1.7 million, including $0.5 million to build out our new Columbia, Maryland facility.

Net cash provided by financing activities was $32.8 million for the twelve months ended December 31, 2006. Net cash provided by financing activities was $57.8 million for the twelve months ended December 31, 2005 and consisted principally of $40.0 million in net proceeds from the issuance of convertible notes and $21.4 million in net proceeds from the issuance of common and preferred stock. The cash provided by financing activities in 2006 was primarily from the proceeds of our initial public offering in August 2006 and the issuance of $20.0 million of convertible promissory notes in October 2006, which was offset by the redemption of the $20.6 million convertible note, also in October 2006.

Capital Resources.

Our future capital requirements will depend on many factors, including:

- the level of cash flows from Osteocel sales;
- the scope and results of our research and preclinical development programs;
- the scope and results of our clinical trials, particularly regarding the number of patients required for our Phase III trial for Prochymal;
- the timing of and the costs involved in obtaining regulatory approvals for our biologic drug candidates, which could be more lengthy or complex than obtaining approval for a new conventional drug, given the FDA s limited experience with late-stage clinical trials and marketing approval for stem cell therapeutics;
- the costs of building and operating our manufacturing facilities, both in the near term to support Osteocel sales and our clinical activities and also in anticipation of expanding our commercialization activities;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including litigation costs and liabilities;
- the costs of repaying our debt; and
- the costs of enlarging our work force consistent with expanding our business and operations and status as a public company, and as necessary to enhance and train our sales network in anticipation of the approval of our biologic drug candidates for commercial sale.

As a result of these factors, we may need or choose to seek additional funding prior to our becoming cash flow positive on an operational basis. We would likely seek such funding through public or private financings or some combination of them. Although not our current focus, we might also seek funding through collaborative arrangements if determined to be necessary or appropriate. Additional funding may not be available to us on acceptable terms, or at all. If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our technologies or biologic

drug candidates. If we raise capital through the sale of equity, or securities convertible into equity, dilution to our then existing stockholders would result. If we raise additional capital through the incurrence of debt, we would likely become subject to covenants restricting our business activities, and holders of debt instruments would have rights and privileges senior to those of our equity investors. In addition, servicing the interest and repayment obligations under these borrowings would divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we are unable to obtain adequate financing on a timely basis, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our business, financial condition and results of operations.

We expect that our available cash and interest income, including the availability under our line-of-credit, will be sufficient to finance currently planned activities through early 2008. These estimates are based on certain assumptions, which could be negatively impacted by the matters discussed under Risk Factors.

If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, which may have a material adverse affect on our business. See Risk Factors.

Off-Balance Sheet Arrangements.

We have no off-balance sheet financing arrangements and we have not entered into any transactions involving unconsolidated subsidiaries or special purpose entities.

Summary Disclosures about Contractual Obligations and Commercial Commitments.

The following table reflects a summary of our contractual cash obligations and other commercial commitments as of December 31, 2006:

	Payment Due by Fiscal Year				
	Total	Less Than 1 Year	Years 1 3	Years 4 5	More Than 5 Years
Long-term debt	$ 25,049	$ 49	$ 20,000	$	$ 5,000
Operating lease facilities	9,952	852	2,910	2,191	3,999
Capital leases facilities	2,004	1,124	880		
Capital leases equipment	20	5	15		
Interest payments	9,340	2,117	4,002		3,221
Total contractual cash obligations	$ 46,365	$ 4,147	$ 27,807	$ 2,191	$ 12,220

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Due to the short duration of our investment portfolio and the high quality of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. Therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio.

We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectability and establishment of appropriate allowances in connection with our internal controls and policies.

We do not enter into hedging or derivative instrument arrangements.

Item 8. Financial Statements and Supplementary Data

Osiris Therapeutics, Inc.

Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Osiris Therapeutics, Inc. as of December 31, 2006 and 2005, and the related statements of operations, stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2006. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Osiris Therapeutics, Inc. as of December 31, 2006 and 2005, and its results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

/s/ STEGMAN & COMPANY

Baltimore, Maryland
March 14, 2007

OSIRIS THERAPEUTICS, INC.
BALANCE SHEETS
(amounts in thousands)

	December 31, 2006	2005
ASSETS		
Current assets:		
Cash	$ 714	$ 597
Short-term investments	38,467	42,774
Accounts receivable	1,596	974
Inventory	1,892	101
Other current assets	966	266
Total current assets	43,635	44,712
Property and equipment, net	3,942	3,792
Restricted cash	297	190
Deferred financing costs, net	567	2,050
Other assets	727	270
Total assets	$ 49,168	$ 51,014
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	$ 8,339	$ 4,565
Note payable, current portion	49	65
Capital lease obligations, current portion	1,129	1,027
Deferred revenue, current portion	952	952
Total current liabilities	10,469	6,609
Notes payable and long-term line-of-credit, net of current portion	25,000	47,411
Capital lease obligations, net of current portion	895	2,024
Deferred revenue, net of current portion	397	1,349
Long-term interest payable and other liabilities	1,120	3,016
Mandatorily redeemable convertible preferred stock Series D 3,750 shares designated, 3,213 shares issued and outstanding in 2005		64,267
Total liabilities	37,881	124, 676
Stockholders equity (deficit):		
Convertible Preferred Stock, issuable in series, $0.001 par value, 16,250 shares authorized, 12,250 shares designated and 10,651 shares outstanding in 2005		32,746
Common stock, $.001 par value, 90,000 shares authorized 27,321 and 9,098 shares outstanding in 2006 and 2005	27	9
Additional paid-in-capital	198,763	36,127
Accumulated deficit	(187,503)	(142,544)
Total stockholders equity (deficit)	11,287	(73,662)
Total liabilities and stockholders equity (deficit)	$ 49,168	$ 51,014

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

OSIRIS THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(amounts in thousands, except per share data)

	Years Ended December 31,		
	2006	**2005**	**2004**
Product Sales	$ 8,291	$ 957	$
Cost of goods sold	3,697	444	
Gross profit	4,594	513	
Revenue from collaborative research licenses and grants	1,181	3,013	3,911
Operating expenses:			
Research and development	37,590	16,927	11,888
General and administrative	4,340	2,229	1,641
Fees paid to related parties	451	65	63
Share-based payment to related party	3,668		
Total operating expenses	46,049	19,221	13,592
Loss from operations	(40,274)	(15,695)	(9,681)
Interest income (expense):			
Interest income	2,069	504	25
Interest expense	(6,754)	(4,804)	(872)
Total interest expense, net	(4,685)	(4,300)	(847)
Net loss	$ (44,959)	$ (19,995)	$ (10,528)
Basic and diluted net loss per share	$ (2.70)	$ (2.23)	$ (1.19)
Weighted average common shares outstanding, in thousands (basic and diluted)	16,663	8,959	8,814

