OSIRIS THERAPEUTICS, INC.
Form 10-K
March 31, 2014

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2013

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)

Maryland	**71-0881115**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
7015 Albert Einstein Drive, Columbia, Maryland	**21046-1707**
(Address of principal executive offices)	(Zip Code)

443-545-1800
(Registrant's telephone number, including area code)

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

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

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

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 ý

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 ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý 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. ý

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

Large accelerated filer o	Accelerated filer ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

On June 28, 2013, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of voting Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on the NASDAQ Global Market was approximately $332,203,550.

The number of shares of the registrant's Common Stock outstanding as of March 27, 2014 is 34,221,412.

Documents Incorporated by Reference:

Portions of the Registrant's definitive proxy statement for its 2014 Annual Meeting of Stockholders (the "Proxy Statement") to be filed no later than 120 days after the close of the fiscal year are incorporated herein by reference in Part III.

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OSIRIS THERAPEUTICS, INC.
Annual Report on Form 10-K
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PART I

ITEM 1. Business.

CAUTIONARY STATEMENTS ABOUT 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. Statements included or incorporated herein which are not historical facts are forward looking statements. 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, but these terms are not the exclusive means of identifying forward looking statements.

Forward looking statements reflect management's current views with respect to future events and performance and are based on currently available information and management's assumptions regarding future events. While management believes that its assumptions are reasonable, forward-looking statements are subject to various known and unknown risks and uncertainties and actual results may differ materially from those expressed or implied herein. In connection with the "safe harbor provisions" of the Private Securities Litigation Reform Act of 1995, we note that certain factors, among others, which could cause future results to differ materially from the forward-looking statements, expectations and assumptions expressed or implied herein are discussed in greater detail under Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Item 1A "Risk Factors," and may be discussed elsewhere herein or in other documents we file with the Securities and Exchange Commission, or SEC. Examples of forward-looking statements may include, without limitation, statements regarding any of the following: our product development efforts; the success of our product candidates in development; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and commercialization strategy for marketed Biosurgery products (including Grafix®, Ovation®, OvationOS™ and Cartiform®); our cash needs; patents, trademarks and other proprietary rights; the safety and ability of our products perform as intended or expected; our ability to supply a sufficient amount of our marketed products or product candidates and, if or insofar as approved or otherwise commercially available, products to meet demand; our costs to comply with governmental regulations; our plans for or success of sales and marketing; our plans regarding facilities; our ability to establish and maintain reimbursement for our commercially available products; types of regulatory frameworks we expect will be applicable to our products and potential products; and results of our scientific research.

Readers are cautioned that 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 Maryland corporation.

Company Overview

We are a leading stem cell company headquartered in Columbia, Maryland, focused on developing and marketing products to treat medical conditions in the wound, orthopedic, and sports medicine markets. We are a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. We have developed an extensive intellectual property portfolio to protect our technology and commercial interests.

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From 2010 to 2013, we operated in two business segments, Biosurgery and Therapeutics. In October 2013, we sold our Therapeutics segment for up to $100.0 million in initial and contingent consideration and we are now focused on developing and commercializing our Biosurgery business. Our Biosurgery business works to harness the ability of cells and novel constructs to promote the body's natural healing with the goals of improving surgical outcomes and offering better treatment options for patients and physicians. Our Therapeutics business historically focused on developing biologic stem cell drug candidates from a readily available and non-controversial source adult bone marrow. Those activities, except insofar as focused on fulfilling our remaining obligations in connection with the sale of our Therapeutics business, have largely ceased.

The three pillars of our business strategy are to continue our history of innovation, bring about commercial transformation, and ensure differentiation of our company. To innovate, we seek to make new products available to address unmet medical needs through R&D and commercial efforts in our areas of focus in wound care, orthopedics and sports medicine. Disease targets for products commercialized or in development include diabetic foot ulcers, venous stasis ulcers, dermal burns, and sports medicine products for motion preservation. Our commercial transformation is defined by establishing a proprietary sales infrastructure and driving long-term revenue growth. To differentiate, we will seek to identify and introduce barriers to entry, through means such as superior science, clinical data and intellectual property rights. Since 2010, we have launched commercial distribution of several Biosurgery products, including Grafix, Ovation, Cartiform, and OvationOS, each of which we developed and manufacture. We intend to build on the success of our first generation implantable biosurgery product, Osteocel® for regenerating bone in orthopedic indications, which since sold to Nuvasive, Inc. in 2008.

We began operations on December 23, 1992 and were a Delaware corporation until, with approval of our stockholders, we reincorporated as a Maryland corporation on May 31, 2010.

Grafix is a three-dimensional placental tissue matrix for use as a wound covering for application directly to acute and chronic wounds, including diabetic foot ulcers, venous leg ulcers, and burns. Flexible and conforming to complex anatomies, this tissue matrix retains a rich source of extracellular matrix, growth factors and mesenchymal stem cells, or MSCs.

OvationOS, a viable bone matrix, is our newest product to be used for bone repair and regeneration. It is a cancellous bony matrix containing viable endogenous MSCs and osteoprogenitor cells. It contains key components for bone regeneration, including structural biologic matrix, reservoir of growth factors and endogenous MSCs. OvationOS is a functionally complete alternative to autograft, the "gold standard" in bone regeneration. These components naturally have the following capacities:

osteoinduction (stimulating recruitment of neighboring host (endogenous) cells in the patient)

osteoconduction (serving as a scaffold to support bone growth)

osteogenesis (bone-forming)

angiogenesis (blood vessel-forming, important for supply of nutrition and factors to newly forming tissue)

Cartiform is viable cartilage mesh designed for use in cartilage repair, such as marrow stimulation procedures. Cartiform maintains a type II collagen architecture and functioning chondrocytes to preserve the natural properties of hyaline cartilage and recruit the patient's MSCs for improved chondrogenesis.

We believe that Grafix, OvationOS, and Cartiform are regulated by the United States Food and Drug Administration, or FDA, under 21 CFR Part 1271 Part 361 of the Public Health Service Act, Human Cells, Tissues and Cellular and Tissue-based Products , or HCT/Ps. We are registered with the FDA as a tissue establishment and are accredited by the American Association of Tissue Banks.

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Extensive donor screening, serological testing, bioburden testing and sterility testing is performed on every lot to demonstrate suitability for transplantation. Our Biosurgery products are all manufactured in our Columbia, Maryland facility. Each lot is tested to confirm viable cell content post thaw.

In October 2013, following the receipt of an untitled letter from the FDA, we announced an agreement with the FDA on the regulatory status of our marketed Biosurgery products, Grafix and Ovation, and confirmed the HCT/Ps pathway for Grafix indicated as a wound cover for the treatment of acute and chronic wounds. At that time we announced our intentions to file a Biologic License Agreement ("BLA") for Grafix to enable us expanded label claims. We will continue transitioning our Ovation product line over to our newly launched OvationOS formulation, and agreed to complete this transition no later than the second half of 2014.

We market and distribute Grafix directly to hospitals, clinics and physician offices primarily through our direct sales organization and with limited marketing through agents and distributors. We are focused on developing a proprietary direct sales force in the field of wound care. We began to distribute Cartiform and OvationOS during 2013, and currently market those products directly to hospitals and through selected specialty distributors.

A significant market for Grafix is chronic wounds, which are primarily treated in the outpatient setting. Reimbursement by public and private providers for outpatient treatments typically requires approvals from the payers which are granted after in depth and sometimes independent reviews. In furtherance of our efforts to obtain full reimbursement for use of Grafix in the outpatient setting, we conducted a prospective randomized clinical trial comparing Grafix to conventional wound care and reported results of this study in 2013. We refer to this as Protocol 302.

This study included a multicenter, adaptive design, randomized clinical trial to evaluate the efficacy and safety of Grafix for the treatment of chronic diabetic foot ulcers. Patients in the study were randomized in a 1:1 ratio to receive either Grafix or conventional standard of care for a chronic diabetic foot ulcer sized between 1 cm^2 and 15 cm^2. The primary efficacy endpoint was complete wound closure, defined as 100% re-epithelialization, by week 12. Additional secondary efficacy endpoints included time to initial wound closure, proportion of patients with at least 50% reduction in wound size by Day 28 and number of applications of Grafix versus control. The trial was conducted at 20 wound care clinics across the U.S.

On August 13, 2013, we reported that our randomized clinical trial comparing Grafix to conventional wound care, Protocol 302, had met the pre-specified stopping rules for overwhelming efficacy as determined by the data monitoring committee during a planned interim analysis. The study also met all top-line secondary endpoints, demonstrating faster wound closure and a reduction in the number of treatments needed to achieve wound closure. As a result, the blinded phase of the trial was discontinued, and Grafix was made available to all control patients.

Grafix was assigned transitional pass-through status under Medicare's outpatient prospective payment system in July 2012. The Centers for Medicare and Medicaid Services, commonly referred to as CMS, has confirmed pass-through status will remain in effect at least through year-end 2014. In January 2013, CMS issued permanent Healthcare Common Procedure Coding System (HCPCS) Q-codes for Grafix, which assist healthcare providers in facilitating reimbursement in the commercial and Medicare patient populations.

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In the fourth quarter of fiscal 2013, we announced our intention to initiate a new randomized, controlled clinical trial for Grafix for the treatment of venous leg ulcers. We have commenced a pilot evaluation to inform the design of this clinical trial, which we expect to formally initiate during fiscal 2014.

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, or ESC, 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, or HSC, responsible for generating cells associated with the circulatory and immune systems, MSCs 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 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. Also, technical difficulties in purifying and growing ESCs and safety concerns have prevented widespread clinical evaluation.

In adults, two major classes of stem cells exist in bone marrow: HSCs and MSCs. Throughout life, 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, 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 certain 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.

MSCs differentiate into connective tissue cells such as chondrocytes and osteoblasts, responsible for chondrogenesis of cartilage and osteogenesis of bone. Cells have different utilities and potential applications depending on the extent and type of differentiation. Processing and manufacturing techniques must be designed to ensure that the necessary characteristics of the cell for the intended application are maintained.

All of our Biosurgery products all contain viable cells, including naturally occurring MSCs.

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Strategy

We are the first company to receive marketing approval of a stem cell drug and strive to become the world's leading provider of cellular and novel tissue therapies. The three pillars of our business strategy are to continue our history of innovation, bring about transformation, and to ensure differentiation of our company.

To innovate. We seek to make new products available to address unmet medical needs through R&D in our areas of focus in wound care, orthopedics and sports medicine. We intend to advance our pipeline by leveraging our research expertise and in stem cell therapy. Disease targets for products commercialized or in development include diabetic foot ulcers, venous stasis ulcers, dermal burns, and sports medicine products for motion preservation. Due to our experience, we believe we have gained the clinical, regulatory, manufacturing and commercial capabilities to internally develop and commercialize biologic and novel tissue products. We intend to build on the success of our first generation implantable product, Osteocel® for regenerating bone in orthopedic indications, which we sold to Nuvasive, Inc. in 2008.

To transform. We seek to drive revenue growth through commercial excellence. We will work to ensure market access for our products and deliver them to our patients through a best-in-class infrastructure composed of a highly trained specialty biologics sales force. Our company culture is aligned to deliver the best customer experience through quality scientific and medical support.

To differentiate. We will seek and introduce barriers to entry, through means such as superior clinical data and strong intellectual property. Since 2010, we have launched commercial distribution of several Biosurgery products, including Grafix, Ovation, Cartiform, and OvationOS, each of which we developed and manufacture internally. We retain proprietary trade secret information for each of our products.

Intellectual Property

Our broad intellectual property portfolio originates from our pioneering scientific efforts. Those efforts have helped establish a considerable patent position in adult stem cell technology that we developed. In connection with the sale of our culture expanded mesenchymal stem cell (ceMSC) business to Mesoblast, as described further below, we retained access to these proprietary adult stem cell technologies for use in furtherance of our Biosurgery business. In addition, we continue to build our intellectual property position with additional patents and extensions related to our newer Biosurgery products. We are committed to protecting our intellectual property position by continuously monitoring the competitive landscape and are prepared to act in the event of product infringement.

In October 2013, we entered into a Purchase Agreement with a wholly owned subsidiary or Mesoblast Limited for the sale of our ceMSC business, including Prochymal and other related assets. However, also pursuant to the Purchase Agreement, we retained a royalty free license to all transferred intellectual property, insofar as necessary to continue in our other businesses, including our Biosurgery business. We have agreed not to compete with Mesoblast in the ceMSC business for a period of eight years.

Patent life determination depends on the date of filing of the application and other factors promulgated under patent law and regulatory laws including, for example, the United States Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act. 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, or of a Biologics License Application, or BLA, plus the time between the submission date of an NDA or BLA 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

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approves applications for patent term extension. Where appropriate and when eligible, we expect to apply for patent term extensions in an effort to bolster market exclusivity beyond nominal patent expiration dates.

We also rely upon trade secrets to protect our proprietary information. A significant amount of our technology, including our teaching regarding the manufacturing processes of our Biosurgery products, is maintained by us as trade secrets. Through our experience with MSCs and MSC-based product development, we have developed expertise and know-how in this field. We have the capability to manufacture clinical grade products in-house. To protect this 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.

Manufacturing

Our current Biosurgery products are derived from donated human tissue for transplant. Grafix is derived from human placental tissue and OvationOS and Cartiform are derived from donated human cadaveric tissue. We contract with tissue recovery agencies for the source tissue for our Biosurgery products. Once an initial qualification of the donor is performed the tissue is sent to our processing center overnight. The agencies also compile the donor medical records, collect medical and social history, and collect samples for serological testing. These agencies operate on a fee for service basis. We intend to enter into contracts with additional tissue recovery agencies in the future if required and available to fulfill expected product demand.

The processing of our Biosurgery products is in many ways more like the process of organ donation than standard tissue processing. This is because it is essential that the tissue integrity is maintained like that of the native tissue. We overcome this challenge through a proprietary cryopreservation and frozen storage process that is designed to maintain the integrity of the material. Following completion of this process, and after passing quality control testing, quality assurance and medical director review, the Biosurgery product is released for distribution.

Sales, Marketing and Distribution

We currently intend to continue to self-commercialize all of our Biosurgery products through the efforts of focused direct distribution and marketing staff, as well as through a network of specialty distributors for certain target markets. Our marketing of Grafix is targeted at facilities caring for chronic wound patients in the United States. As discussed above, we have received transitional pass-through status from CMS, and Q-codes for Grafix, which will assist in facilitating reimbursement in the physician office and hospital outpatient settings.