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

OSIRIS THERAPEUTICS, INC.
STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)
(amounts in thousands, except for share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Deferred	Accumulated	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Capital	Compensation	Deficit	(Deficit)
Balance at January 1, 2004	2,545,454	$ 13,000	8,748,703	$ 9	$ 93,708	$ (259)	$ (112,021)	$ (5,563)
Exercise of options to purchase common stock ($0.40 to $0.80 per share)			36,405		16			16
Share based payment director services ($0.40 per share)			12,500		5			5
Issuance of common stock to settle lawsuit ($0.40 per share)			93,750		38			38
Issuance of common stock to settle debt ($18.00 per share)			9.000		162			162
Issuance of convertible preferred stock, Series C ($4.50 per share)	548,090	2,243						2,243
Fair value of warrants issued in connection with financing arrangements					400			400
Forfeiture of stock options					(10)	10		
Amortization of deferred compensation from stock option grants					67	37		104
Write-off of stockholder loans receivable						119		119
Net loss							(10,528)	(10,528)
Balance at December 31, 2004	3,093,544	15,243	8,900,358	9	94,386	(93)	(122,549)	(13,004)
Exercise of options to purchase common stock ($0.40 to $0.80 per share)			27,148		12			12
Share-based payment director services ($0.40 per share)			45,000		18			18
Conversion of restricted stock units to management ($0.40 per share)			125,000		50			50
Issuance of convertible preferred stock, Series E ($2.50 per share)	7,557,000	17,503						17,503
Redemption premium on mandatorily redeemable convertible preferred stock, Series D, redeemable at $20.00 per share					(58,305)			(58,305)
Deferred compensation from stock option grants					247	(247)		
Forfeiture of stock options					(17)	17		
Amortization of deferred compensation from stock option grants					13	46		59
Net loss							(19,995)	(19,995)

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OSIRIS THERAPEUTICS, INC.
STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)
(amounts in thousands, except for share data)

Balance at December 31, 2005	10,650,544	32,746	9,097,506	9	36,404	(277)	(142,544)	(73,662)
Exercise of options to purchase common stock ($0.40-$0.80 per share)			178,378		73			73
Exercise of warrants to purchase common stock ($0.40 per share)			875,000	1	349			350
Share-based payment director services ($6.84 - $11.00 per share)			22,807		198			198
Share-based payment consulting services ($6.84 per share)			6,250		43			43
Reclassification due to adoption of new accounting standard					(277)	277		
Initial public offering of common stock, net of offering costs			3,500,000	3	34,399			34,402
Conversion of convertible preferred stock into common stock	(10,650,544)	(32,746)	2,833,914	3	32,743			
Conversion of mandatorily redeemable preferred stock into common stock			8,033,388	8	64,259			64,267
Conversion of convertible notes payable into common stock			2,774,076	3	25,320			25,323
Share-based payment employee compensation					1,725			1,725
Share-based payment related party					3,527			3,527
Net loss							(44,959)	(44,959)
Balance at December 31, 2006		$	27,321,319	$ 27	$ 198,763	$	$ (187,503)	$ 11,287

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

OSIRIS THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS
(amounts in thousands)

	Years Ended December 31,		
	2006	**2005**	**2004**
Cash flows from operating activities:			
Net loss	$ (44,959)	$ (19,995)	$ (10,528)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,546	1,515	1,790
Non cash share-based payments	5,494	109	104
Stockholder loan write-off			119
Non cash interest expense	5,653	3,497	523
Changes in operating assets and liabilities:			
Accounts receivable	(622)	(913)	(1,102)
Inventory and other current assets	(2,491)	(276)	14
Other assets	(457)	(120)	47
Accounts payable and accrued expenses	3,374	1,875	(1,789)
Deferred revenue	(952)	(952)	(2,952)
Long-term interest and other liabilities	(1,896)	640	(562)
Net cash used in operating activities:	(35,310)	(14,620)	(12,132)
Cash flows from investing activities:			
Purchases of property and equipment	(1,696)	(338)	(50)
Proceeds from sale of short-term investments	40,112	2,200	
Purchase of short-term investments	(35,805)	(44,974)	
Net cash provide by (used in) investing activities	2,611	(43,112)	(50)
Cash flows from financing activities:			
Principal payments on capital lease obligations and notes payable	(21,692)	(1,000)	(845)
Restricted cash	(107)	23	22
Proceeds from convertible notes payable	20,000	39,957	9,690
Proceeds from the issuance of common and preferred stock, net of offering costs	34,824	21,360	2,464
Payment of debt financing costs	(209)	(2,499)	
Net cash provided by financing activities	32,816	57,841	11,331
Net increase in cash	117	109	(851)
Cash at beginning of year	597	488	1,339
Cash at end of year	$ 714	$ 597	$ 488

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

OSIRIS THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS (Continued)
(amounts in thousands)

	Years Ended December 31,		
	2006	**2005**	**2004**
Supplemental disclosure of cash flows information:			
Cash paid for interest	$ 1,260	$ 448	$ 349
Cash paid for taxes			
Supplemental schedule of non cash investing and financing activities:			
Conversion of notes payable to common stock	21,762		
Conversion of related parties notes payable to Series D Mandatorily Redeemable Convertible Preferred Stock		2,350	
Conversion of accrued interest into common stock	3,558		
Conversion of related party convertible notes payable accrued interest and premium into Series D Mandatorily Redeemable Convertible Preferred Stock		355	
Common stock issued to settle lawsuit			38
Common stock issued to settle debt			162
Share-based payment related party for financing services	3,527		
Redemption premium on Series D Mandatorily Redeemable Convertible Preferred Stock		58,305	

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

OSIRIS THERAPEUTICS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2007 AND 2006
(amounts in thousands, except for share and per share data)

1. Initial Public Offering, Non-Cash Charges and Reverse Stock Split

On August 9, 2006, we consummated our initial public offering, consisting of 3,500,000 shares of common stock at a public offering price of $11.00, resulting in net proceeds to us of approximately $34.4 million (after deducting payment of underwriters discounts and commissions, as well as offering expenses). Our common stock began trading on the NASDAQ Global Market on August 4, 2006.

In connection with the initial public offering, the Company effected a 1-for-4 reverse stock split of the issued and outstanding common stock. Information relating to common stock and common stock-equivalents set forth in this report (including the share numbers in the preceding paragraph) have been restated to reflect this split for all periods presented. Upon consummation of the initial public offering, all outstanding shares of the Class I, Series 2003, Series B, Series C, Series E and the Mandatorily Redeemable Series D convertible preferred stock were converted into an aggregate of 10,867,302 shares of our common stock. In addition, approximately $21.8 million of our convertible notes payable, together with accrued interest, were converted into an aggregate of 2,774,076 shares of our common stock.

Immediately following the initial public offering, we had 27,198,307 shares of common stock outstanding.

We incurred $7.0 million in non-cash charges relating to the completion of the initial public offering. Included in General and Administrative expenses is a charge of $0.8 million for stock-based compensation related to the accelerated vesting of certain employee stock options pursuant to employment agreements. We also recognized a $3.5 million share-based payment to related party related to warrants that were priced upon the completion of the initial public offering and $0.2 million in share-based compensation for stock awarded to our directors for service on our board. Interest expense includes $2.7 million in previously deferred financing costs and premiums that were expensed as a result of debt that was converted into common stock at the completion of the initial public offering.

In the fourth quarter of 2006, we incurred $0.7 million in non-cash interest expense as a result of the early redemption of debt, as discussed more fully in Note 4.

2. Description of Business and Significant Accounting Policies

Description of business

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

We are dependent upon the registration of our core products for sale before we can expand our commercial operations. We expect to submit product applications for approval with the United States Food and Drug Administration (FDA) in the future and plan to continue to seek additional equity and debt financing as the need arises. We believe our long-term cash position is inadequate to fund all of the

costs associated with the full range of testing and clinical trials required by the FDA for our core products. We expect that our available cash and interest income, including the availability under our line-of-credit, will be sufficient to finance currently planned activities through early 2008.. We have several research collaboration agreements that provide funding.

No assurance can be given that (i) we will be able to expand our operations prior to FDA approval of our biologic drug candidates, or (ii) that FDA approval will ever be granted for our biologic drug candidates.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Due to the inherent uncertainty involved in making those assumptions, actual results could differ from those estimates. We believe that the most significant estimates that affect our financial statements are those that relate to revenue recognition, deferred tax assets, and stock-based compensation.

Short-term investments

Short-term investments consist primarily of investment grade auction rate certificates with maturities of less than three months. Short-term investments are valued at cost, which approximates their fair value.

Accounts Receivable

Our accounts receivable are reported at their net realizable value. As of December 31, 2006 and 2005, there was no allowance for doubtful accounts as we believe the reported amounts are fully collectible. During the year ended December 31, 2006, we recognized $3 of bad debt expense. We did not recognize any bad debts expense in 2005. Accounts receivable balances are not collateralized.

Inventory

We commenced sales of our first commercial product in July 2005 and began carrying inventory on our balance sheet thereafter. Inventory consists of tissue products in process and available for distribution. We determine our inventory values using the first-in, first-out method. Inventory of supplies purchased to manufacture of biologic drug candidates and manufactured biologic drug candidate doses are presently used exclusively for research and development activities, including clinical trials. These items are expensed as incurred, consistent with our accounting for all other research and development costs.

Property and equipment

We record property and equipment, including improvements that extend useful lives, at cost, while maintenance and repairs are charged to operations as incurred. We calculate depreciation using the straight-line method based on estimated useful lives ranging from three to seven years for furniture, equipment and internal use software. We amortize leasehold improvements and assets under capital leases over the shorter of the estimated useful life of the asset or the lease term.

Valuation of long-lived assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or group of assets may not be fully recoverable. These events or changes in circumstances may include a significant deterioration of operating results, changes in business plans, or changes in anticipated future cash flows. If an impairment indicator is present, we evaluate recoverability

by a comparison of the carrying amount of the assets to future undiscounted net cash flows we expect the assets to generate. We group assets at the lowest level for which there is identifiable cash flows that are largely independent of the cash flows generated by other asset groups. If the total of the expected undiscounted future cash flows is less than the carrying amount of the asset, an impairment loss is recognized for the difference between the fair value and carrying value of assets. Fair value is generally determined by estimates of discounted cash flows. The discount rate used in any estimate of discounted cash flows would be the rate required for a similar investment of like risk. There were no impairment losses recognized during the years 2006, 2005 or 2004.

Assets to be disposed of are reported at the lower of carrying values or fair values, less estimated costs of disposal.

Deferred financing costs

We amortize the costs we incur to obtain debt financing over the terms of the underlying obligations using the effective interest method. The amortization of debt financing costs is included in interest expense. In 2006, we refinanced a $20.6 million convertible promissory note to a foreign investor, and we converted $21.8 million of convertible debt into common stock concurrent with our initial public offering. In connection with these transactions, in 2006, we recognized $2.1 million in interest expense for the deferred costs associated with these instruments, which were paid off. In 2005, we recognized $476 in interest expense from the amortization of these costs.

Revenue recognition

Our revenue recognition policies are in accordance with the Securities and Exchange Commission s (SEC) Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*.

In July 2005, we launched our first commercial product, Osteocel. We recognize revenue on Osteocel sales when legal title to the product has passed to the customer, which is generally when the product is shipped from our Baltimore, MD facilities. We have agreements with our customers that specify the terms of sale, including price. During 2006 and 2005, sales of our Osteocel product were primarily to two customers. We have entered into several strategic agreements with other pharmaceutical companies focusing on the development and commercialization of our stem cell drug products. In 2003, we entered into such an agreement with Boston Scientific Corporation pertaining to our cardiac drug development and we received a $5 million fee for licensing the use of our technology. This fee is being recognized as revenue over a 63-month period, $952 of which was recognized in each of 2006, 2005 and 2004. Also in 2003, we entered into a similar agreement with JCR Pharmaceuticals Co., Ltd. (JCR) pertaining to our hematologic malignancies drugs for distribution in Japan. We recognized $500 of revenue in 2005 and $2 million in 2004 from the JCR agreement.

Revenues from collaborative research licenses and grants are recognized as earned upon either the incurring of reimbursable expenses directly related to the particular research plan or the completion of certain development milestones as defined within the terms of the collaborative agreement. Payments received in advance of research performed are designated as deferred revenue. We recognize non-refundable upfront license fees and certain other related fees on a straight-line basis over the development period. Fees associated with substantive at risk, performance based milestones are recognized as revenue upon their completion, as defined in the respective agreements. Incidental assignment of technology rights is recognized as revenue as earned and was received from an unrelated third party.

Historically, we have also recognized revenue from governmental grants for research products and in 2005 we recorded $1.4 million in grant revenue as we completed work on three separate grants. In 2004, we earned $844 from governmental research grants. Revenue from research grants is recognized as the related

research expenditures are incurred. The Company no longer solicits governmental grants, and did not recognize any revenue from grants during 2006.

Cost of Goods Sold

In July 2005, we launched Osteocel. Costs of goods sold consist primarily of the costs to obtain the tissue and other chemicals and supplies, plus labor and allocated overhead costs and the costs of operating the clean-room facilities.

Research and development costs

Research and development costs are expensed as incurred.

Income taxes

Deferred tax liabilities and assets are recognized for the estimated future tax consequences of temporary differences, income tax credits and net operating loss carry-forwards. Temporary differences are primarily the result of the differences between the tax bases of assets and liabilities and their financial reporting values. Deferred tax liabilities and assets are measured by applying the enacted statutory tax rates applicable to the future years in which deferred tax liabilities or assets are expected to be settled or realized. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense, if any, consists of the taxes payable for the current period and the change during the period in deferred tax assets and liabilities. For all periods presented, valuation allowances have been provided for the full amount of net deferred tax assets and no income tax expense or benefit has been recognized.

Business Segments

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

Comprehensive income

In 2006, 2005 and 2004, except for our net loss, we did not have any components of comprehensive income as defined in the accounting literature.

Loss per Common Share

Basic loss per common share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share adjusts basic loss per share for the potentially dilutive effects of shares issuable under our stock option plan, and the conversion of our preferred stock and convertible debt, using the treasury stock method. Common equivalent shares from the conversion of preferred stock and convertible debt and the exercise of stock options and warrants are excluded from the computation of diluted loss per share as their effect is anti-dilutive. Since our initial public offering in August 2006, the market value of our common stock is determined based upon the closing price on the NASDAQ Global Market. Prior to August 2006 when our common stock started publicly trading, our Board of Directors determined the fair value of our common stock.

Stock-Based Compensation

Prior to January 1, 2006, we accounted for share-based compensation in accordance with Accounting Principles Board Opinion No. 25, (ABP 25) Accounting for Stock Issued to Employees, and related interpretations. We also followed the disclosure requirements of SFAS No. 123, Accounting for Stock-Based Compensation, as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. As a result, no expense was recognized for options to purchase our common stock that were granted with an exercise price equal to fair market value at the day of the grant. Effective January 1, 2006, we adopted the provisions of SFAS No. 123R, Share-Based Payment, which establishes accounting for equity instruments exchanged for services. Under the provisions of SFAS No. 123R, share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the employee s requisite service period (generally the vesting period of the equity grant). We elected the modified prospective transition method as provided by SFAS No. 123R and, accordingly, financial statement amounts for the prior periods presented in this Form 10-K have not been restated to reflect the fair value method of expensing share-based compensation.

As a result of adopting SFAS No. 123R on January 1, 2006, our net income for the year ended December 31, 2006 was $5.5 million lower than had we continued to account for stock-based compensation under ABP No. 25. Net loss per common share for the year ended December 31, 2006, was increased by $0.33 by the adoption of SFAS No. 123R.

The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123, Accounting for Stock-Based Compensation for periods prior to January 1, 2006.