We conducted a randomized clinical trial comparing Grafix to conventional wound care, Protocol 302, which was also designed to further facilitate health care reimbursement for Grafix. This multicenter, randomized controlled clinical trial evaluated the efficacy and safety of Grafix for the treatment of chronic diabetic foot ulcers. Patients enrolled in this study received either Grafix or control treatment for a chronic diabetic foot ulcer sized between 1 cm^2 and 15 cm^2. The control was standard wound care, saline gauze dressing. Randomization of Grafix to control was 1:1. The primary efficacy endpoint of this study was complete wound closure, defined as 100% re-epithelialization, by week 12. Additional secondary efficacy endpoints include time to initial wound closure, number of patients with at least 50% reduction in wound size by Day 28 and number of applications of Grafix versus control. The trial was conducted at 20 wound care clinics across the US.

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On August 13, 2013, we reported that this study had met the pre-specified stopping rules for overwhelming efficacy as determined by the data monitoring committee during a planned interim analysis of 97 patients. All top-line secondary endpoints also demonstrated clinical benefit of Grafix over control, including faster wound closure and a reduction in the number of treatments needed to achieve wound closure. As a result, the blinded phase of the trial was discontinued immediately, and all patients randomized to the control arm were offered treatment with Grafix.

Given the successful outcome of Protocol 302, our multi-center randomized controlled trial focused on the treatment of diabetic foot ulcers, and after more widespread publication of the clinical trial data, we anticipate that Grafix will become more widely adopted for treatment of chronic wounds, including diabetic foot ulcers, with the support of the clinical trial data.

Our marketing of OvationOS is targeted to orthopedic surgeons and neurosurgeons practicing in the United States. Cartiform is utilized by orthopedic surgeons specializing in sports medicine. We may in the future seek to enter into strategic partnerships with device or other orthopedic distributors to facilitate distribution and market penetration of OvationOS.

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 United States 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 regulatory approvals of products, and marketing and selling those products. Accordingly, our competitors may succeed in more rapidly obtaining approval for products and achieving widespread market acceptance. If we obtain necessary regulatory approval and commence significant commercial distribution of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited commercial-scale experience.

Our wound care products compete with other companies and organizations that are marketing products in direct competition with Grafix. At present, there are over 140 products being utilized for the treatment of chronic wounds, ranging from enzymatic debridement agents to biologics such as advanced skin substitutes. Of these 140 products, there are numerous direct skin substitute competitors to Grafix, including bioengineered products and other HCT/Ps (human cells, tissues, and cellular and tissue-based products). Additionally, there are competitors executing clinical trials with intent to file BLAs and to seek FDA approvals upon successful trial completion. OvationOS will compete with bone tissue products such as Osteocel® and Trinity®, while Cartiform competes with cartilage allografts. In addition to these, other potential competitors are developing a variety of additional competing products, including other amniotic membrane products. The limited patent protection for our Biosurgery products reduces the barrier for entry and makes our Biosurgery products susceptible to increased risk of competition.

We expect to compete based upon, among other things, the efficacy of our products and our intellectual property portfolio. 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 highly efficacious products, and to be successful with these products commercially before others are able to develop competitive products.

In addition, our tissue products and other biologic therapies may be expensive as compared to other therapies and this may make it more difficult for us to compete.

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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. Certain products we develop will require marketing approval, or licensure, by governmental agencies prior to commercialization in some or all jurisdictions. In particular, drugs and biologic 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 any required approvals will be granted.

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. Products regulated as so-called "Part 361 HCT/Ps" (meaning that they comply with section 361 of the Public Health Service Act and the regulations in 21 CFR 1271) are regulated differently from biologics or drugs. This is 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. Unlike drugs and biologic products, FDA regulations do not require premarket approval for HCT/Ps; however, strict adherence to federally mandated cGTP regulations are required. These regulations are analogous to the cGMP regulations described above in terms of manufacturing standards. In addition, the FDA's regulations include other requirements to prevent the introduction, transmission and spread of communicable disease. The FDA's regulations require tissue establishments to register and list their HCT/Ps with the FDA and to evaluate donors through screening and testing.

We received an "untitled letter" dated September 26, 2013 from the FDA stating, among other things, that both Grafix and Ovation do not meet these regulatory requirements because they are dependent upon the metabolic activity of living cells for their primary function and are not intended for autologous use or allogeneic use in a first or second degree relative; and that Ovation does not meet the minimal manipulation criterion. After discussions with, and providing additional information to, the FDA, we reached an agreement with the FDA confirming the regulatory status of Grafix and allowing the product to remain on the market as an HCT/P and without FDA pre-marketing approval, as a wound cover for the treatment of acute and chronic wounds. We further committed to the FDA that, before marketing Grafix for certain expanded indications, we would submit a Biologics License Application (BLA) to the FDA and seek pre-marketing approval for any such additional indication. We also agreed to continue to transition our Ovation product line over to OvationOS, and agreed to complete that transition by no later than the second half of 2014. We believe that commercial distribution of OvationOS, a viable bone matrix for bone growth, does not require pre-market approval by the FDA because we believe that this product meets the regulatory definition of HCT/Ps.

The analysis and determination of compliance of a product with these regulatory requirements is complex and dependent upon numerous factors, and is readily subject to varying interpretations and conclusions. Should the FDA decide that Grafix, OvationOS or any of our other Biosurgery products do not meet the regulatory definition of HCT/Ps, we will not be able to produce and redistribute these products unless and until we submit a BLA and obtain pre-marketing approval from the FDA, which would likely require clinical trials and could take years to obtain, at significant expense. This would have a material adverse effect on our business, financial condition and results of operations.

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We maintain state licensure as a human tissue bank in Maryland, California, Florida, and New York. These are the only states in which this specific licensure is required for us. We also received and actively maintain American Association of Tissue Banks (AATB) accreditation.

Regulatory Approval Process

Biologic drug candidates that we may develop will require approval from the FDA and corresponding agencies in other countries before they can be marketed. These may include any our Biosurgery products that may be determined not to qualify as a Part 361 HCT/P, and will also likely include all of our Biosurgery products when sought to be marketed in Europe, where products that would otherwise qualify as a Part 361 HCT/P in the United States are more heavily regulated. These approvals require, among other things, that we demonstrate the safety and efficacy of the product, and in any event are costly and time consuming. The FDA regulates human therapeutic products in one of three broad categories: biologics, drugs, or medical devices. The FDA generally requires the following steps for pre-market approval or licensure of a new biological product or new drug product:

- preclinical laboratory and animal tests conducted in compliance with the FDA's Good Laboratory Practice, or GLP, requirements to assess biological activity and safety;

- submission to the FDA of an IND application or equivalent application in other territories, which must become effective before clinical testing in humans can begin;

- documentation of the product's chemistry, manufacturing controls, formulation, and stability;

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

- submission of a BLA to the FDA, (or equivalent thereof in other territories) for marketing that includes adequate results of preclinical testing and clinical trials to determine whether the product is safe, and effective for its intended use; and

- regulatory approval of the product, including inspection and approval of the product manufacturing facility as compliant with cGMP requirements.

Typically, clinical testing involves a three-phase process, designated phase 1, phase 2 and phase 3. The largest clinical studies, phase 3 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 addition, often a regulatory agency will require Phase 4 or post-marketing trials to collect additional data about the drug on the market. An agency may, at its discretion, alter, suspend, or terminate the testing based upon the data which have been accumulated to that point and its assessment of the risk/benefit to the patient.

Upon review of a BLA or NDS or equivalent, the regulatory authority may grant marketing authorization, request additional clinical data or deny approval if the agency determines that the application does not satisfy its approval criteria. Review of a marketing application typically takes one to three years, but may last longer, especially if the agency 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 supplemental applications.

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, established pursuant to the Prescription Drug User Fee Act ("PDUFA") and its amendments. PDUFA also imposes an annual product fee for prescription drugs and biologics ($98,380), and an annual establishment fee ($526,500) on facilities used to manufacture prescription drugs and biologics. Fee waivers or reductions are

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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 solely as orphan drugs.

Before approving a marketing application, all facilities and manufacturing techniques used for the manufacture of products must comply with applicable FDA regulations governing cGMP. In the United States, a local field division of the FDA is responsible for completing this inspection and for providing a recommendation for or against approval. This effort is intended to assure appropriate facility and process design in order 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 inspection 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 and cost and put forth significant effort in the areas of training, record keeping, production, and quality control. Following approval, the manufacture, holding, and distribution of a product requires the continued allocation of significant resources to maintain full compliance in these areas.

After regulatory approval has been obtained, the agency will typically require post-marketing reporting to monitor potential 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, a supplement may be required.

Additionally, once a drug product has been authorized to enter commercial distribution, numerous additional regulatory requirements apply. These include, among others, cGMPs; 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 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 drug reactions related to a drug product in any existing or future markets could cause regulatory authorities to withdraw market approval for such product.

Comparable requirements are applicable to our current Biosurgery products when sought to be marketed in many foreign countries, including those of the European Union where human cells, tissues, and cellular and tissue-based products are more heavily regulated and require pre-marketing approval similar to that required of drugs and biologics in the United States.

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 ("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

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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. Any 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 distribution of human tissue and tissue products, 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. In addition, procurement of certain human organs, and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act ("NOTA"), which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We include in our pricing structure amounts to tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, and in addition to certain costs associated with processing, preservation, quality control and storage of the tissue, marketing and medical education expenses, and costs associated with the development of tissue processing technologies. NOTA payment allowances may be interpreted to limit the amount of costs and expenses that we can recover in our pricing for our products, thereby reducing our future revenue and profitability. If we were to be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions.

Foreign Regulation

We expect to 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. Although there is now a centralized European Union approval mechanism in place, this applies only to certain specific medicinal product categories. 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.

Employees

As of December 31, 2013, our headcount was 70 full-time and 5 part-time employees. Of this total, 13 were engaged in research and development and clinical trials in our Biosurgery business, 33 were engaged in Biosurgery manufacturing activities, 19 were engaged in sales and marketing activities and

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10 were engaged in administration, finance, and facilities. All of our employees have entered into non-disclosure agreements with us regarding our intellectual property, trade secrets and other confidential or proprietary information. None of our employees are represented by a labor union or covered under a collective bargaining agreement, and we have not 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
Lode Debrabandere, Ph.D.	48	President and Chief Executive Officer (since December 2013, Chief Operating Officer from October 2012 through November 2013 and Vice President of Therapeutics from July 2006 through September 2012)	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).
Michelle LeRoux Williams, Ph.D.	39	Chief Scientific Officer (since May 2007)	Dr. Williams joined Osiris in 2001 as the Director of Orthopedics and was responsible for the development of Osteocel from the initial concept through product launch in 2005. Dr. Williams also advanced the Chondrogen program from preclinical testing through the Phase I/II clinical trial. Prior to joining Osiris, Dr. Williams completed an NIH postdoctoral fellowship in tissue engineering at Columbia University, evaluating cellular constructs for the repair and regeneration of cartilage in arthritis patients.

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Name	Age	Position	Other Offices or Positions Held During the Past Five Years
Philip R. Jacoby, Jr.	61	Chief Financial Officer, Treasurer and Corporate Secretary (since October 2005)	Mr. Jacoby has over 30 years of financial and management experience with public and privately held companies. Mr. Jacoby joined Osiris in April 2005 as our Corporate Controller and principal accounting officer in preparation for our initial public offering. Prior to joining Osiris, Mr. Jacoby was the Vice President and Corporate Controller for FTI Consulting, Inc. (NYSE FCN) for five years. Upon graduation from the University of Maryland, he spent over eight years with Arthur Andersen & Co.
Frank D. Czworka, Jr.	45	Vice President and General Manager of Wound Care (since February 2014, employed since August 2011)	Mr. Czworka joined Osiris in 2011 as General Manager of Wound Care and was promoted to Vice President in February 2014. Mr. Czworka has over 20 years of sales and marketing experience in the Life Science industry with a demonstrated track record of building specialty sales forces and developing product access in managed markets, including public and private payer accounts. Mr. Czworka worked for Auxillium Pharmaceuticals from 2009 through 2011 and was Vice President of Sales at MedImmune, LLC from 2000 through 2009. He has a BSBA degree in Marketing from the University of Central Florida.

Available Information

Our website address is *www.osiris.com* . Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available on our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission, or SEC. The public may read and copy

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these materials at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains such reports, proxy and information statements and other information, and the Internet address is *http://www.sec.gov* . Information contained on our website is not and should not be deemed a part of this annual report or any other report or filing filed with the SEC.

ITEM 1A. Risk Factors.

Risks Related To Our Business

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

Until fiscal 2009, we incurred losses in each year since our inception, and may incur additional losses over the next several years. As of December 31, 2013, we had an accumulated deficit of $201.8 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 in the foreseeable future as we seek to:

- finalize our controlled trial with Grafix for diabetic foot ulcers;
- continue other studies and initiate and pursue additional studies and possible clinical trials for our Biosurgery products, including Grafix for venus leg ulcers and possibly other potential indications;
- manage regulatory issues and requirements related to the marketing and distribution of our products and product candidates, including issues related to FDA approval and third party payor reimbursement;
- maintain, expand and protect our intellectual property; and
- continue to add sales, operational, financial, accounting, facilities engineering and information systems personnel, consistent with expanding our operations.

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.

The current credit and financial market conditions may exacerbate certain risk affecting our business.

We rely upon third parties for certain aspects of our business, including collaboration partners, wholesale distributors, contract clinical trial providers, contact manufacturers and third-party suppliers. Because of the tightened global credit and continuing volatility in the financial markets, there may be a delay or disruption in the performance or satisfaction of commitments to us by these third parties, which could adversely affect our business.

We depend on key personnel.

Our future success depends to a significant extent on the skills, experience and efforts of our scientific, management, and sales personnel. These include Lode Debrabandere Ph.D., Michelle L. Williams, Ph.D., Philip R. Jacoby, Jr., and Frank Czworka. We also rely upon the guidance and experience of Peter Friedli, the Chairman of our Board of Directors. The loss of any or all of these individuals could harm our business and might significantly delay or prevent the achievement of

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research, development or business objectives. We are party to an employment agreement with Dr. Debrabandere. The existence of an employment agreement does not, however, guarantee retention of any officer or employee, and we may not be able to retain any of these individuals, whether or not we have an employment agreement with them. Except for 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.