	Years ended December 31,	
	2005	**2004**
Net loss, as reported	$ (19,995)	$ (10,528)
Add stock-based employee compensation included in reported net loss	109	104
Deduct total stock-based employee compensation determined under fair-value-based method for all awards	(8)	(46)
Pro forma net loss	$ (19,894)	$ (10,470)
Basic and diluted loss per share, as reported	$ (2.23)	$ (1.19)
Basic and diluted loss per share, pro forma	$ (2.23)	$ (1.19)

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

The pro forma impact of applying the fair value method prescribed by SFAS No. 123 to historical financial results is not representative of the impact that may be expected in the future due to changes resulting from additional grants in future years and changes in assumptions such as volatility, interest rates and expected life used to estimate fair value of the grants in future years.

Share-based compensation expense included in the accompanying statements of operations was:

	Year ended December 31,		
	2006	**2005**	**2004**
Cost of goods sold	$	$	$
Research and development	755		
General and administrative	4,738	109	104
Share-based compensation	$ 5,493	$ 109	$ 104

Concentration of credit risk

We maintain cash and short-term investment balances in accounts that exceed federally insured limits, although we have not experienced any losses on such accounts. We invest our excess cash in investment grade securities, generally with maturities of three months or less. We provide credit, in the normal course of business, to the distributors of our product. Our receivables at December 31, 2006 consist primarily of amounts due from two commercial customers, and we expect these receivables to be collected.

Significant New Accounting Pronouncements

In May 2005, the Financial Accounting Standards Board (FASB) issued SFAS No. 154, Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS No. 154 requires retrospective application to prior periods financial statements for changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS No. 154 also requires that a change in depreciation, amortization, or depletion method for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The implementation of SFAS No. 154 on January 1, 2006 did not have a material impact on the results of operations, financial position or cash flows.

In November 2005, FASB issued, FASB Staff Position (FSP) FAS 115-1 and FAS 124-1, The Meaning of Other-than-Temporary Impairment and Its Application to Certain Investments (FSP 115-1) which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP 115-1 also includes accounting considerations subsequent to the recognition of an other-than temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP 115-1 is effective for reporting periods beginning after December 15, 2005. Our adoption of FSP 115-1 on January 1, 2006 did not have a material impact on our results of operations, financial position or cash flows.

In July 2006, FASB issued FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes, an interpretation of FASB No. 109 (FIN 48) that clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAF 109, Accounting for Income Taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement effects of a tax position when it is more likely than not of being sustained on examination, based on the technical merits of the position. In addition, FIN 48 indicates that the measurement of a tax position that meets the more likely than not threshold shall consider the amounts and probabilities of the outcomes that could be realized upon ultimate settlement. This interpretation is effective for fiscal years beginning after December 15, 2006. We expect the impact of adopting FIN 48 to be immaterial.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements. SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosure requirements regarding fair value measurements. SFAS No. 157 does not require any new fair value measurements. We are required to adopt the provisions of SFAS No. 157 effective January 1, 2008 although earlier adoption is permitted. We do not believe the adoption of this standard will have a material effect on our financial position, results of operations or cash flows.

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements n Current Year Financial Statements (SAB 108). SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year s financial statements are materially misstated. SAB 108 is effective for fiscal years ending

after November 15, 2006. The implementation of SAB 108 did not have a material impact on the results of operations, financial position or cash flows.

Reclassifications

Certain amounts in the prior years financial statements have been reclassified to conform to the 2006 presentation.

3. Property and equipment

Property and equipment consist of the following at December 31,:

	2006	2005
Laboratory and manufacturing equipment	$ 4,720	$ 3,758
Computer hardware, furniture and fixtures	1,213	1,103
Leased assets	11,725	11,725
Leasehold improvements	4,517	4,437
Construction in process	545	
	22,720	21,023
Accumulated depreciation and amortization	(18,778)	(17,231)
Property and equipment, net	$ 3,942	$ 3,792

4. Notes Payable and Capital Lease Obligations

	December 31, 2006	2005
Bank Loan, payable in quarterly installments and bearing interest at LIBOR plus applicable margins, 7.33% 7.83% in 2006	$ 49	$ 114
Boston Scientific Corporation. Line of credit, 8%, to be repaid from future product sales, up to $50 million may be borrowed for product development	5,000	5,000
Term Note, 5%, convertible into common stock at $6.00/share		2,000
Term Note, 6%, convertible at the sole option of the Holder, due in 2008		20,600
Term Notes, 6%, convertible into common stock at initial public offering at Specified prices		19,762
Term Notes, 10%, convertible into common stock at $18 per share and under Specified conditions	20,000	
	25,049	47,476
Less current portion	(49)	(65)
Notes payable long-term	$ 25,000	$ 47,411
Total capital lease obligations	$ 2,024	$ 3,051
Less current portion	(1,129)	(1,027)
Capital lease obligations, long-term	$ 895	$ 2,024

During June 1995, we borrowed $750 from a commercial bank in connection with the acquisition and renovation of our Baltimore, Maryland facilities. This loan is partially guaranteed by an agency of the State of Maryland and matures in September 2007. This loan bears interest at LIBOR plus 2.0% to 2.5% (7.33% to 7.83% at December 31, 2006). Compensating balance arrangements with Wachovia Bank require us to maintain a cash balance of 105% of the non-guaranteed portion of this loan, which is shown as a component of restricted cash in the accompanying balance sheet. At December 31, 2006 and 2005, this compensating balance requirement was $17 and $34, respectively.

In September 2004, we issued a convertible promissory note to a foreign investor for $2.0 million. This note bore interest at 5% and the principal and accrued interest was converted into 397,853 shares of our common stock upon the completion of our initial public offering on August 9, 2006.

During 2005, we had issued convertible promissory notes outstanding to twenty-six shareholders for a total of $19.8 million. These notes accrue interest at 6% per annum, and provide for redemption premiums starting at 9% of the principal amount and escalating up to 27% of the principal amount, depending upon the date of redemption or conversion to Common Stock. All twenty-six convertible promissory notes, together with accrued interest were subsequently converted into 2,376,223 shares of our common stock upon the completion of our initial public offering on August 9, 2006.

In November 2005, we issued a $20.6 million promissory note to a foreign investor. This note bore interest at 6% and had redemption premiums that started at 9% and increase over time up to 27%. Interest payments were due in November 2006, 2007 and upon maturity in November 2008. This note was convertible into our common stock only if the initial public offering took place after December 2006. In October 2006, we issued $20.0 million in convertible promissory notes in a private placement to Swiss investors and used the proceeds from these notes, plus an additional $3.6 million in cash to redeem the $20.6 million promissory note.

In October 2006, we issued $20.0 million in convertible promissory notes in a private placement to several Swiss investors. The notes bear interest at a rate of 10%, with semi-annual payments of accrued interest becoming due and payable on April 30 and October 30 of each calendar year, until maturity on April 30, 2009. The notes are convertible at the option of the respective holders at any time after February 9, 2007, into shares of common stock at the conversion price of $18.00 per share. The notes automatically convert into common stock at the same conversion price, if at any time after February 9, 2007, the closing price of the Company s common stock for ten consecutive trading days equals $25.00 per share or greater. The notes provide for redemption at any time at the option of the Company, with 30-day written notice.

Future maturities of Notes Payable and Capital Lease Obligations

For years subsequent to 2006, scheduled annual maturities of notes payable and capital lease obligations outstanding as of December 31, 2006, are as follows:

	Notes Payable	**Capital Lease Obligations**	**Total**
2007	$ 49	$ 1,129	$ 1,178
2008		885	885
2009	20,000	7	20,007
2010		3	3
2011			
Thereafter	5,000		5,000
	$ 25,049	$ 2,024	$ 27,073

5. Preferred Stock Conversion

All our convertible preferred stock was converted into common stock upon the completion of our initial public offering in August 2006, as follows:

	December 31, 2006	2005	No. Shares of Common Stock Issued Upon Conversion at IPO (Aggregate Liquidation Preference / Conversion Price) Per Share
Convertible preferred stock, Class I, Series 2003, $0.001 par value, 2,000,000 shares designated, issued and outstanding in 2005	$	$ 10,000	500,000
Convertible preferred stock, Series B, $0.001 par value, 750,000 shares designated, 545,454 shares issued and outstanding in 2005		3,000	136,364
Convertible preferred stock, Series C, $0.001 par value, 3,500,000 shares designated, 548,090 shares issued and outstanding in 2005		2,243	308,300
Convertible preferred stock, Series E, $0.001 par value, 8,000,000 shares designated, 7,557,000 shares issued and outstanding in 2005		17,503	1,889,250
	$	$ 32,746	2,833,914

We issued 2,000,000 shares of our Class I, Series 2003 convertible preferred stock to a collaborative partner as part of an agreement related to product development, clinical trials and FDA approval. These shares were converted into 500,000 shares of our common stock at the conversion price of $20.00 per share.

We issued 545,454 shares of our Series B convertible preferred stock in 2003, as part of a collaborative agreement. These shares were converted into 136,364 shares of our common stock at the conversion price of $22.00 per share.

We issued 548,090 shares of our Series C convertible preferred stock in 2004 at the price of $4.50 per share. These shares were converted into 308,300 shares of our common stock at the conversion price of $8.00 per share.

We issued 7,557,000 shares of our Series E convertible preferred stock in 2005 at a price of $2.50 per share. These shares were converted into 1,889,250 shares of our common stock at the conversion price of $10.00 per share.

Also in 2005, we issued 3,213,335 shares of Series D Mandatorily Redeemable Convertible Preferred Stock at a price of $2.00 per share. These shares were converted into 8,033,388 shares of our common stock at the conversion price of $0.80 per share.

These Series D shares included a mandatory redemption feature whereby if the Company did not complete an initial public offering prior to June 1, 2007 and the shares were not previously converted into common stock, the Company must then redeem the shares at a price of $20.00 per share. The Series D Mandatorily Redeemable Convertible Preferred Stock is recorded as a liability in the balance sheet at December 31, 2005, in accordance with SFAS No. 150 Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. In addition to the initial net proceeds of $6.0 million from the Series D offering, a redemption premium of $58.3 million was recorded as a liability.

6. Share-Based Compensation

In April 2006, we adopted our 2006 Omnibus Plan, in addition to our Amended and Restated 1994 Stock Incentive Plan. The Plans authorize the issuance of various forms of stock-based awards, including incentive and non-qualified stock options, stock purchase rights, stock appreciation rights and restricted and unrestricted stock awards. A total of 850,000 shares of our common stock have been reserved for issuance under the 2006 Omnibus Plan and 736,378 shares were reserved under our Amended and Restated 1994 Stock Incentive Plan. We ceased all grants under the Amended and Restated 1994 Stock Incentive Plan concurrent with our initial public offering in August 2006. At December 31, 2006, there were 785,010 shares available for future awards under the 2006 Omnibus Plan.

We generally issue stock option awards that vest over four years and have a ten-year life. We estimate the fair value of stock options using the Black-Scholes option-pricing model. Our common stock started trading on the public market in August 2006, and the historical data to determine volatility does not presently exist. We determine volatility by using the historical stock volatility of other companies with similar characteristics. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

The fair value of stock options granted during each of the periods was estimated using the following assumptions:

	Years ended December 31,					
	2006		2005		2004	
Assumptions						
Risk-free interest rate	4.75	%	4.21	%	3.93	%
Dividend yield	0.0	%	0.0	%	0.0	%
Expected life of option grants	5-years		5-years		5-years	
Expected stock price volatility	74.11	%	85.64	%	100	%

A summary of stock option activity for the years ended December 31, 2006, 2005 and 2004 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2004	389,043	$ 0.94		
Granted	435,000	$ 0.40		
Exercised	(36,405)	$ (0.46)		$
Forfeited or canceled	(243,986)	$ (0.51)		
Outstanding at December 31, 2004	543,652	$ 0.70	7.9-years	
Granted	106,000	$ 0.40		
Exercised	(27,148)	$ (0.41)		$ 7
Forfeited or canceled	(56,024)	$ (3.45)		
Balance, December 31, 2005	566,480	$ 0.40	8.4-years	
Granted	314,500	$ 4.06		
Exercised	(178,378)	$ (0.41)		$ 1,827
Forfeited or canceled	(6,687)	$ (1.36)		
Balance, December 31, 2006	695,915	$ 2.05	8.3-years	$ 16,149
Exercisable at December 31, 2006	417,336	$ 0.40	7.7-years	$ 10,400

A summary of stock options outstanding at December 31, 2006, by price range is as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life (in years)	Weighted-Average Exercise Price	Number Outstanding	Weighted-Average Exercise Price
$ 0.40 to $ 0.79	525,602	7.9	$ 0.40	417,055	$ 0.40
0.80 to 2.00	1,563	6.6	0.80	281	0.80
2.01 to 10.99	157,250	9.5	6.88		
$11.00 to $16.00	11,500	9.6	11.45		
	695,915	8.3	$ 2.05	417,336	$ 0.40

The weighted fair value of options granted during the years ended December 31, 2006, 2005 and 2004 were $7.11, $2.84 and $0.32, respectively.

Both contemporaneous and retrospective valuations were performed by the Board of Directors for options granted from January 2005 through the date of our initial public offering. As a result of these valuations, the Company, for financial reporting purposes, retrospectively adjusted the fair market value of the equity instruments granted during certain periods.

During 2003, we cancelled and reissued 126,366 stock options that had previously been granted at amounts equal to the estimated fair value of the underlying stock. The exercise price of the reissued stock options was reduced to $0.40 per share at a time when the estimated fair value of the common stock was $6.00 per share. We are accounting for these options as if they were simply repriced. As such, we accounted for these repriced options using variable accounting under FASB Interpretation No. 44. Accounting for Certain Transactions Involving Stock Compensation (an Interpretation of APB No. 25) Consequently, during each reporting period we record compensation expense relating to the vested portion of the repriced options to the extent that the fair market value of our common stock exceeds the exercise price of such options. Compensation expense of $530, $35 and $67 was recognized during the years ended December 31, 2006, 2005 and 2004, respectively.

In connection with the stock options exercised during the year ended December 31, 2006, we received cash proceeds of $72. At December 31, 2006, there was $1.3 million of total unrecognized compensation costs related to non-vested stock options, which is expected to be recognized over a weighted average period of three years.

7. Related Party Transactions

General. Peter Friedli, the Chairman of our Board of Directors, has been responsible for procuring since 1993, either directly or through affiliated entities, an aggregate of approximately $200 million in debt and equity financing for us and our predecessor company. Mr. Friedli is the beneficial owner of greater than 47% of our common stock as of December 31, 2006. Of the shares beneficially owned by Mr. Friedli, 20,000 shares were received by him as Board compensation since 1996, 12,500 shares were granted in recognition of his fundraising efforts, as discussed below, and the remaining shares were acquired through investment or purchase from third parties.