The potential of our Biosurgery products and products under development to treat conditions may not be realized .

We are continually evaluating the potential of our Biosurgery products and products under development. Our products are susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate efficacy or other characteristics that may prevent or limit their commercial use, or if required, marketing approval. If the treatment potential of our products is not realized, the value of our technology, our development programs and our products could be significantly reduced. Because our Biosurgery products are comprised of human tissue, any negative developments regarding the therapeutic potential or side effects of human tissue products could have a material adverse effect on our business, financial condition and results of operations.

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

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our products and product candidates creates significant challenges in regards to product development and optimization, processing and manufacturing, government regulation, third-party reimbursement and market acceptance. For example, questions persist with regard to the necessity of FDA approval for some cell-based products, and therefore, the pathway to commercialization of our Biosurgery products may be more complex and lengthy. Additionally, cell-based products are subject to donor-to-donor variability, which can make standardization more difficult. As a result, the development and commercialization pathway for our products may be subject to increased uncertainty, as compared to the pathway for conventional products.

Our Biosurgery products represent new classes of therapy that the marketplace may not understand or accept.

The market may not understand or accept our products. We are developing products that represent novel treatments or therapies and which will compete with a number of more conventional products and therapies manufactured and marketed by others, including major pharmaceutical companies. The novel nature of our Biosurgery products creates significant challenges in regards to product development and optimization, manufacturing, government regulation, and third-party reimbursement. As a result, the development pathway for our Biosurgery products may be subject to increased scrutiny, as compared to the pathway for more conventional products.

The degree of market acceptance of any of our developed or potential products will depend on a number of factors, including:

- the clinical safety and effectiveness of our products and their perceived advantage over alternative treatment methods;
- our ability to convince health care providers that the use of our products in a particular procedure is more beneficial than the standard of care or other available methods;
- our ability to explain clearly and educate others on the use of human placental tissue, to avoid potential confusion with and differentiate ourselves from the ethical controversies associated with human fetal tissue;

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ethical controversies that may arise regarding the use of human tissue of any kind, including tissues derived from deceased donor, and distribution for profit of our deceased donor products;

adverse reactions involving our biosurgery products or the products or product candidates of others that are human tissue 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 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 and distribution of our Biosurgery products will depend on obtaining reimbursement from third-party payors.

We distribute our Biosurgery products in the United States. We may expand our distribution to other countries in the future. In the United States and elsewhere, the market for any pharmaceutical or therapeutic 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. Biosurgery products like Grafix and OvationOS may have higher costs or fees associated with them compared with more traditional products, due to the higher cost and complexity associated with their research, development and production, and the complexity associated with their distribution which requires special handling, storage 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 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.

In the countries of Europe and in some other countries, the pricing of prescription and therapeutic products and services, and reimbursement, are subject to increased governmental control. In addition, many other countries require pre-marketing approval for human tissue based products, or otherwise more extensively regulate human tissue based products than does the United States.

Regardless of whether we are required to conduct a successful clinical trial in order to market a product in the United States or a foreign country, we may nevertheless be required to conduct one or more clinical trials, and to publish one or more peer reviewed journal articles supporting the product, before we are able to obtain third party reimbursement. We may also be required to conduct additional clinical trials that compare the cost effectiveness of our products to other available therapies before third party payors will provide reimbursement. Conducting clinical trials is expensive and will result in delays in wide scale commercialization and reimbursement. Publishing of peer reviewed journal articles may also be costly and result in delays. In addition, even if our products otherwise meet the requirements for reimbursement, pricing negotiations with third party payors may take months and result in significant delay in obtaining approval for reimbursement.

Reimbursement policies also sometimes differ depending upon the setting in which the product is to be used. The use of our Biosurgery products in a hospital setting as part of a surgical or other more extensive procedure may have a reimbursement pathway that differs from a use in an outpatient setting for a more narrowly defined procedure. Thus, for example, the reimbursement pathway for Grafix which we expect to be used more often in an outpatient setting may differ form that for OvationOS which we expect to be used more often in an in-patient hospital setting as part of a surgical procedure.

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These differences may limit or make reimbursement more difficult for some products as compared to others, and influence our product development and marketing efforts in ways that may ultimately prove to be detrimental to us or our business.

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 U.S. legislation should impact our business specifically and negatively as compared to other health care product businesses generally, we might nevertheless 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 human tissue necessary to produce our Biosurgery products may impact our ability to produce these products on a large scale.

Our Biosurgery products consist of human tissue. This tissue is obtained by us from not-for-profit donor procurement agencies. Grafix and Ovation are processed from human placental tissue. Ovation OS is processed from deceased donor bone. Cartiform is processed from deceased donor cartilage. While we are not aware of significant supply issues, and placental tissue and deceased donor bone and cartilage is generally available to us, the supplier agencies may not be able to provide us with sufficient amounts of tissue to meet the demand. In addition, the use of human tissue as a treatment for human disease and medical conditions has increased over recent years and continues to increase, creating greater and continually increasing competition and demand for donated human tissue. Even if we are successful in in our efforts to expand our compliment of Biosurgery products, we may not be able to secure quantities of human tissue sufficient to meet the demand.

Our Biosurgery products are derived from human tissue and therefore have the potential for disease transmission.

The utilization of human tissue creates the potential for transmission of communicable disease, including but not limited to human immunodeficiency virus (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, cartilage and placental tissue 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

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on our reputation with our customers and our ability to distribute our products, which could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to process our Biosurgery products in sufficient quantities to expand our market for the products.

We may encounter difficulties in the production of our Biosurgery products due to our limited manufacturing capabilities. This difficulty could reduce redistribution efforts of our products, increase our distribution costs or cause production delays, any of which could damage our reputation and effect our operations. Even if we have access to quantities of human tissue sufficient to allow us otherwise to expand our manufacturing capabilities, we may not be able to produce sufficient quantities of the product at an acceptable cost, or at all.

We use or may 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.

We are subject to a number of risks associated with our dependence upon our collaborative relationships, including:

- our collaborators may not cooperate with us or perform their obligations under our agreements with them;
- we cannot control the quality, amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them, and our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us;
- refusal to or failure of our collaborators to perform their responsibilities in a timely manner, including breach;
- the right of the collaborator to terminate its collaboration agreement with us for reasons outside our control, and in some cases on limited notice;
- business combinations and changes in a collaborator's business strategy may adversely affect the party's willingness or ability to complete its obligations;
- loss of significant rights to our collaborative parties if we fail to meet our obligations;
- disagreements as to ownership of clinical trial results or regulatory approvals;
- withdrawal of support by a collaborator following development or acquisition by the collaborator of competing products; and
- disagreements with a collaborator regarding the collaboration agreement or ownership of intellectual property or other proprietary rights.

Due to these factors and other possible events, we could suffer delays in the research, development or commercialization of our products or we may become involved in litigation or arbitration, which would be time consuming and expensive.

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We are currently dependent upon third-parties for services and raw materials needed for the processing of our Biosurgery products, and for distribution.

In order to produce our Biosurgery products we require biological media, reagents and other highly specialized materials. This is in addition to the human tissue donations used to manufacture our biosurgery products. These items must be manufactured and supplied to us in sufficient quantities and in compliance with cGMP. To meet these requirements, we have entered into supply agreements with firms that manufacture these components to cGMP standards.

We expect to continue to rely on third parties to sell or redistribute our biosurgery products. Proper shipping and distribution requires compliance with specific storage and shipment procedures. 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. If any of these third parties fail or are unable to perform in a timely manner, our ability to manufacture and deliver could be compromised, and our business would be harmed.

Use of third-party manufacturers may increase the risk that we will not have adequate quantities of our biosurgery products.

Our biosurgery product supply chain and processing infrastructure depends on the performance of a number of complex contracts between us on the one hand and our suppliers and redistributors on the other. If any of our suppliers, distributors or other business partners cannot or do not perform their contractual obligations, then our production efforts may suffer. If we cannot or do not perform our contractual obligations, then we may be subject to arbitration, mediation or litigation that could have an adverse material effect on us.

Reliance on third-parties 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, product seizures or recalls, operating restrictions and criminal prosecutions. Any of these actions could significantly and adversely affect supplies of our products and could have a material adverse effect on our business, financial condition and results of operations.

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If our processing and storage facility 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 product, raw and other materials, and work in process.

We lease approximately 61,203 square feet of space in Columbia, Maryland that houses essentially all of our corporate operations. Currently, we maintain insurance coverage totaling $21.8 million against damage to our property and equipment, an additional $5.0 million to cover business interruption and extra expenses, and $6.0 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 human tissue may negatively affect public perception of us or our products, or may result in increased scrutiny of our products and product candidates from a regulatory approval perspective, thereby reducing demand for our products, restricting our ability to market our products, or adversely affecting the market price for our common stock.

The commercial success of our Biosurgery products depends in part on general public acceptance of the use of human tissue for the treatment of human diseases and other conditions. While not as controversial as the use of embryonic stem cells and fetal tissue, the use of placental tissue and adult tissue has been the subject of substantial debate regarding related ethical, legal and social issues. 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 placental or adult tissue from the use by others of embryonic stem cells or fetal tissue. Ethical concerns have been raised by some about the use of donated human tissue in a for-profit setting. This could result in a negative perception of our company or our products.

Future adverse events in the field of cellular based therapy or changes in public policy could also result in greater governmental regulation of our products and potential regulatory uncertainty or delay relating to any required testing or approval.

Many of our competitors have greater resources or capabilities than we have, or may succeed in developing better products or in developing products more quickly than we do.

In the marketplace, we compete with other companies and organizations that are marketing or developing products competitive with Grafix and our other Biosurgery products and products under development. In many cases, the competing product or candidate is based on traditional pharmaceutical, medical device or other non-cellular therapy and technologies. Competitors competing with our Biosurgery products include: Advanced Biohealing, the manufacturer of Dermagraft which competes with Grafix; Organogenesis, the manufacturer of Apligraf which competes with Grafix. In addition to those listed above, we have other potential competitors developing a variety of treatments and therapies for the same conditions for which we market our products.

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 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 products now or in the future under development by us, or any products manufactured or marketed by us, non-competitive or otherwise obsolete.

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The use of our Biosurgery products 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. None of our products have been widely used over an extended period of time, and therefore our safety data are limited. We derive the raw materials for our products from human donor sources, the production process is complex, and the handling requirements are specific, all of which increase the likelihood of quality failures and subsequent product liability claims. 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, among other things:

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

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

In addition to costs incurred in product development and management of the regulatory approval and reimbursement processes, we will incur additional operating expenses in connection with the expansion of our Biosurgery business.

We expect to continue to incur significant operating expenses in connection with our planned expansion of our biosurgery business, as we seek to:

- develop our distribution network of third party distributors and independent sales professionals for the distribution of Grafix, OvationOS and other Biosurgery products;
- continue to expand our internal sales force and marketing capabilities, through the hiring of sales and marketing professionals and building an internal sales and marketing organization;
- hire additional manufacturing, quality control, and quality assurance, and management personnel as necessary to expand our processing operations;
- expand our processing capacity for our Biosurgery products, which will require that we maintain a portion of our space as an FDA compliant and validated product manufacturing facility; and
- expand and protect our intellectual property portfolio for our Biosurgery products.

Our redistribution fees from our Biosurgery products have been limited to date. Our ability to scale up our production capabilities for larger quantities of these products remains to be proven. Our costs in marketing and distributing these products will also increase as production increases.

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Risks Related to Regulatory Approval and Other Government Regulations

Should the FDA determine that any of our products do not meet regulatory requirements that permit qualifying human cells, tissues and cellular and tissue-based products to be processed, stored, labeled and distributed without pre-marketing approval, we may be required to stop processing and distributing such products, or to narrow the indications for which those products are marketed.

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 Grafix as a wound cover for the treatment of acute and chronic wounds, including diabetic foot ulcers, does not require pre-market approval by the FDA because we believe that this product meets the regulatory definition of human cells, tissue, and cellular and tissue-based products, or so-called Part 361 HCT/Ps (meaning that they comply with section 362 of the Public Health Service At (PHSA) and 21 CFR 1271). We received an "untitled letter" dated September 26, 2013 from the FDA stating, among other things, that both Grafix and Ovation do not meet these regulatory requirements because they are dependent upon the metabolic activity of living cells for their primary function and are not intended for autologous use or allogeneic use in a first or second degree relative; and that Ovation does not meet the minimal manipulation criterion. After discussions with, and providing additional information to, the FDA, we reached an agreement with the FDA confirming the regulatory status of Grafix and allowing the product to remain on the market as an HCT/P and without FDA pre-marketing approval, as a wound cover for the treatment of acute and chronic wounds. We further committed to the FDA that, before marketing Grafix for certain expanded indications, we would submit a Biologics License Application (BLA) to the FDA and seek pre-marketing approval for any such additional indication. We also agreed to continue to transition our Ovation product line over to OvationOS, and agreed to complete that transition by no later than the second half of 2014. We believe that commercial distribution of OvationOS, a viable bone matrix for bone growth, does not require pre-market approval by the FDA because we believe that this product meets the regulatory definition of HCT/Ps.

The analysis and determination of compliance of a product with these regulatory requirements is complex and dependent upon numerous factors, and is readily subject to varying interpretations and conclusions. Should the FDA decide that Grafix, OvationOS or any of our other Biosurgery products do not meet the regulatory definition of HCT/Ps, we will not be able to produce and redistribute these products unless and until we submit a BLA and obtain pre-marketing approval from the FDA, which would likely require clinical trials and could take years to obtain, at significant expense. This would have a material adverse effect on our business, financial condition and results of operations.

Our ability to expand the marketed indications for Grafix and OvationOS is limited by Federal regulations, and will likely require the submission to the FDA of a biologics license application, or BLA, and the receipt of pre-marketing approval from the FDA, for the particular indication.

We cannot process, market or distribute our Biosurgery products without compliance with the United States Food Drug and Cosmetics Act, and comparable laws in foreign countries. Part 361 HCT/Ps may be processed, stored and distributed in the United States without FDA approval, provided that the product complies with the requirements of Part 361 of the PHSA and 21 CFR 1271. Absent such compliance, a BLA is required as a condition to marketing and sale of the product. In order to obtain a BLA we would be required to conduct extensive preclinical studies and clinical trials to demonstrate that the product is safe and effective and obtain required regulatory approvals. This process is costly and the product may fail to perform as we expect. Moreover, a product may ultimately fail to show the desired safety and efficacy traits despite having progressed successfully through preclinical or initial clinical testing. We would need to devote significant additional research and development, financial resources and personnel to obtain the necessary regulatory approvals, if required.

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At present, we have not initiated efforts to obtain a BLA for any of our Biosurgery products; and for Grafix and OvationOS for specific indications, we rely upon the exception to the BLA requirement afforded Part 361 HCT/Ps. However, compliance with these requirements will likely limit our activities in respect of these products. For example, we will not be able to enhance tissue based products in a manner which would result in the product being more than "minimally manipulated" within the meaning of 21 CFR 1271. These and other limitations applicable to HCT/Ps limit the indications for which these products may be marketed. Moreover, the FDA continues to review and inspect marketed products, manufacturers and manufacturing facilities, and even if a BLA is not required initially, the FDA or its foreign equivalents may create additional regulatory burdens in the future or may reevaluate or modify current regulatory frameworks in a manner adverse to us. Later discovery of previously unknown problems with a product, manufacturer or facility including those of or associated with a competitor or competing product may result in the imposition of additional restrictions on us or our products, including a withdrawal of the product from the market. This would have a material adverse effect on our business, financial condition and results of operations.

If we decide to pursue but are not able to conduct clinical trials properly and on schedule, or if any such clinical trials prove to be unsuccessful, we would be unable to secure sought after, or any required, regulatory approvals.

We may pursue additional clinical trials for our Biosurgery products to enhance our ability to successfully market these products, or to obtain pre-marketing approval if required by the FDA for us to market certain products, or to market our products for expanded indications. Clinical trials are costly and time consuming. The completion of clinical trials may be delayed or terminated, or the costs may be increased, 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.

If we are unable to conduct clinical trials properly and on schedule, any potential marketing benefit may be lost, the reputation of the product could be damaged, and any required marketing approval may be delayed or denied by the FDA.

Tissue based products are generally subjected to greater regulatory scrutiny in many other countries as compared to the United States. These requirements may be costly and result in delay or otherwise preclude the distribution of our Biosurgery products in some foreign countries, any of which would adversely affect our ability to generate operating revenues.

Tissue based products are regulated differently in different countries. We believe that commercial distribution of Grafix as a wound cover for the treatment of acute and chronic wounds, including diabetic foot ulcers, and the commercial distribution of OvationOS, a viable bone matrix for bone

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growth, do not require pre-market approval by the FDA in the United States because we believe that these products meet the regulatory definition of human cells, tissue, and cellular and tissue-based products, and qualify as Part 361 HCT/Ps. Many foreign jurisdictions have a different and more difficult regulatory pathway for human tissue based products, which may prohibit the distribution of these products until the applicable regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain, and we may never seek such approvals, or if we do, we may never gain those approvals. Any sought after or required approvals in Europe will likely require that we conduct clinical trials, which are themselves are costly and time consuming, and subject to risk and uncertainty, and may prove to be unsuccessful. Any adverse events in our clinical trials for one of our products could negatively impact our other products.

If we seek regulatory approval in the United States or elsewhere for our Biosurgery products, whether to enhance our ability to successfully market these products, or if we are required to do so by the FDA or equivalent foreign regulatory agencies, we may not be successful.

Should we decide to seek regulatory approval in the United States or elsewhere for our Biosurgery products, or should we be required to obtain such approvals before we can market a product generally or for a specific indication, any of the following factors may cause marketing approval to be delayed, limited or denied:

- our products will require significant pre-clinical and clinical development 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 or its foreign counterpart may not agree with our interpretations;
- it may take many years to complete the testing of our products, 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 product;
- approval may be delayed if the FDA or its foreign counterpart requires us to expand the size and scope of the clinical trials; or
- negative results from clinical trials or failure to obtain pre-marketing approval of a HCP/T product not otherwise requiring such approval may result in a negative public perception of the product and loss of market share and revenue.

If we seek marketing approval whether or not then necessary to market a particular product and that approval marketing approval is delayed, limited or denied, our ability to market products, and our ability to generate product sales, would be adversely affected.

We and our business are subject to rules and regulations regarding organ donation and transplantation.

Compliance with the issued operating standards established by The American Association of Tissue Banks ("AATB") is a requirement in order to become a licensed tissue bank. In addition, some states have their own tissue banking regulations. We are licensed to have permits as a tissue bank in Maryland, California, New York and Florida.

In addition, procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act ("NOTA"), which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks for their expenses associated

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with the recovery, storage and transportation of donated human tissue that they provide to us for processing. We include in our pricing structure amounts paid to tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, in addition to certain costs associated with processing, preservation, quality control and storage of the tissue, marketing and medical education expenses, and costs associated with the development of tissue processing technologies. NOTA payment allowances may be interpreted to limit the amount of costs and expenses that we can recover in our pricing for our products, thereby reducing our future revenue and profitability. If we were to be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our results of operations.

In Europe, regulations, if applicable, differ from one county to the next. Because of the absence of a harmonized regulatory framework and proposed regulation for advanced therapy medicinal products in Europe, as well as for other countries, the approval process for human derived cell or tissue based medical products could be extensive, lengthy, expensive, and unpredictable. Our Biosurgery products are subject to the country's regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. These regulations include requirements for registration, listing, labeling, adverse-event reporting, and inspection and enforcement. Some countries have their own tissue banking regulations.

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.

Risks Related to Intellectual Property

Given our patent position in regard to our Biosurgery products, if we are unable to protect the confidentiality of our proprietary information and know-how related to these products, 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, including our teaching regarding the processing of our Biosurgery products, 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 processing methodology for Grafix 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

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independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Because FDA approval is generally not required for tissue based products which are not more than minimally manipulated, competitors might choose to enter this market and produce a substantially similar product, and we may not be able to prevent the marketing and distribution 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 redistribution of these Biosurgery products may be limited.

Moreover, if our Biosurgery products infringe or are alleged to infringe intellectual property rights of third parties, 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 redistribution of the product that is the subject of the suit.

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 our patent position does not adequately protect our 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.

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, design around, or circumvent any patents owned, assigned or licensed to us and those that we may obtain in the future. Patents with such claims tend to be more vulnerable to challenge by other parties than patents with extremely narrow claims. Also, our pending patent applications may not issue, may issue with substantially narrower claims than currently pending claims, or we may not receive any additional patents. Further, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property.

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. A significant amount of our technology, including our teaching regarding the production processes for our Biosurgery products, is unpatented and is maintained by us as trade secrets. The lack of patent protection for our Biosurgery products reduces the barrier for entry by others and makes these products susceptible to increased competition, which could be harmful to our business.

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

Significant aspects of our Biosurgery product technology, especially the teaching regarding the manufacturing processes for these products, are unpatented and maintained by us as trade secrets. In an effort to protect these trade secrets, we require our employees, consultants, collaborators and advisors to execute confidential disclosure agreements before 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. 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, and the manufacture or distribution of our Biosurgery products, may infringe or be alleged 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 enjoined from certain activities including a stop or delay in research, development, manufacturing or sales activities related to the product or biologic drug candidate that is the subject of the suit.

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

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 and reexamination proceedings declared by the United States Patent and Trademark Office and opposition proceedings before the patent offices for other countries (e.g. the European Patent Office) or similar adversarial proceedings, regarding intellectual property rights with respect to our products and technology. 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 greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties

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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. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes may arise as to the rights related to or resulting from the use of such intellectual property.

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.

Litigation may be necessary to enforce patents issued or licensed to us, to protect trade secrets or know-how, or to determine the scope and validity of proprietary rights. Litigation, opposition or interference proceedings could result in substantial additional costs and diversion of management focus. If we are ultimately unable to protect our technology, trade secrets or know-how, we may be unable to operate profitably.

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 protect our proprietary rights. 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 invalid or is unenforceable, or may refuse to enjoin the other party from using the technology at issue. 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. 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, though we would seek protective orders where appropriate, 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.

The biotechnology industry, including our fields of interest, is highly competitive and subject to significant and rapid technological change. Accordingly, our success will depend, in part, on our ability to respond quickly to such change through the development and introduction of new products. Our ability to compete successfully against currently existing and future alternatives to our products, and against competitors who compete directly with us, will depend, in part, on our ability to: attract and retain skilled scientific and research personnel; develop technologically superior products; develop competitively priced products; obtain patent or required regulatory approvals for our products; and be early entrants to the market; manufacture, market and sell our products, independently or through collaborations. If a third party were to commercialize a competitive product, 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.

Risk Factors Regarding the Sale of our ceMSC Business

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

The terms of our Purchase Agreement with Mesoblast for the sale of our ceMSC business provide for payment to us of $50 million in initial consideration, and up to an additional $50 million upon the achievement by Mesoblast of certain clinical and regulatory milestones. Additionally, we will be entitled to earn single to low double digit cash royalties on future sales by Mesoblast of Prochymal and other products utilizing the acquired ceMSC technology.

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Of the $50 million in initial consideration, we have received an aggregate of $35 million thus far, consisting of $20 million in cash and $15 million in Mesoblast ordinary shares. The balance of the initial consideration ($15 million) is scheduled to be paid to us in cash on April 10, 2014.

Our ability to receive the second $50 million is subject to satisfaction of a series of milestones, all of which are largely dependent upon the clinical and regulatory success of Mesoblast and other factors not in our control. These include many if not all of the risks and uncertainties that our ceMSC business was subject to prior to its sale to Mesoblast, including product development, efficacy and regulatory risks. We have received no such payments thus far, nor do we have any expectation of receiving any such payments in the foreseeable future. Our ability to earn royalty payments from Mesoblast is subject to these same risks and will require performance by Mesoblast that results in its meeting some or all of the milestones referred to above, and is thereafter also dependent upon the commercial success of Mesoblast's ceMSC business. Royalties, if any, are payable to us in cash. Any portion of the second $50 million that becomes payable to us will be payable, at the discretion of Mesoblast, in Mesoblast ordinary shares, based on a then current valuation of such shares.

Payment of the initial consideration made in Mesoblast ordinary shares ($15 million), and any portion of the second $50 million in consideration paid in Mesoblast ordinary shares, is subject to a one year holding period, with limited downside protection for a drop in the Mesoblast share price over the holding period. Therefore, these payments are subject to investment risk, and because the Mesoblast ordinary shares are traded on the Australian Stock Exchange (ASX) and the per share price is denominated in Australian Dollars, these amounts are also subject to foreign currency exchange risk.

Accordingly, we have no assurances that any of these amounts will, in fact, ever be paid to or received by us, or if paid will be available to us to fund our business operations. If we do not receive these payments, or if we are unable to liquidate on favorable terms any amounts paid to us in Mesoblast ordinary shares, we will have less cash available to fund our remaining operations and to support the continued development and pursuit of our Biosurgery business, and our financial condition or results of operations could be materially adversely affected.

The Purchase Agreement exposes us to contingent liabilities and other risks that could adversely affect our business or financial condition.

In the Purchase Agreement, we have made customary representations and warranties and the parties have agreed to indemnify each other for breaches of representations, warranties and covenants contained in the Purchase Agreement. Also pursuant to the Purchase Agreement, we have retained a royalty free license to all transferred intellectual property, insofar as necessary for us to continue in our other businesses, including our Biosurgery business, and we have agreed not to compete with Mesoblast in the ceMSC business for a period of eight years. The Purchase Agreement also subjects us to other risks typical in business transactions of this type, including payment and performance risks. Should disputes arise or should we incur liability for breach of any of these representations, warranties or obligations, or should any of these other risks materialize, our business, financial condition or results of operations could be materially adversely affected.

Our long term business prospects will depend on the success of our Biosurgery business.

As a result of the sale of our ceMSC business, including Prochymal, our Biosurgery business is our sole remaining business, and our overall business is less diverse. Our long term business prospects will, therefore, be dependent almost entirely on the success of our Biosurgery business. This business involves significant risks and challenges in regards to product development and optimization, manufacturing, government regulation, intellectual property, third-party reimbursement and market acceptance, among other risks previously disclosed by us.

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Payment of a portion of the purchase price for our Therapeutics business through the delivery of Mesoblast ordinary shares as permitted under the Purchase Agreement subjects us to significant additional risks.

Mesoblast ordinary shares delivered to us as payment under our Purchase Agreement with Mesoblast for the sale of our ceMSC business are subject to a one year holding period. Although we are afforded downside price protection for a drop over the holding period in the market price of Mesoblast ordinary shares delivered as payment, this downside protection is limited. To the extent the market price of the shares decreases over the holding period, Mesoblast has agreed to pay us for the decrease. This payment is to be made at least one half in cash and, at the option of Mesoblast, up to one half in additional shares of Mesoblast stock. Any additional Mesoblast stock will also have to be held for one year, for which period there will be no further downside price protection, and therefore the equity price risk will persist in respect of any additional Mesoblast shares issued to us. The Mesoblast ordinary shares are traded on the Australian Securities Exchange (ASX) and the share value is denominated there in Australian Dollars. Hence, there also exists an associated foreign currency exchange rate risk. There is no corresponding mitigation of the foreign currency exchange rate risk, and any devaluation of the Australian Dollar will directly impact the value of the Mesoblast shares to us.

Of the $50 million in initial consideration, $15 million has been paid to us in Mesoblast ordinary shares. Accordingly, we are subject to investment risk and foreign currency exchange risk in respect of our ownership of these shares. In addition, any portion of the second $50 million in consideration payable to us under the Purchase Agreement if and only if certain milestones are met by Mesoblast, is payable to us, at the discretion of Mesoblast, in Mesoblast ordinary shares, based on a then current valuation of such shares. In the event of any negative events with respect to or otherwise affecting Mesoblast or the value of its ordinary shares, the value of Mesoblast ordinary shares held or acquired by us at any time would be negatively affected and we could lose, in whole or in part, the value to us of that portion of the consideration paid to us by Mesoblast under the Purchase Agreement. If we are unable to liquidate on favorable terms any amounts paid to us in Mesoblast ordinary shares, we will have less cash available to fund our remaining operations and to support the continued development and pursuit of our biosurgery business, and our financial condition or results of operations could be materially adversely affected.