Consulting Agreement. Since 1995, we and our predecessor company have been party to a Consulting Agreement, originally with Friedli Corporate Finance AG, and now Friedli Corporate Finance, Inc., or FCF, for the provision of business and advisory services to us. Mr. Friedli is the sole owner of FCF. Under this agreement, FCF has provided general business, financial and investment advice to us, and has served as a liaison between us and FCF clients who have invested in us, many of which are located in Switzerland. This Consulting Agreement had also granted to FCF a right of first refusal with respect to any debt or equity financings by us, and contains a provision requiring us to allocate ten percent of the shares in this

offering to FCF. The Consulting Agreement between us and FCF was terminated upon the closing of our initial public offering. The base compensation paid by us under this agreement was $47 in 2006, $65 in 2005, and $63 in 2004. In addition, pursuant to this Consulting Agreement, we paid $50 as expense reimbursements in 2005 and $350 in 2006, to or as directed by FCF.

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

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

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

- the issuance and sale in 2005 of 3,187,056 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock at a purchase price of $2.00 per share, representing aggregate gross proceeds of $6.4 million;

- the issuance and sale in 2005 of $19.4 million of our Convertible Preferred Notes;

- the issuance and sale in 2005 of 7,557,000 shares of our Series E Convertible Preferred Stock at a purchase price of $2.50 per share, representing aggregate gross proceeds of $18.9 million; and

- the issuance and sale in 2006 of $20 million of our Convertible Notes.

Mr. Friedli also arranged the placement through a European investment bank of a $20.6 million convertible promissory note in late fall 2005. In connection with all of these transactions, an aggregate of $71.9 million in gross proceeds was raised for us. We paid referral fees and costs of $3.4 million to accounts designated by Mr. Friedli, including accounts of third parties unrelated to Mr. Friedli. We also paid expense reimbursement of $350 to Mr. Friedli and issued 12,500 shares of our common stock to him in recognition of his fundraising efforts on our behalf in 2004 and 2005. In addition, specific to the placement of the $20.6 million convertible promissory note, we paid placement agency fees to the European investment bank.

In addition, the Company will pay an amount for costs up to three percent (3%) of the aggregate amount of the Notes issued in 2006, of which one-third was paid to Friedli Corporate Finance, Inc., and up to two thirds will be paid to others or Friedli Corporate Finance, as directed by Friedli Corporate Finance, Inc. Included among the purchasers of the Notes is Peter Friedli, individually, who purchased $4,500,000, and New Venturetec, Inc., a Swiss publicly traded company approximately 3% owned by Mr. Friedli who serves as its President, which purchased an additional $4,000,000 of the Notes. The Board of Directors of the Company, including all of the Company s independent directors, but with Mr. Friedli abstaining, unanimously approved the offering and sale of the Notes, including the sale of a portion of the Notes to Mr. Friedli and New Venturetec, Inc. and the arrangements with Friedli Corporate Finance, Inc.

New Venturetec/Pine Loans. In 2004, we obtained $2.35 million in debt financing through two entities affiliated with Mr. Friedli. The first of these entities was a wholly owned subsidiary of New Venturetec, Inc.. The other entity is Pine, Inc., a company which at the time of the financing was majority owned and managed by Mr. Friedli. These convertible demand notes accrued interest at 10% and included a 10% premium due upon redemption.

In this financing, the New Venturetec subsidiary lent us $1.35 million, and Pine lent us $1.0 million. In consideration of these loans, we issued to the lenders promissory notes in the principal amount of the sums lent to us. To facilitate these borrowings and other financings, and for commitments of consideration in respect of yet additional financing if needed, we issued warrants for an aggregate of 1,250,000 shares at an exercise price of $0.40 per share. Mr. Friedli subsequently arranged for the acquisition of those warrants and they have since been cancelled. In recognition of his efforts in procuring the cancellation of all of these

warrants, we issued an additional warrant to Mr. Friedli, exercisable for up to 1,000,000 shares of our common stock at $11.00 per share, the price for which shares were sold in the initial public offering. This warrant expires in May 2011.

The loans made by the New Venturetec subsidiary and Pine, plus premium and accrued interest totaling $355, were converted into 1,352,325 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock in early 2005, representing an effective price of $2.00 per share at the same price as was paid by other purchasers. Each share of our Series D Mandatorily Redeemable Convertible Preferred Stock will convert into 2.5 shares of our common stock upon completion of this offering.

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

- The New Venturetec subsidiary described above purchased in 2005 an additional 47,244 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock at $2.00 per share, representing aggregate gross proceeds of $94. It also purchased in 2005 400,000 shares of our Series E Preferred Stock at $2.50 per share, representing aggregate gross proceeds of $1.6 million.

- US Venture 05, Inc., a venture fund for which Mr. Friedli is president and investment manager, purchased in 2005 4,000,000 shares of our Series E Preferred Stock at $2.50 per share, representing aggregate gross proceeds of $10.0 million. Mr. Friedli has no ownership interest in this investor.

- World Communication Development AG, a Swiss corporation of which Mr. Friedli is a member of the board of directors, purchased in 2005 66,666 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock at $2.00 per share, representing aggregate gross proceeds of $133. Mr. Friedli has no ownership interest in this investor.

- Joyce Ltd., an entity which at the time was majority owned by Mr. Friedli, purchased 340,495 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock in 2005 at $2.00 per share, representing aggregate gross proceeds of $681.

- Mr. Friedli purchased 488,118 shares of our Series D Mandatorily Redeemable Convertible Preferred Stock in 2005 at $2.00 per share, representing aggregate gross proceeds of $976.

Lockup Agreement.

On October 30, 2006, we entered into a Lockup Agreement with Mr. Friedli and certain entities with which he is affiliated, Venturetec, Inc. and U.S. Venture 05, Inc. Pursuant to the Lockup Agreement, Mr. Friedli and such entities have agreed with the Company, subject to limited exceptions, not to transfer Company securities held by them without approval of the Company, until January 30, 2008.

8. Warrants

At December 31, 2006, we had warrants to purchase our common and preferred stock outstanding as shown in the following table.

	Common Stock # of Shares	Weighted Average Price	Preferred Stock # of Shares	Weighted Average Price
Warrants outstanding, January 1, 2005	2,175,625	1.16	17,928	12.00
Warrants granted				
Warrants exercised				
Warrants expired	(50,625)	39.00	(17,928)	12.00
Warrants outstanding, December 31, 2005	2,125,000	$ 0.40		$
Warrants granted	1,000,000	11.00		
Warrants cancelled	(1,250,000)	0.40		
Warrants exercised	(875,000)	0.40		
Warrants outstanding, December 31, 2006	1,000,000	$ 11.00		$

Following is the summary of the status of outstanding warrants to purchase our common stock at December 31, 2006.

Warrant Price	Common Shares	Weighted Average Remaining Contractual Life	Intrinsic Value
$11.00	1,000,000	4.5 years	$ 14,320

In August 2006, when the price of the 2006 warrant was determined, we computed its value using the Black-Scholes option pricing method, using a risk free interest rate of 4.80%, the expected life of 2.5-years and a stock volatility factor of 44.66%. Since the Company just recently completed its initial public offering and previously its stock did not trade, we determined the volatility by selecting a comparable public company in the biotech industry and tracking its stock prices over the past 2.5-years. The value of this warrant was determined to be $3.5 million which as been recorded in the accompanying statement of operations as General and Administrative expenses.

The 875,000 warrants that were exercisable at $0.40 per share as of January 1, 2006 were all exercised concurrent with the closing of our initial public offering in August 2006.