Risks Related to Our Common Stock

We have identified a material weakness in our internal control over financial reporting and we may be unable to develop, implement and maintain appropriate controls in future periods. If the material weakness is not remediated, then it could result in a material misstatement to our financial statements.

We have identified a material weakness in our internal control over financial reporting and, as a result of such weakness, our management, with the participation of our principal executive officer and principal financial officer, concluded that our disclosure controls and procedures and internal control over financial reporting were not effective as of December 31, 2013. The material weakness related to the maintenance of effective controls over the application and monitoring of our accounting for income taxes. With respect to our controls over the application and monitoring of our accounting for income taxes, we did not have controls designed and in place to ensure effective oversight of the work performed, and the accuracy of, financial information or professional conclusions provided by, third-party tax advisors. This and related events contributed to the delay in the filing of our Annual Report on Form 10-K for fiscal 2013. Unless and until remediated, this material weakness could result in material misstatements to our interim or annual consolidated financial statements and disclosures that may not be prevented or detected on a timely basis. In addition, we may experience delay or be unable to meet our reporting obligations or to comply with SEC rules and regulations, which could result in delisting actions by the NASDAQ Stock Market and investigation and sanctions by regulatory authorities. Any of these results could adversely affect our business and the trading price of our common stock.

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

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

- results of clinical trials or those of our competitors;
- regulatory developments in the United States and foreign countries, both generally or specific to us and our products;
- 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.

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

Certain provisions of Maryland General Corporation Law (MGCL) and of our Maryland charter and Maryland bylaws contain provisions that 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 include, but are not limited to, the following:

classification of the board of directors with staggered terms of three years, which prevents a majority of the incumbent directors from being replaced at a single annual stockholders' meeting;

authorization of the board of directors to issue shares of preferred stock generally without stockholder approval;

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requirements that special meetings of stockholders may only be called by the chairman of the board of directors, upon request of stockholders holding at least 20% of the capital stock issued and outstanding, or upon a resolution adopted by, or an affirmative vote of, a majority of the 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.

Maryland law also prohibits "business combinations" between us and an interested stockholder or an affiliate of an interested stockholder for five years after the most recent date on which the interested stockholder becomes an interested stockholder. These business combinations include a merger, consolidation, share exchange or, in certain circumstances specified in the statute, an asset transfer or issuance or reclassification of equity securities. Maryland law defines an interested stockholder as any person who beneficially owns 10% or more of the voting power of the corporation's stock, or an affiliate or associate of the corporation who, at any time within the two-year period prior to the date in question, was the beneficial owner of 10% or more of the voting power of the corporation's then-outstanding voting stock. A person is not an interested stockholder if the board of directors of the corporation approved in advance the transaction by which the person otherwise would have become an interested stockholder. However, such approval may be conditional.

After the five-year prohibition, any business combination between the corporation and an interested stockholder or an affiliate of an interested stockholder generally must be recommended by the board of directors and approved by the affirmative vote of at least 80% of the votes entitled to be cast by holders of the then-outstanding shares of voting stock, and two-thirds of the votes entitled to be cast by holders of the voting stock other than stock held by the interested stockholder with whom or with whose affiliate the business combination is to be effected or stock held by an affiliate or associate of the interested stockholder. These super-majority vote requirements do not apply if the holders of the common stock receive a minimum price, as defined under Maryland law, for their stock in the form of cash or other consideration in the same form as previously paid by the interested stockholder for its stock.

The statute permits various exemptions from its provisions, including business combinations that are approved or exempted by the board of directors before the time that the interested stockholder becomes an interested stockholder. Our Board of Directors has not exempted us from the business combination statute. Consequently, unless the Board of Directors adopts an exemption from this statute in the future, the statute will be applicable and may affect business combinations between us and other persons. The statute may discourage others from trying to acquire control of us or increase the difficulty of consummating any such acquisition.

Our bylaws also contain a provision exempting us from the "control share acquisition" provisions of the MGCL (Sections 3-701 through 3-709). We can provide no assurance that such provision of our bylaws will not be amended or eliminated in the future. Should this happen, the control share acquisition provisions would become effective and may discourage others from trying to acquire control of us and increase the difficulty of consummating any offer.

Subtitle 8 of Title 3 of the MGCL ("Subtitle 8") permits a Maryland corporation with a class of equity securities registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and with at least three independent directors to elect to be subject to any or all of five provisions:

a classified board;

a two-thirds vote requirement to remove a director;

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a requirement that the number of directors be fixed only by the vote of the directors;

a requirement that a vacancy on the board be filled only by the remaining directors and for the remainder of the full term of the directorship in which the vacancy occurred rather than until the next annual meeting of stockholders as would otherwise be the case; and

a majority requirement for the calling of a special meeting of stockholders.

An eligible Maryland corporation like us can elect into this statute by provision in its charter or bylaws or by a resolution of its board of directors, without stockholder approval. Furthermore, we can elect to be subject to the above provisions regardless of any contrary provisions in the charter or bylaws. Pursuant to Subtitle 8, we have elected to provide that vacancies on our Board of Directors may be filled only by the remaining directors and for the remainder of the full term of the class of directors in which the vacancy occurred. Through provisions in our charter and bylaws unrelated to Subtitle 8, we have a classified board, and the number of our directors may be fixed only by the vote of the directors.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent others from influencing significant corporate decisions, and provisions in our charter allowing for a stockholder vote by consent in lieu of a meeting may make it easier for stockholders holding a majority of our common stock to take action.

Our executive officers, directors and beneficial owners of 5% or more of our common stock and their affiliates, in aggregate, beneficially own approximately 54% of our outstanding common stock as of March 1, 2014. Included among this 54%, Peter Friedli, the Chairman of the Board of Directors, and certain entities with which he is affiliated, beneficially own approximately 43% of our outstanding common stock as of March 1, 2014. 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.

Moreover, as permitted by the MGCL, our charter provides that the holders of common stock entitled to vote generally in the election of directors may take action or consent to any action by delivering a consent in writing or by electronic transmission of the stockholders entitled to cast not less than the minimum number of votes (which is generally either a majority of votes cast or a majority of votes entitled to be cast) that would be necessary to authorize or take the action at a stockholders meeting if the corporation gives notice of the action not later than ten (10) days after the effective date of the action to each holder of the class of common stock and to each stockholder who, if the action had been taken at a meeting, would have been entitled to notice of the meeting.

Accordingly, these persons acting together, and Mr. Friedli specifically, currently has, and will continue to have, a significant influence over the outcome of all corporate actions requiring stockholder approval, including any actions that may be taken by stockholder consent in lieu of a meeting.

ITEM 1B. Unresolved Staff Comments.

Not Applicable.

ITEM 2. Properties.

Our corporate headquarters are located in Columbia, Maryland, where we lease approximately 61,000 square feet, currently at a rent of approximately $1.4 million per annum. This lease expires in July 2016, and includes options to extend the term of the lease for two additional five year periods.

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ITEM 3. Legal Proceedings.

From time to time in the ordinary course of business, we are subject to claims, asserted or unasserted, or named as a party to lawsuits, arbitrations, or investigations. Litigation, in general, and intellectual property and securities litigation in particular, can be expensive and disruptive to normal business operations. Moreover, the results of legal proceedings cannot be predicted with any certainty and in the case of more complex legal proceedings, such as intellectual property and securities litigation, the results are difficult to predict at all. We are not aware of any asserted or unasserted legal proceedings or claims that we believe would have a material adverse effect on our financial condition or results of our operations.

ITEM 4. Mine Safety Disclosures.

Not Applicable.

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PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock trades on the NASDAQ Global Market under the symbol "OSIR." The following table lists the high and low sale prices per share for our common stock based on the prices as reported on the NASDAQ Global Market for the periods indicated.

	2013		2012	
	High	Low	High	Low
Quarter Ended				
March 31	$ 11.66	$ 6.55	$ 6.09	$ 4.38
June 30	11.76	9.45	14.46	4.47
September 30	27.40	10.01	12.08	8.05
December 31	19.75	13.03	11.94	8.05

Stockholders

As of February 12, 2014, there were approximately 149 stockholders of record of our common stock and, according to our estimates, approximately 5,877 beneficial owners of our common stock.

Dividends

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

Unregistered Sales of Securities and Use of Proceeds

In August 2013, the Chairman of our Board of Directors exercised an outstanding warrant for 1,000,000 shares of our common stock at the exercise price of $11.00 per share. The warrant was exercised using the Net Exercise Method on August 14, 2013, resulting in the net issuance of 567,610 shares of our common stock. This issuance was exempt under Section 4(2) of the Securities Act of 1033, as amended. At December 31, 2013, we no longer have any outstanding warrants.

Issuer Purchase of Equity Securities

There were no repurchases by us of our securities during fiscal 2013 or 2012.

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Stock Performance Graph

The following graph shows the cumulative total return, assuming the investment of $100 on January 1, 2009 on an investment in each of our common stock, the NASDAQ Composite Index (U.S. and Foreign) and the NASDAQ Biotechnology Index. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.

	30-Jun-2007		31-Dec-2007		30-Jun-2008		31-Dec-2008		30-Jun-2009		31-Dec-2009		30-Jun-2010		31-Dec-2010		30-Jun-2011		31-Dec-2011		30-Ju 201
3.24	125.09	119.26	111.30	116.48	118.98	178.61	177.41	127.78	124.07	61.67	66.11	68.52	53.80	67.41	72.13	67.22	71.67	47.41	49.54	47.41	101
7.54	126.35	131.12	128.73	110.62	111.29	101.53	76.54	74.19	89.07	103.02	110.14	116.39	102.38	114.97	128.76	134.99	134.62	117.24	126.45	150.06	142
9.23	112.84	120.11	117.38	109.78	111.54	117.54	102.56	95.99	105.38	118.04	118.59	132.01	112.46	125.87	136.39	146.32	155.82	136.32	152.49	180.10	190

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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 herein by reference to the information contained in the Company's Proxy Statement for the 2014 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 an independent registered public accounting firm. You should read the data below in conjunction with our financial statements, related notes and other financial information appearing in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data." These historical results are not necessarily indicative of results that may be expected for future periods. The data presented for fiscal 2012, 2011, 2010 and 2009 has been restated from prior year's presentation to account for our former Therapeutics business as discontinued operations, as discussed more fully in the Notes to Financial Statements.

	Year Ended December 31,				
	2013	2012	2011	2010	2009
	(in thousands, except per share data)				
Statements of Operations Data:					
Product revenues	$ 24,308	$ 7,849	$ 1,263	$ 183	$
Cost of product revenues	6,656	2,551	531	62	
Gross profit	17,652	5,298	732	121	
Operating expenses:					
Research and development	4,952	5,501	4,340	4,399	
Selling, general and administrative expenses	15,533	5630	7,169	6,450	
Total operating expenses	20,485	11,131	11,509	10,849	
Loss from operations of continuing operations	(2,833)	(5,833)	(10,777)	(10,728)	
Other income (expense), net	414	49	100	175	1,277
Loss from continuing operations, before income taxes	(2,419)	(5,784)	(10,677)	(10,553)	1,277
Income tax benefit (expense)	1,326	37	775	(241)	2,699
Income (loss) from continuing operations	(1,093)	(5,747)	(9,902)	(10,794)	3,976
Income (loss) from discontinued operations, net of income taxes	42,731	(5,318)	24,794	23,919	10,596
Net income (loss)	$ 41,638	$ (11,065)	$ 14,892	$ 13,125	$ 14,572
Basic loss per share from continuing operations	$ (0.04)	$ (0.17)	$ (0.30)	$ (0.33)	$

Basic and diluted income (loss) per share	$ 1.25	$ (0.33)	$ 0.45	$ 0.40	$ 0.45
Weighted average shares of common stock used in computing basic and diluted income (loss) per share	33,307	32,859	33,820	32,784	32,742

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	At December 31,				
	2013	2012	2011	2010	2009
	(in thousands)				
Balance Sheet Data:					
Cash and investment securities	$ 59,010	$ 34,092	$ 47,265	$ 67,608	$ 100,715
Working capital(1)	73,316	33,993	43,393	27,423	52,362
Total assets	92,097	41,464	54,273	77,784	107,596
Long-term liabilities	355	531	430	3,798	44,597
Accumulated deficit	(201,754)	(243,392)	(232,327)	(247,219)	(260,344)
Total stockholders' equity	80,949	35,890	45,818	27,457	12,560

(1) Working capital is computed as the excess of current assets over current liabilities.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that characterize our business. In particular, we encourage you to review the risks and uncertainties described under "Risk Factors" included as Item 1A in this Annual Report on Form 10-K. These risks and uncertainties could cause actual results to differ materially from those forecasted in forward-looking statements or implied by past results and trends. Forward-looking statements are statements that attempt to project or anticipate future developments in our business; we encourage you to review the examples of forward-looking statements included in this Annual Report on Form 10-K under Item 1 at the beginning of this report. These statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated), and we undertake no obligation to update or revise the statements in light of future developments.

The following is a discussion and analysis of our financial condition, results of operations, liquidity and capital resources for each of the three years in the period ended December 31, 2013 and significant factors that could affect our prospective financial condition and results of operations. You should read this discussion together with our financial statements and notes included in "Item 8. Financial Statements and Supplementary Data."

In October 2013, we sold our Therapeutics segment for up to $100.0 million in initial and contingent consideration and we are now focused on developing and commercializing our Biosurgery business. As a result of this sale, we eliminated our Therapeutics segment from our continuing operations and we have presented the assets, liabilities and results of this segments operations as discontinued operations for all periods. The following discussion of our financial condition and results of operations excludes the results of our discontinued operations unless otherwise noted. See Note 2, "Discontinued Operations" in the accompanying consolidated financial statements for further discussion of these discontinued operations.

Business Overview

We are a leading stem cell company headquartered in Columbia, Maryland and focused on developing and marketing products to treat conditions in the wound care, orthopedic and sports medicine markets. We currently market and distribute Grafix and Ovation for acute and chronic wounds, Cartiform, a viable cartilage mess for cartilage repair and OvationOS, a viable bone matrix for bone growth. We believe our stem cell products have significant therapeutic potential because of their ability to regulate inflammation, promote tissue regeneration and prevent pathological scar formation.

We began operations on December 23, 1992 and were a Delaware corporation until, with approval of our stockholders, we reincorporated as a Maryland corporation on May 31, 2010.