9. Income Taxes

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

	2006	2005
Deferred Tax Assets:		
Net operating loss carry-forwards	$ 63,157	$ 50,818
Research and experimentation credit carry-forwards	5,142	4,803
Property and equipment	1,546	1,662
Other	51	51
	69,896	57,334
Valuation allowance	(69,896)	(57,334)
Net deferred tax assets	$	$

Our deferred tax assets have been fully reserved in both 2006 and 2005 since their ultimate future realization cannot be assured. The valuation allowance increased by $12.6 million for the year ended December 31, 2006. We presently have available for federal income tax purposes, approximately $164 million of net operating loss carry-forwards and $5.1 million of research and experimentation credit carry-forwards, which expire beginning in 2009 through 2026. However, as a result of changes in our ownership since inception, the amount of these carry-forwards available to offset future taxable income and income taxes could be subject to annual limitations under IRC Section 382.

10. Research Collaboration Agreements and Deferred Revenue

Boston Scientific Agreement. In 2003, we entered into a long-term collaboration agreement with Boston Scientific Corporation (BSC) focusing upon the development and commercialization of the use of Mesenchymal Stem Cells technology to treat cardiovascular disease. The BSC agreement, which entitles us to a licensing fee and to royalties on resulting revenue includes both a BSC equity investment and significant BSC debt financing for the cardiovascular project.

We received a $5 million licensing fee for the use of its technology by BSC. This revenue is being recognized as revenue over a 63-month period, $952 of which was recognized in 2006, 2005 and 2004. As provided for in the agreement, BSC purchased 2 million shares of the our Class 1, Series 2003 Convertible Preferred Stock for $10 million. These shares were converted into 500,000 shares of common stock concurrent with our initial public offering in August 2006. If we achieve certain milestones, BSC will purchase up to an additional $20 million of common stock, at prices ranging from $60 to $112 per share and pay license fees of up to $25.0 million.

We have a $50.0 million line of credit with Boston Scientific. In March 2004, the Company drew $5 million under this line of credit, which is recorded as long-term debt and accrues interest at 8%. We can only use borrowings in connection with Provacel development efforts. Advances under the loan agreement are secured by an interest granted to Boston Scientific in the license agreement, including the right to develop, market and distribute MSC products in the covered field and our right to receive payments under the license. At December 31, 2006, the Company estimates that it was entitled to draw approximately $9 million more on this line of credit.

JCR Pharmaceuticals Agreement. Also in 2003, we entered into a strategic alliance with JCR Pharmaceuticals Co., Ltd. (JCR). Under the JCR agreement, we have granted to JCR the exclusive right in Japan to use our technology in conjunction with the treatment of hematologic malignancies using hematopoietic stem cell transplants. The JCR agreement entitles us to a licensing fee and to royalties on any resulting revenue. Upon commencement of the agreement, JCR purchased 545,454 shares of our Series B Convertible Preferred Stock for $3.0 million. These shares were converted into 136,363 shares of our common stock concurrent with our initial public offering in August 2006. They also paid us a $3.0 million licensing fee, which was recognized as revenue over twelve months, including $2.0 million in 2004. In 2005, upon the completion of certain milestones, we received $500 in additional licensing fees, which was recognized as revenue.

11. Defined Contribution Plan

We have a 401(k) plan that is available to all employees. Employee contributions are voluntary and are determined on an individual basis up to the amount allowable under federal regulations. Employer contributions to the plan are at the discretion of the Board of Directors and vest over a seven year period beginning after the third year of eligibility. No employer contributions have been made to date.

12. Commitments and Contingencies

We lease approximately 118,000 square feet of laboratory, production, warehouse and office space under an amended lease agreement that expires in 2008. We have an option to renew this lease through 2023 and have not made a decision regarding the exercise of our renewal option. This lease was originally arranged by the Maryland Economic Development Corporation and the City of Baltimore who arranged the financing of the building improvements. We have an outstanding letter of credit of $150 that is used as security for this lease. The letter of credit is fully collateralized by restricted cash. We sublease a portion of the office and warehouse space to a third party on a month-to-month basis and record the $10 monthly rent as a reduction of our facilities expense.

During 2006, we entered into a sublease agreement for approximately 61,000 square feet of laboratory, production, warehouse and office space in Columbia, Maryland. We have also entered into a direct lease with the owner of this facility that is effective upon the expiration of the sublease and expires in July 2016. This lease has two five-year renewal options. We have an outstanding letter of credit of $130 that is used in lieu of a security deposit for this lease. The letter of credit is fully collateralized by restricted cash.

We also have entered into various financing arrangements to lease laboratory and other equipment. The terms of these facilities and equipment leases are considered capitalized leases, and the following amounts are included in our balance sheets at December 31, 2006 and 2005:

	2006	2005
Facilities leases	$ 8,568	$ 8,568
Equipment leases	3,157	3,157
	11,725	11,725
Less accumulated amortization	(10,351)	(9,635)
Leased property and equipment, net	$ 1,374	$ 2,090

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

	Facilities	Equipment	Total
2007	$ 1,236	$ 8	$ 1,224
2008	906	8	914
2009		8	8
2010		3	3
2011			
	2,142	27	2,169
Less interest	(138)	(7)	(145)
Present value of minimum lease payments	2,004	20	2,024
Less current portion	(1,124)	(5)	(1,129)
Capital lease obligations, net of current portion	$ 880	$ 15	$ 895

The future minimum lease payments due under the operating lease for our Columbia, Maryland facility are as follows:

	Columbia Facility
2007	$ 852
2008	876
2009	978
2010	1,056
2011	1,082
2012 2016	5,108
	$ 9,952

Agreement. In 1994, we entered into a Technology Transfer and License Agreement with Case Western Reserve University (CWRU) under which we purchased rights to certain mesenchymal stem cell and related technology and patents. We are required to pay royalties on revenues related to CWRU developed technology, with minimum royalties of $50 per year. We paid CWRU $50 in 2006, 2005 and 2004.

13. Quarterly Financial Data (Unaudited)

Following is a summary of our Unaudited quarterly results for the years ended December 31, 2006 and 2005:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2006				
Total revenues	$ 1,400	$ 1,987	$ 2,841	$ 3,244
Product sales	1,105	1,689	2,539	2,958
Cost of goods sold	489	762	1,113	1,333
Research and development expenses	4,368	10,922	9,242	13,058
General and administrative expenses and fees	1,138	1,209	5,300	812
Net loss	(5,121)	(11,605)	(15,565)	(12,668)
**Net loss per common share, basic and diluted	(0.56)	(1.27)	(0.75)	(0.46)
2006				
Total revenues	$ 385	$ 1,339	$ 1,285	$ 961
Product sales			284	673
Cost of goods sold			220	224
Research and development expenses	2,657	3,592	3,464	7,214
General and administrative expenses and fees	752	487	554	501
Net loss	(3,868)	(2,740)	(4,678)	(8,055)
**Net loss per common share, basic and diluted	(0.43)	(0.38)	(0.52)	(0.88)

** Loss per share is calculated on a quarterly basis and may not be additive to year-to-date amounts.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures.