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From 2010 to October 2013, we operated as two business segments, Therapeutics and Biosurgery. Our Therapeutics business focused on developing biologic stem cell drug candidates from a readily available and non-controversial source adult bone marrow. Our Biosurgery business, created in 2009, works to harness the ability of cells and novel constructs to promote the body's natural healing with the goals of improving surgical outcomes and offering better treatment options for patients and physicians.

In October 2013, we sold our Therapeutics business to a wholly-owned subsidiary of Mesoblast Limited (ASX: MSB; USOTC: MBLYT) in a transaction that is worth up to $100 million plus royalties. The agreement with Mesoblast provides for the receipt by us of $50 million in initial consideration for closing and delivery of the assets, and for up to an additional $50 million in payments, but only upon Mesoblast achieving certain clinical and regulatory milestones. In addition, we are entitled to earn single to low double-digit cash royalties on future sales by Mesoblast of Prochymal and other products utilizing the acquired CeMSC technology. Mesoblast has assumed all future development costs and efforts. As of December 31, 2013, of the $50 million in initial consideration, we had received $35 million, comprised of $20 million in cash and $15 million of Mesoblast stock, which is restricted from resale until December 2014. We expect to receive the remainder of the initial consideration, in the amount of $15 million, in cash, on April 10, 2014. We have entered into a separate transition services agreement with Mesoblast to assure a seamless transition, and once we fulfill our duties under this agreement, will be able to focus our full attention on our Biosurgery business. We expect to complete all our responsibilities under the transitional services agreement during fiscal 2014.

We are a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products.

Financial Operations Overview

Revenue

We manufacture human tissue based products in our Columbia, Maryland facility and distribute these products through a network of independent distributors as well as through the efforts of employee sales personnel. We presently manufacture and distribute Grafix and Ovation for the treatment of chronic wounds, Cartiform, a viable cartilage mesh for cartilage repair and OvationOS for bone growth. All these products are cryo-preserved and stored in special freezers at -80 degrees Celsius. Customers have the product shipped to them on dry ice. Legal title usually passes to the customer when the product leaves our shipping dock. We do have consignment inventory at certain hospital sites and in those situations, title instead passes to the customer when the product is used in a surgical procedure. Due to the nature of the products and the manufacturing process, we generally do not allow sales returns.

During the third quarter of fiscal 2010, we launched Grafix as the first product in our then newly established Biosurgery segment , for limited commercial distribution. We began distribution of a second product, Ovation, in early fiscal 2011. These products follow our first generation Biosurgery product, Osteocel, which we sold to Nuvasive, Inc. in 2008 for approximately $80 million in aggregate consideration. We have continued to increase our distribution volume for Grafix and our other current Biosurgery products throughout fiscal 2011, 2012 and 2013, both through in-house personnel as well as through our expanding distributor network. The increase in product revenue and gross profit since commercial launch is due to volume increases. We anticipate continuing to increase our organizational focus on the development and commercialization of Biosurgery products in the foreseeable future.

Research and Development Costs

Our research and development costs consist of expenses incurred in identifying, developing and testing biologic tissue based products. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for independent monitoring and analysis of

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our clinical trials, costs of contract research and manufacturing, costs of facilities, and the costs of manufacturing clinical trial materials and quality control supplies. Our historic research and development costs included these and other costs specific to our efforts focused on our biologic drug candidates, including costs of manufacture of clinical batches of our biologic drug candidates.

Consistent with our historic focus on the development of biologic drug candidates with potential uses in multiple indications, many of our historic 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. From inception in December 1992 through December 31, 2013, we incurred aggregate research and development costs of approximately $436 million.

Biosurgery research and development expenses for the comparable periods were $4.3 million in fiscal 2011, $5.5 million in fiscal 2012, and $5.0 million in fiscal 2013, which includes costs incurred for a study, Protocol 302, which began during the second quarter of Fiscal 2012 and was designed to allow for the collection of data necessary to obtain the permanent HCPCS Q-codes for Grafix, which are required for Medicare and Medicaid reimbursement when treatment is performed in the outpatient setting.

We expect our research and development expenses to continue to be substantial in the future, as we continue our clinical trial activity for our existing Biosurgery products if and as they advance through the development cycle, and if 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 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 product candidates in order to focus our resources on more promising product 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 product 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 product candidates needed for clinical trials and regulatory submissions;
- the efficacy and safety profile of the product candidate; and
- the costs and timing of, and the ability to secure, regulatory approvals.

As a result of these uncertainties, 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 product 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. Generally, we have experienced a decrease in general and administrative

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costs as the result of our continued cost cutting efforts and the refinement of many of our general business processes, as well as a reduction in share-based compensation expense. Beginning in fiscal 2012, we incurred additional general and administrative expenses related to increased distribution efforts for our Biosurgery products. We expect future expense increases to continue as a result of hiring additional operational, financial, accounting, facilities engineering and information systems personnel as we continue to increase distribution of our Biosurgery products. We did not experience any significant reductions in our general and administrative expenses as the result of the sale of our Therapeutics business.

Other Income, Net

Other income consists of interest earned on our cash and investments available for sale and realized gains and losses incurred on the sale of these investments. Interest expense consists of interest incurred on capital leases. We do not expect to incur material interest expense in the future as we do not have a material amount of equipment under capital lease or any outstanding debt.

Income Taxes

In October 2013, we entered into an agreement with a wholly owned subsidiary of Mesoblast Limited for the sale of our culture-expanded mesenchymal stem cell (ceMSC) business, including Prochymal, in a transaction valued up to $100 million. Of the $50 million in initial consideration, $20 million was paid in cash and $15 million was paid in shares of Mesoblast Limited stock, prior to the close of fiscal 2013. The remaining $15 million payment is anticipated to be made in April 2014. The $50 million in initial consideration was recognized for financial statement reporting purposes and reported as a $49.4 million gain from sale of discontinued operations. For income tax purposes, the $35 million received was recognized in fiscal 2013 and the balance of the initial consideration of $15 million will be recognized in fiscal 2014 for income tax purposes. The tax effect of the remaining $15 million consideration was reported as a deferred tax liability in the amount of $6.1 million. This deferred payment also requires that interest be accrued in the amount of $70,000 that will increase the income taxes payable.

Amended income tax returns were filed for fiscal years 2010, 2011 and 2012 to reverse the calculation of the Orphan Drug Tax Credit taken in those years and increase the net operating loss carryforwards which will be utilized to offset the gain generated from sale of discontinued operations. The amended 2010 federal income tax return will generate an income tax recoverable in the amount of $79,000. The inventory of deferred tax assets has been updated for these income tax amendments.

Until fiscal 2010, we had not recognized any net 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 various credit carry-forwards. The income from the upfront fees we received from Genzyme Corporation was required to be recognized over several years from 2008 through 2012 for financial statement reporting purposes. For income tax purposes, the income was required to be fully recognized in 2009 and 2010. This resulted in our releasing $3.2 million of the valuation allowance on our net deferred tax assets in fiscal 2010. We recorded a full valuation allowance against our net deferred tax assets as of December 31, 2013 and 2012. In the event that we become profitable within the next several years, we have general business credits (before a 100% valuation allowance) of approximately $74.6 million that may be utilized prior to us having to recognize any income tax expense or make payments to the taxing authorities other than the alternative minimum tax. In addition, windfall equity based compensation deductions in the amount of $5.4 million are tracked but not recorded to the balance sheet until they are recognized and reduce income taxes payable.

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In fiscal 2011, we recorded a combination of the income tax benefits of $775,000 from continuing operations and an income from discontinued operations, which was reflected net of income taxes of $818,000. The tax provision for fiscal 2011 reflects an effective tax rate benefit for continuing operations of 7.3% compared to a U.S. statutory tax rate of 35%. In fiscal 2012, we recognized an income tax benefit of $37,000 from continuing operations, in connection with truing up our tax asset accounts in connection with the filing of our 2011 income tax returns.

The total tax provision for 2013 is a combination of the income tax benefit of $1.3 million from continuing operations and the gain from sale of discontinued operations, which is reflected net of income taxes of $1.7 million. The tax provision for 2013 reflects an effective tax rate benefit for continuing operations of 54.8% compared to a U.S. statutory tax rate of 35%. This represents the benefit from continuing operations in the current year. We expect to be subject to the alternative minimum tax of $388,000, which is included in the income taxes allocated to the gain from the sale of discontinued operations.

Critical Accounting Policies

General

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

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

Revenue Recognition

In fiscal 2010 we began operations of our Biosurgery business as a separate business segment, focused on developing high-end biologic products for use in wound healing and surgical procedures. We commenced the manufacturing of our first Biosurgery segment product, Grafix, a regenerative wound care product, during the first quarter of 2010. During the first and second quarters of 2010, we distributed the product only for initial clinical evaluation. We launched the product for limited commercial distribution during the third quarter of 2010. We began distribution of another Biosurgery product, Ovation, in early fiscal 2011, and continued to increase our distribution volume of both products throughout fiscal 2011 and 2012. During fiscal 2013, we launched Cartiform, a viable cartilage mesh for cartilage repair and OvationOS, a viable bone matrix. We recognized revenues of $24.3 million, $7.8 million and $1.3 million on distribution of our Biosurgery products in fiscal 2013, 2012 and 2011, respectively, compared to $183,000 during the period in fiscal 2010 subsequent to commercial launch.

We generally recognize revenue on the distribution of our Biosurgery products when we ship the frozen product to our customers. Legal title typically passes to the customers when the product leaves our shipping dock for most transactions. In certain hospitals, however, we do maintain consignment inventory and in these instances title passes to the customer when the product is used in a surgical

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procedure. Due to the nature of the products and the manufacturing process, we generally do not allow sales returns or refunds.

Investments Available for Sale and Other Comprehensive Income

Investments available for sale consist primarily of marketable securities with maturities less than one year. Investments available for sale are valued at their fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in accumulated other comprehensive income. All realized gains and losses on our investments available for sale are recognized in results of operations as investment income, a component of "Other income (expense), net".

Investments available for sale are evaluated periodically to determine whether a decline in their value is "other than temporary." Management reviews criteria such as the magnitude and duration of the decline, as well as the reasons for the decline, to predict whether the loss in value is other than temporary. If a decline in value is determined to be other than temporary, the value of the security is reduced and a corresponding charge to earnings is recognized.

Accounts Receivable

Accounts receivable are reported at their net realizable value. We charge off uncollectible receivables when the likelihood of collection is remote. We set credit terms with individual customers, and consider receivables outstanding longer than the time specified in the respective customer's contract, typically 75-days, to be past due. As of December 31, 2013 and 2012, accounts receivable in the accompanying balance sheet are reported net of a $78,000 and a $25,000 allowance for doubtful accounts, respectively. We believe the reported amounts are fully collectible. Accounts receivable balances are not collateralized. We have incurred bad debt expense of $80,000, $22,000 and $3,000 related to our Biosurgery operations during fiscal 2013, 2012 and 2011, respectively.

Inventory

We commenced limited distribution of our Biosurgery products during the third quarter of 2010, and began carrying inventory on our balance sheet thereafter. Inventory consists of raw materials, biologic products in process, and products available for distribution. We determine our inventory values using the first-in, first-out method. Inventory is valued at the lower of cost or market, and excludes units that we anticipate distributing for clinical evaluation.

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 expected to be generated by the assets. Assets are grouped 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 fiscal years 2013, 2012 or 2011.

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Discontinued Operations

We report the results of our discontinued operations separately from the results of our continuing operations below the income (loss) from continuing operations on the Statements of Comprehensive (Loss) Income. Cash flows from discontinued operations are also reported separately in the operating activities section of the Statements of Cash Flows. The Balance Sheets include separate line items for current assets and liabilities associated with discontinued operations.

Derivative Accounting

We account for derivative financial instruments under ASC 815, Derivatives and Hedging. The company does not trade derivative instruments as a part of its normal continuing operations. The company holds a derivative instrument for the price protection of the value of the Mesoblast stock held from falling below $15.0 million for a one year period and is included in trading securities on the Balance Sheets. The fair value of the price protection instrument was $1.7 million at December 31, 2013.

Fair Value Accounting

We report the value of our financial assets under ASC 825, Financial Instruments, at fair value in the accompanying financial statements. Fair value is defined as the price at which an asset could be exchanged or a liability transferred (an exit price) in an orderly transaction between knowledgeable, willing parties in the principal or most advantageous market for the asset or liability. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or inputs are not available, valuation models are applied.

Research and Development Costs

We expense internal and external research and development ("R&D") costs, including costs of funded R&D arrangements and the manufacture of clinical batches of our biologic drug candidates used in clinical trials, in the period incurred.

Biosurgery research and development expenses were $5.0 million, $5.5 million, and $4.3 million, in fiscal 2013, 2012 and 2011 respectively, which includes costs incurred for Protocol 302 designed to allow for the collection of data necessary to obtain the permanent HCPCS Q-codes that began during the second fiscal quarter of 2012.

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.

We recognize in our financial statements the impact of a tax position, if that position is more likely than not to be sustained upon an examination, based on the technical merits of the position. Interest and penalties related to income tax matters are recorded as income tax expense. At December 31, 2013 and 2012, we had no accruals for interest or penalties related to income tax matters.

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Share-Based Compensation

We account for share-based payments using the fair value method.

We recognize all share-based payments to employees and non-employee directors in our financial statements based on their grant date fair values, calculated using the Black-Scholes option pricing model. Compensation expense related to share-based awards is recognized on a straight-line basis based on the value of share awards that are expected to vest during the requisite service period on the grant date, which is revised for forfeitures.

Income per Common Share

Basic income per common share is calculated by dividing net income by the weighted average number of common shares outstanding during the period. Diluted income per common share adjusts basic income per share for the potentially dilutive effects of common share equivalents, using the treasury stock method, and includes the incremental effect of shares that would be issued upon the assumed exercise of stock options and warrants.

Diluted loss from continuing operations for the year ended December 31, 2013 excluded all 1,233,767 shares issuable upon the exercise of options, as their impact on our loss from continuing operations is anti-dilutive. As a result, basic and diluted weighted average common shares outstanding are identical.

Diluted loss per common share for the year ended December 31, 2012 excludes the 1,000,000 shares issuable upon the exercise of an outstanding "out-of the money" warrant, and all 1,826,114 of our outstanding options as of December 31, 2012, as their impact on our net loss is anti-dilutive. As a result, basic and diluted weighted average common shares outstanding are identical.