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. An evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Annual Report on Form 10-K was made under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (a) are effective to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is timely recorded, processed, summarized and reported and (b) include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. This Annual Report on Form 10-K does not include a report on management s assessment regarding internal control over financial reporting or an attestation report of the company s registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. There have not been any changes in our internal control over financial reporting that occurred during the year ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The information with respect to the identity, business experience and directorships of the directors of the Company and their remuneration is incorporated by reference to the information set forth in the section captioned Election of Directors in the Company s Proxy Statement for the 2007 Annual Meeting of Stockholders, which is anticipated to be filed pursuant to Regulation 14A no later than one hundred twenty (120) days following the end of the fiscal year reported upon (the Proxy Statement). The information with respect to the identity and business experience of executive officers of the Company is set forth in the Section captioned Executive Officers of the Registrant in Part I of this Annual Report on Form 10-K. The information with respect to the Company s Audit Committee is incorporated by reference to the information set forth in the section captioned Meetings and Committees of the Board of Directors in the Proxy Statement. The information with respect to material changes in the nominating process for the Board of Directors, if any is, incorporated by reference to the information set forth in the appropriate subsection of the section captioned Election of Directors in the Proxy Statement. The information with respect to compliance with Section 16(a) of the Exchange Act is incorporated by reference to the section captioned Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement. The information with respect to the Company s Code of Ethics is incorporated by reference to the section captioned Code of Ethics in the Proxy Statement.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth under the caption Executive Compensation and Other Information in the Company s Proxy Statement for the 2007 Annual Meeting of Stockholders which is anticipated to be filed pursuant to Regulation 14A no later than one hundred twenty (120) days following the end of the fiscal year reported upon.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to the information set forth under the caption Security Ownership of Management and Principal Stockholders in the Company s Proxy Statement for the 2007 Annual Meeting of Stockholders which is anticipated to be filed pursuant to Regulation 14A no later than one hundred twenty (120) days following the end of the fiscal year reported upon.

Item 13. Certain Relationships and Related Transactions and Director Independence.

The information required by this item, if any, is incorporated by reference to the information set forth under the caption Certain Relationships and Related Transactions in the Company s Proxy Statement for the 2007 Annual Meeting of Stockholders which is anticipated to be filed pursuant to Regulation 14A no later than one hundred twenty (120) days following the end of the fiscal year reported upon.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to the information set forth under the caption Principal Accountant Fees and Services in the Company s Proxy Statement for the 2007 Annual Meeting of Stockholders which is anticipated to be filed pursuant to Regulation 14A no later than one hundred twenty (120) days following the end of the fiscal year reported upon.

Part IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

1. The following financial statements are included in Item 8 of this Annual Report:

Report of Independent Registered Public Accounting Firm
Balance Sheets as of December 31, 2006 and 2005
Statements of Operations for the years ended December 31, 2006, 2005 and 2004
Statements of Stockholders Equity (Deficit) for the years ended December 31, 2006, 2005 and 2004
Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004
Notes to Financial Statements

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable.

2. Exhibits

Exhibit Number	**Description of Exhibit**
3.1	Articles of Amendment and Restatement of the Registrant
3.2	Bylaws of the Registrant
4.1	Form of Common Stock Certificate.
10.1	Amended and Restated 1994 Stock Incentive Plan, as amended.
10.2	2006 Omnibus Plan.
10.3	Director Compensation Policy.
10.4	Employment Agreement by and between the Registrant and C. Randal Mills, Ph.D., dated as of May 15, 2004.
10.5	Employment Agreement by and between the Registrant and Cary J. Claiborne, dated as of December 3, 2004.
10.6	Employment Agreement by and between the Registrant and Harry Carmitchel, dated as of September 1, 2004.
10.7	Employment Agreement by and between the Registrant and Earl R. Fender, dated as of June 12, 2006.
10.8	Loan Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003, as amended.
10.9	Amendment No. 1 to the Loan Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 12, 2004.
10.10	Security Agreement from the Registrant to Boston Scientific Corporation, dated as of March 12, 2004.
10.11	*Contract Manufacturing Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.12	*Development Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.13	Investment Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.14	Investor Rights Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.

10.15*	License Agreement by and between the Registrant and Boston Scientific Corporation, dated as of March 5, 2003.
10.16	Investor Rights Agreement by and between the Registrant and JCR Pharmaceuticals, Inc. dated August 26, 2003.
10.17	*License Agreement by and between the Registrant and JCR Pharmaceuticals, Inc. dated August 26, 2003.
10.18	*Distribution and Supply Agreement by and between the Registrant and Blackstone Medical, Inc., dated as of November 10, 2005.
10.19	Technology Transfer and License Agreement by and between the Registrant and Case Western University, dated as of January 1, 1993, as amended.
10.20	*Marketing Collaboration and License Agreement by and between the Registrant and BioWhittaker, Inc., dated as of August 11, 1999.
10.21	Registration Rights Agreement by and between the Registrant and Cambrex Corporation, dated November 28, 2005.
10.22	Form of Convertible Promissory Note, dated October 30, 2006
10.23	Lease Agreement by and between the Registrant and SAGA Limited Partnership, dated as of January 18, 1995, as amended.
10.24	Second Amended and Restated Sublease Agreement by and between the Registrant and Maryland Economic Development Corporation, dated as of June 30, 1998, as amended.
10.25	Lease Agreement by and between Gateway S-8, LLLP and Nova Telecommunications, Inc., dated August 11, 1998, as amended.
10.26	Sublease Agreement by and between the Registrant and Broadwing Corporation, dated as of June 2, 2006.
10.27	Agreement of Lease by and between the Registrant and Columbia Gateway S-28, L.L.C., dated June 6, 2006.
10.28	Consulting Agreement by and between the Registrant and Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, dated November 1995, as amended.
10.29	Termination Letter from Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, to the Registrant, dated May 10, 2006.
10.30	Indemnification Letter from Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, and Peter Friedli to the Registrant, dated May 19, 2006.
10.31	Warrant to Purchase up to 4,000,000 shares of Common Stock granted by Registrant to Peter Friedli, dated May 24, 2006.
10.32	Lock-up Agreement dated as of October 30, 2006 by and among the Registrant, Peter Friedli, Friedli Corporate Finance, Inc. and US Venture 05, Inc.
10.33	Letter Agreement dated October 30, 2006 by and between the Registrant and Friedli Corporate Finance, Inc.
10.36	Employment Agreement by and between the Registrant and Lode Debrabandere, dated as of July 31, 2006.
11.1.1	Statement re: Computation of Per Share Loss (included in Note 2 to Financial Statements included in Part II Item 8 herein).
23.1.1	Consent of Independent Registered Public Accounting Firm (filed herewith).
31.1.1	Rule 15d-14(a) Certification of C. Randal Mills, Chief Executive Officer (filed herewith).

31.2.1	Rule 15d-14(a) Certification of Cary J. Claiborne, Chief Financial Officer (filed herewith).
32.1.1	Section 1350 Certification of C. Randal Mills, Chief Executive Officer, and Cary J. Claiborne, Chief Financial Officer (filed herewith).

Previously filed as an Exhibit to the Registrant s Registration Statement on Form S-1, which was declared effective by the United States Securities and Exchange Commission on August 3, 2006.

Previously filed as an Exhibit to the Registrant s Current Report on Form 8-K, as filed with the United States Securities and Exchange Commission on November 2, 2006.

* Confidential treatment has been granted for certain portions thereof pursuant to an order of the United States Securities and Exchange Commission issued in connection with our Registration Statement on Form S-1, declared effective on August 3, 2006.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

	Osiris Therapeutics, Inc	
March 26, 2007	By:	/s/ C. RANDAL MILLS C. Randal Mills, President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ C. RANDAL MILLS C. Randal Mills	President and Chief Executive Officer (principal executive officer)	March 26, 2007
/s/ CARY J. CLAIBORNE Cary J. Claiborne	Chief Financial Officer, and Corporate Secretary (principal financial officer)	March 26, 2007
/s/ PHILIP R. JACOBY, JR. Philip R. Jacoby, Jr.	Corporate Controller and Assistant Corporate Secretary (principal accounting officer)	March 26, 2007
/s/ GREGORY H. BARNHILL Gregory H. Barnhill	Director	March 26, 2007
/s/ PETER FRIEDLI Peter Friedli	Director	March 26, 2007
/s/ FELIX GUTZWILLER Felix Gutzwiller	Director	March 26, 2007
/s/ JAY M. MOYES Jay M. Moyes	Director	March 26, 2007