Diluted income per common share for 2011 excludes 1,311,686 "out-of the money" stock options and the 1,000,000 shares issuable upon the assumed exercise of our outstanding warrant, discussed in Note 8 below, as their effect is anti-dilutive.

Derivative Instruments

Generally, we do not enter into hedging or derivative instrument arrangements. In connection with the sale of our Therapeutics business, we did receive $15 million of Mesoblast Limited ordinary shares which are restricted from sale for a period of twelve months. Mesoblast has provided us with limited down-size protection in the event that the value of the shares when the restrictive period expires is lower than the price when the shares were issued. In the event the price is lower, Mesoblast will pay us the difference in price, 50% of which will be in cash and the balance in either cash or additional Mesoblast shares, at the sole discretion of Mesoblast. In the event Mesoblast issues additional shares in this regard, the new shares would be subject to a new twelve month restriction period. We account for this as a derivative instrument.

Results of Operations

Year ended December 31, 2013 compared to December 31, 2012

Product Revenues & Gross Profit

During fiscal 2013, our revenue from product distribution more than tripled to $24.3 million, as we continued to focus on the commercialization of our Biosurgery products. The increases in revenue were achieved through the expansion of our in-house sales and marketing team, as well as increases from our product distributors. We experienced growth in sales in both Grafix and Ovation and during the fiscal year introduced OvationOS, a viable bone matrix for bone growth, and Cartiform, a viable cartilage mesh for cartilage repair. Although revenue from the distribution of these two new products

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was under $1 million during fiscal 2013, we believe they will contribute to our future growth. Our gross profit increased in fiscal 2013 to 73% compared to 67% in the prior year, primarily as the result of operational efficiencies as we more heavily utilize our production facilities. Throughout fiscal 2013, we continued to operate our manufacturing facilities at our Columbia, Maryland location using one shift and have capacity to facilitate further growth without substantial increases in our clean room and manufacturing facilities.

Research and Development Expenses

Research and development expenses in fiscal 2013 were $5.0 million compared to $5.5 million in fiscal 2012. A little over half of our fiscal 2013 R&D spending was related to Protocol 302 to evaluate the efficacy of Grafix compared to the standard of care in the treatment of diabetic foot ulcers. The remaining R&D costs were spent on both new product development and product improvements. These efforts resulted in the introduction of OvationOS and Cartiform, and in novel packaging and application improvements to our Grafix product line. We expect to continue to make substantial investments in research and development activities during fiscal 2014, as we further our research into using Grafix in the treatment of venous leg ulcers and other indications.

Selling, General and Administrative Expenses

Selling, general and administrative expenses rose to $15.3 million during fiscal 2013 compared to $5.5 million in fiscal 2012. The significant majority of these cost increases were incurred in sales and marketing efforts to increase our product distribution and to build up our infrastructure in the areas of reimbursement for public and private health care providers. During fiscal 2013, we hired our own in-house direct sales force, primarily for Grafix, and invested in training and more extensive product support capabilities. Selling, general and administrative costs were 62.9% of product revenue in fiscal 2013 compared to 69.8% during fiscal 2012. We will continue to heavily invest in our sales, marketing and reimbursement capabilities in fiscal 2014 and also incur additional costs to augment our human resources, finance and information technology capabilities to support our expanding sales force.

Other Income, net

Other income, net in fiscal 2013 consisted of the net realized investment income earned on our investments available for sale, together with unrealized gain of approximately $400,000 on the market value increase of the Mesoblast stock we received in connection with the sale of our Therapeutics business. We carry the Mesoblast stock as Trading Securities. Our fiscal 2013 Other income, net also included approximately $50,000 from the market value decline of the derivative resulting from the limited downside protection afforded us on the market value of the Mesoblast stock. Other income, net in fiscal 2013 was $414,000, compared to $49,000 in fiscal 2012. Fiscal 2012 Other income, net was comprised solely of the net investment gains on our investments available for sale.

Income Taxes

In fiscal 2013, we sold our Therapeutics business for initial consideration of $50 million, all of which was recognized for financial reporting purposes. The resulting gain from the sale of discontinued operations was substantially greater than the $2.4 million loss before income taxes that we reported on our operations of continuing operations and the loss from the operations of discontinued operations of $6.7 million. For income tax purposes, only $35 million of the initial consideration is taxable in fiscal 2013, resulting in a deferred tax liability of approximately $6 million. The remaining $15 million of initial consideration is taxable in fiscal 2014 and we expect to utilize a portion of our net deferred tax assets to largely offset this income.We expect to be subject to the alternative minimum tax in the net amount of $388,000, as well as $70,000 in accrued interest. Amended tax returns were filed an dwill

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generate a refund in the amount of $79,000. We have recorded a full valuation allowance against our net deferred tax assets as of December 31, 2013 and 2012.

Fees Paid to Related Parties, Including Share-Based Payments

We compensate non-employee members of our Board of Directors by grants of stock ranging from 2,500 - 10,000 shares annually, and we permit the directors to take their payments in either cash or stock or a combination thereof. During fiscal 2013, our non-employee Directors were awarded the value of 31,250 shares of our common stock which had a fair market value of $7.73 per share. This was paid with $62,000 of cash and 23,250 shares of stock valued at $180,000. During fiscal 2012, our non-employee Directors were awarded the value of 30,000 shares of our common stock which had a fair market value of $5.08 per share. This was paid with $25,000 in cash and 25,000 shares of stock valued at $127,000.

Year ended December 31, 2012 compared to December 31, 2011

Product Revenues & Gross Profit

During fiscal 2012, we continued to expand our distribution efforts in our Biosurgery segment, both through in-house personnel as well as through our expanding distributor network. During fiscal 2012, we recognized $7.8 million of product revenues from the distribution of Grafix and Ovation and realized gross profit of $5.3 million, compared to $1.3 million of product revenues and $732,000 of gross profit during 2011. The increase in revenue and gross profit in 2012 is due to volume increases, as we continued to expand our distribution network. During fiscal 2012 and 2011, we continued to distribute a substantial amount of these products for clinical evaluation to drive more widespread adoption. During the period where we did not fully utilize our manufacturing facilities, our costs to manufacture these products vary significantly. Realized gross profits represent 67% of revenues during fiscal 2012 compared to 58% of revenues during fiscal 2011.

Research and Development Expenses

Research and development expenses for 2012 were $5.5 million as compared to research and development expenses of $4.3 million for 2011. The increase in research and development expenses in our Biosurgery segment in fiscal 2012 reflected increased process improvement efforts and development expenses incurred in exploring additional products to bring to market, and the enrollment of Protocol 302, the clinical trial required to obtain cost reimbursement for Grafix.

Selling General and Administrative Expenses

Selling, general and administrative expenses during fiscal 2012 were $5.5 million compared to $5.2 million during fiscal 2011. The decrease is the result of continued cost cutting efforts and the refinement of many of our general business processes, as well as an increased focus of internal resources on our Biosurgery operations.

Other Income, net

Other income, net consists of our net realized investment income earned on our investments available for sale. Other income, net was $49,000 during fiscal 2012 and $100,000 during fiscal 2011. The decrease between years reflects the reductions in investments available for sale to fund operations combined with the very low yields offered on investment grade securities during fiscal 2012.

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Income Taxes

An income tax benefit of $37,000 was recognized during fiscal 2012 as a result of the true-up of tax asset accounts in connection with the filing of our 2011 tax returns, compared to an income tax benefit of $775,000 from continuing operations in fiscal 2011.

Fees Paid to Related Parties, Including Share-Based Payments

Share-based payments to members of our Board of Directors were $127,000 during fiscal 2012, compared to $1.9 million during fiscal 2011. The fiscal 2011 charge includes a one-time non cash charge of approximately $1.7 million related to the extension of the expiration date of a warrant held by the chairman of our board of directors. This transaction was approved by our stockholders at our 2011 annual meeting of stockholders. Non-employee members of our board of directors are compensated by an annual award of stock that is paid in either unrestricted shares of our common stock or cash, or a combination of stock and cash. During fiscal 2012, we issued 25,000 shares of common stock and paid $25,000 cash to our non-employee directors. During fiscal 2011, we issued 25,000 shares of common stock and paid $36,000 cash to these individuals.

Liquidity and Capital Resources

Liquidity

At December 31, 2013, we had $2.4 million in cash and $39.5 million in investments available for sale. Other receivables as December 31, 2013 include $15 million that is scheduled to be paid to us in cash by Mesoblast in April 2014, and trading securities include $15 million of Mesoblast stock which we will be able to sell starting in December 2014. At December 31, 2013, the fair market value of the Mesoblast stock was $15.4 million and we recognized the $400,000 increase in market value as a component of Other income, net. We have not had any outstanding debt at any time since fiscal 2008.

Cash Flow

The following table sets forth a summary of our cash flows for each of our three most recently completed fiscal years:

	Years Ended December 31,		
	2013	2012	2011
	(amounts in thousands)		
Net cash used in operating activities of continuing operations	$ (2,977)	$ (4,783)	$ (6,176)
Net cash used in operating activities	(13,269)	(13,271)	(20,436)
Net cash provided by investing activities	11,608	13,324	20,504
Net cash provided by financing activities	2,223	140	151

Net cash used in operating activities of continuing operations during fiscal 2013 was $3.0 million, and primarily reflects our net loss of $1.1 million and net increases in our trade receivables and inventory, partially offset by non cash charges.

Net cash used in operating activities of continuing operations during fiscal 2012 was $4.8 million, and reflects our net loss of $5.7 million, partially offset by $1.1 of non-cash charges and net unfavorable changes in working capital.

Net cash used in operating activities of continuing operations was $6.2 million for the year ended December 31, 2011, and primarily reflects our net loss of $9.9 million, partially offset by $3.2 million of non-cash charges, which include $1.7 million of stock based charges related to the extension of the term of a warrant that had been issued to our Chairman.

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Net cash provided by investing activities was $11.6 million, $13.3 million, and $20.5 million, respectively, during fiscal years 2013, 2012, and 2011, and in each year primarily reflects proceeds from the sales of our investments to fund our operations, as well as the proceeds from the sale of our Therapeutics business.

Net cash provided by financing activities was $2.2 million in fiscal 2013 and was insignificant in each of the two years ended December 31, 2012. The fiscal 2013 cash provided by financing activities is primarily the net proceeds from the exercise of stock options by our employees to purchase our common stock.

Capital Resources.

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

- the scope and results of our research and preclinical development programs;
- the scope and results of our clinical trials;
- the timing of and the costs involved in obtaining regulatory approvals for our biologic product 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 biologics;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including possible litigation costs and liabilities; and
- the costs of enlarging our work force consistent with expanding our business and operations and distribution of our Biosurgery products.

We did not have any outstanding debt at any time during 2013.

Off-Balance Sheet Arrangements.

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

Future Contractual Obligations

The following table sets forth our estimates as to the amounts and timing of contractual payments for our most significant contractual obligations at December 31, 2013. The information in the table reflects future unconditional payments and is based on the terms of the relevant agreements, appropriate classification of item under accounting principles generally accepted in the United States and certain assumptions. Future events could cause actual payments to differ from these amounts.

	Payment Due by Fiscal Year				
Contractual Obligations	**Total**	**Less Than 1-Year**	**Years 1-3**	**Years 4-5**	**More Than 5-Years**
		(amounts in thousands)			
Operating lease facilities	$ 3,068	$ 1,165	$ 1,903	$	$
Capital lease obligations	168	48	96	24	
Contract Research Organizations	200	200			
Total contractual cash obligations	$ 3,436	$ 1,413	$ 1,999	$ 24	$

Contract Research Organizations. We contract with independent contract research organizations, or CROs, to perform many of the tasks required under our clinical trials, and we utilize their testing expertise to ensure the objectivity of the clinical results. Under the terms of these agreements, we

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design the protocol regarding the testing to be performed, and the CRO assists in the enrollment of the patients and testing sites, administers the trial, performs statistical analysis of the results, and compiles the final report.

We pay fees directly to the CROs for their professional services, which may be payable upon specified trial milestones or as they provide services, depending on the structure of the contract. We are also responsible for reimbursing the CROs for certain pass thru expenses they incur in administering the trial. The timing of our payments to the CROs is dependent upon the progress of the various trials, which is highly variable dependent upon the speed with which the CROs are able to enroll patients and testing sites. As such, we are unable to specifically predict the timing of future payments to CROs in connection with a specific clinical trial.

As of December 31, 2013, we had an active contract with a CRO related to one on-going clinical trial (Protocol 302). Although we cannot directly control the timing of the remaining payments, based on our estimates and assumptions as of December 31, 2013, we expect to pay approximately $200,000 in fees to the CRO during 2014.

Leases. 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 was effective as of June 1, 2009 upon the expiration of the sublease and expires in July 2016. During 2009, following the expiration of the sublease agreement, we increased an outstanding letter of credit, which was used in lieu of a security deposit for this lease, to $591,000 according to the terms of the direct lease with the owner of the facility. At each of July 1, 2013, 2012, and 2011, the security deposit required under this lease decreased to $224,000, $298,000 and $372,000, respectively. We reduced our outstanding letter of credit accordingly, and the reduced letter of credit of $224,000 remained outstanding as of December 31, 2013, and has been fully collateralized by restricted cash.

Effect of Inflation.

Inflation and changing prices are not generally a material factor affecting our business. General operating expenses such as salaries, employee benefits and lease costs are, however, subject to normal inflationary pressures.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Risk

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

Derivative Instruments

Generally, we do not enter into hedging or derivative instrument arrangements. In connection with the sale of our Therapeutics business, we did receive $15 million of Mesoblast Limited ordinary shares which are restricted from sale for a period of twelve months. Mesoblast has provided us with limited down-size protection in the event that the value of the shares when the restrictive period expires is lower than the price when the shares were issued. In the event the price is lower, Mesoblast will pay us

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the difference in price, 50% of which will be in cash and the balance in either cash or additional Mesoblast shares, at the sole discretion of Mesoblast. In the event Mesoblast issues additional shares in this regard, the new shares would be subject to a new twelve month restriction period. We account for this as a derivative instrument.

Equity Price Risk and Foreign Currency Exchange Rate Risk

We conduct clinical trial activities in areas that operate in a functional currency other than the United States dollar (USD). As a result, when the USD rises and falls against the functional currencies of these other nations, our costs will either increase or decrease by the relative change in the exchange rate. Foreign currency gains and losses were not material during the three years ended December 31, 2013, and at the present time, we have elected not to hedge our exposure to foreign currency fluctuations.

We are also subject to equity price risk and foreign currency exchange rate risk associated with our prior and any future receipt of shares of Mesoblast ordinary shares as payment under the Purchase Agreement with Mesoblast for the sale of our Therapeutics segment. We are required to hold that stock for one year from the date of receipt, but currently intend to dispose of the Mesoblast stock as soon as we are able to do so. In the meantime we will be subject to equity price risk associated with the ownership of the Mesoblast ordinary shares. The Mesoblast stock is traded on the Australian Securities Exchange and its share value is denominated there in Australian Dollars. Hence there also exists an associated foreign currency exchange rate risk. The equity price risk is mitigated in part by limited price protection for the one year required holding period. To the extent the value of the shares decreases during the holding period, Mesoblast has agreed to pay us for the decrease in value. This payment is to be made at least one half in cash and, at the option of Mesoblast, up to one half in additional shares of Mesoblast stock. Any additional Mesoblast stock issued to us will also have to be held for one year, during which period there will be no further price protection, and therefore the equity price risk (and the foreign currency risk) will persist. There is no corresponding mitigation of the foreign currency exchange rate risk, and a devaluation of the Australian Dollar will directly impact the value of the Mesoblast shares to us.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

OSIRIS THERAPEUTICS, INC.

FINANCIAL STATEMENTS

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* All other information and financial statement schedules are omitted because they are not applicable, or required, or because the required information is included in the consolidated financial statements or notes thereto.

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REPORT OF MANAGEMENT

Management's Report on Financial Statements

Our management, under the supervision of the Company's Chief Executive and Chief Financial Officers, is responsible for the preparation, integrity and fair presentation of information in our financial statements, including estimates and judgments. The financial statements presented in this Annual Report on Form 10-K have been prepared in accordance with accounting principles generally accepted in the United States of America. Our management believes the financial statements and other financial information included in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in this Annual Report on Form 10-K. The financial statements included herein have been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;

- provide reasonable assurance that our transactions are recorded as necessary to permit preparation of our financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorization of our management and our directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness of such controls in future periods are subject to the risk that the controls may become inadequate because of changes in conditions or that the degree of compliance with the policies and procedures may deteriorate.

Our management, including our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2013. In making this assessment, our management used the criteria set forth in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (1992). Based on its assessment, and the material weakness described below, our management concluded that, as of December 31, 2013, our internal control over financial reporting was not effective based on those criteria

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Our management has determined that our processes, procedures and controls related to financial reporting were not effective to ensure effective oversight of the work performed by, and the accuracy of financial information or professional conclusions provided by, third-party tax advisors, regarding

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components of the income tax provision calculation (specifically the allocation between continuing and discontinuing operations), given a one-time significant transaction of disposing of a business segment. Specifically, we recently identified the need for an adjustment to our unaudited financial statements in the computation of the income tax benefit allocated to continuing operations, because the windfall benefit attributable to the permanent tax deduction related to the disqualifying disposition of incentive stock options was not properly considered by the third party tax advisor. This occurred notwithstanding that we had retained a nationally known outside public accounting firm, which we understand to be PCAOB certified, to advise us on, and to analyze and to perform the tax accounting functions related to, these matters. While we do not believe that this affected the accuracy of our financial statements included in the Annual Report on Form 10-K, this control deficiency could result in a material misstatement of the financial statements that would not be prevented or detected. Accordingly, our management, after discussion with our registered independent accounting firm, has concluded that this control deficiency constitutes a material weakness. This material weakness was identified in connection with our assessment of the effectiveness of internal control over financial reporting as of December 31, 2013, and has not yet been remediated.

BDO USA, LLP has issued an attestation report on our internal control over financial reporting. This report is referred to in the Report of Independent Registered Public Accounting Firm on the following page, and is included elsewhere herein.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders of
Osiris Therapeutics, Inc.
Columbia, Maryland

We have audited the accompanying balance sheets of Osiris Therapeutics, Inc. as of December 31, 2013 and 2012 and the related statements of comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2013. In connection with our audits of the financial statements, we have also audited the financial statement schedule listed in the accompanying index. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements and schedule. 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. at December 31, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

Also, in our opinion, the financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Osiris Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 31, 2014 expressed an adverse opinion thereon.

/s/ BDO USA, LLP

Bethesda, Maryland
March 31, 2014

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited Osiris Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Osiris Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Item 9A, Management's Report on Internal Control Over Financial Reporting". Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and described in management's assessment. The Company's processes, procedures and controls related to financial reporting were not effective to ensure effective oversight of the work performed, and the accuracy of financial information provided or professional conclusions reached, by third-party tax advisors regarding components of the income tax provision calculation, specifically the allocation between continuing and discontinued operations, given a one-time significant transaction of disposing of a business segment. As a result, prior to completion of the audit, these amounts required the unaudited financial statements to be adjusted to be in accordance with generally accepted accounting principles, and to be reflected in the audited financial statements.

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This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2013 financial statements, and this report does not affect our report dated March 31, 2014 on those financial statements.

In our opinion, Osiris Therapeutics, Inc. did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Osiris Therapeutics, Inc. as of December 31, 2013 and 2012, and the related statements of comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2013 and our report dated March 31, 2014 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Bethesda, Maryland
March 31, 2014

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OSIRIS THERAPEUTICS, INC.

BALANCE SHEETS

(amounts in thousands, except per share amounts)

	December 31,	
	2013	**2012**
Assets		
Current assets:		
Cash	$ 2,416	$ 1,854
Investments available for sale	39,508	32,238
Trading securities	17,086	
Trade accounts receivable, net of reserves	7,459	2,854
Other receivables	15,265	5
Inventory	1,929	1,278
Prepaid expenses and other current assets	355	603
Current assets of discontinued operations	91	204
Total current assets	84,109	39,036
Property and equipment, net	1,896	2,111
Deferred tax asset	5,849	
Restricted cash	243	317
Total assets	$ 92,097	$ 41,464
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,842	$ 2,096
Capital lease obligations, current portion	45	44
Deferred tax liability	5,849	
Current liabilities of discontinued operations	57	2,903
Total current liabilities	10,793	5,043
Other long-term liabilities	355	531
Total liabilities	11,148	5,574
Commitments and contingencies		
Stockholders' equity		
Common stock, $.001 par value, 90,000 shares authorized, 34,115 shares outstanding 2013, 32,881 shares outstanding 2012	34	33
Additional paid-in-capital	282,702	279,269

Accumulated other comprehensive (loss) income	(33)	(20)
Accumulated deficit	(201,754)	(243,392)
Total stockholders' equity	80,949	35,890
Total liabilities and stockholders' equity	$ 92,097	$ 41,464

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

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OSIRIS THERAPEUTICS, INC.

STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

(amounts in thousands, except per share data)

	Year ended December 31,		
	2013	**2012**	**2011**
Product revenues	$ 24,308	$ 7,849	$ 1,263
Cost of product revenues	6,656	2,551	531
Gross profit	17,652	5,298	732
	73%	67%	58%
Revenue from collaborative research agreements and royalties			
Operating expenses:			
Research and development	4,952	5,501	4,340
Selling, general and administrative	15,291	3,676	7,008
Fees paid to related parties	62	36	87
Share based payments to related parties	180	1,918	74
	20,485	11,131	11,509
Loss from operations	(2,833)	(5,833)	(10,777)
Other income, net	414	49	100
Loss from continuing operations, before income taxes	(2,419)	(5,784)	(10,677)
Income tax benefit	1,326	37	775
Income (loss) from continuing operations	(1,093)	(5,747)	(9,902)
Discontinued operations:			
Income (loss) from operations of discontinued operations, net of income taxes of $818 in 2011	(6,668)	(5,318)	24,794
Gain from sale of discontinued operations, net of income taxes of $1,705 in 2013	49,399		
Income (loss) from discontinued operations	42,731	(5,318)	24,794
Net income (loss)	41,638	(11,065)	14,892

Other comprehensive income (loss)			
Unrealized gain (loss) on investments available for sale	(13)	(40)	23
Comprehensive income (loss)	$ 41,625	$ (11,105)	$ 14,915
Basic and diluted income (loss) per share			
Income (loss) from continuing operations	$ (0.04)	$ (0.17)	$ (0.30)
Income (loss) from discontinued operations	1.29	(0.16)	0.75
Income (loss) per share	$ 1.25	$ (0.34)	$ 0.45
Weighted average common shares (basic and diluted)	33,307	32,859	32,820

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

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OSIRIS THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(amounts in thousands, except for share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2010	**32,793,457**	**$ 33**	**$ 274,646**	**$ (3)**	**$ (247,219)**	**$ 27,457**
Exercise of options to purchase common stock ($.40-$7.74 per share)	9,064		22			22
Share-based payment director services ($7.13 per share)	25,000		178			178
Share-based payment employee compensation			1,506			1,506
Share-based payment related party			1,740			1,740
Net income					14,892	14,892
Unrealized gain on investments available for sale				23		23
Balance at December 31, 2011	**32,827,521**	**$ 33**	**$ 278,092**	**$ 20**	**$ (232,327)**	**$ 45,818**
Exercise of options to purchase common stock ($.40-$7.74 per share)	28,708		87			87
Share-based payment director services ($5.08 per share)	25,000		127			127
Share-based payment employee compensation			963			963
Net loss					(11,065)	(11,065)
Unrealized gain on investments available for sale				(40)		(40)
Balance at December 31, 2012	**32,881,229**	**$ 33**	**$ 279,269**	**$ (20)**	**$ (243,392)**	**$ 35,890**
Exercise of options to purchase common stock ($.40-$22.74 per share)	642,514		2,193			2,193
Share-based payment director services ($7.73 per share)	23,250		180			180
Net exercise of warrant to purchase common stock ($11.00 per share)	567,610	1	(1)			
Share-based payment employee compensation			1,061			1,061
Net Income					41,638	41,638
Unrealized loss on investments available for sale				(13)		(13)
Balance at December 31, 2013	**34,114,603**	**$ 34**	**$ 282,702**	**$ (33)**	**$ (201,754)**	**$ 80,949**

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

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OSIRIS THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

(amount in thousands)

	Year ended December 31,		
	2013	**2012**	**2011**
Cash flows from operating activities:			
Continuing operations			
Income (loss) from continuing operations	$ (1,093)	$ (5,747)	$ (9,902)
Adjustments to reconcile income (loss) from continuing operations to net cash provided by (used in) operations of continuing operations:			
Unrealized gain on trading securities	(401)		
Depreciation and amortization	587	552	577
Non cash share-based payments	583	492	894
Provision for bad debts	80	22	3
Non cash expense extension of expiration date of warrant to related party			1,740
Changes in operating assets and liabilities:			
Accounts receivable	(4,685)	(2,185)	(523)
Inventory	(651)	(511)	(257)
Prepaid expenses, and other current assets	158	(259)	266
Tax receivable and deferred taxes	(160)	2,188	982
Other assets			184
Accounts payable, accrued expenses, and other current liabilities	2,605	665	(140)
Net cash used in operating activities of continuing operations	(2,977)	(4,783)	(6,176)
Discontinued operations			
Income (loss) from discontinued operations	(6,668)	(5,318)	24,794
Adjustments to reconcile loss from discontinued operations to net cash used in operations of discontinued operations:			
Non cash impact of the sale of discontinued operations	(1,705)		
Depreciation and amortization	156	156	168
Non cash share-based payments	658	598	790
Changes in operating assets and liabilities:			
Accounts receivable and other current assets	113	(172)	1,720
Accounts payable and accrued expenses	(2,846)	(419)	(772)
Deferred revenue		(3,333)	(40,960)
Net cash used in operations of discontinued operations	(10,292)	(8,488)	(14,260)
Net cash used in operating activities	(13,269)	(13,271)	(20,436)
Cash flows from investing activities:			
Purchases of property and equipment	(528)	(128)	(81)
Proceeds from sale of discontinued operations, net	19,419		
Proceeds from sale of investments available for sale	55,357	217,185	284,569
Purchases of investments available for sale	(62,640)	(203,733)	(263,984)
Net cash provided by investing activities	11,608	13,324	20,504

Cash flows from financing activities:			
Principal payments on capital lease obligations	(44)	(22)	
Restricted cash	74	75	129
Proceeds from the exercise of options to purchase common stock	2,193	87	22
Net cash provided by financing activities	2,223	140	151
Net increase in cash	562	193	219
Cash at beginning of period	1,854	1,661	1,442
Cash at end of period	$ 2,416	$ 1,854	$ 1,661
Supplemental disclosure of cash flows information:			
Cash paid for income taxes	$ 539	$	$
Supplemental disclosure of non cash activities:			
Equipment acquired under a capital lease		228	
Trading securities from the sales of discontinued operations	15,000		
Purchase price guarantee related to trading securities	1,685		
Proceeds receivable due from sale of discontinued operations	15,000		

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

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Description of Business and Significant Accounting Policies

Description of Business

Osiris Therapeutics, Inc. ("we," "us," "our," or the "Company") is a Maryland corporation headquartered in Columbia, Maryland. We began operations on December 23, 1992 and were a Delaware corporation until, with approval of our stockholders, we reincorporated as a Maryland corporation on May 31, 2010. We are a leading stem cell company focused on developing and marketing products in the orthopedic, sports medicine, and wound healing markets.

From 2010 to 2013, we operated our business in two segments, Biosurgery and Therapeutics. Our Biosurgery business focuses on products for wound healing, cartilage repair, and orthopedics to harness the ability of cells and novel constructs to promote the body's natural healing. Our Therapeutics business focused on developing biologic stem cell drug candidates from a readily available and non-controversial source adult bone marrow, until it was sold, as described further below.

Our Biosurgery business has continued to grow since its inception, and we have increased our organizational focus on the development and commercialization of products in this segment. Consistent with this organizational focus, as discussed further in Note 2 *Discontinued Operations* below, on October 10, 2013, we entered into a Purchase Agreement to sell our Therapeutics segment, including all of our culture expanded mesenchymal stem cell business, including Prochymal and other related assets. We eliminated the Therapeutics segment from our continuing operations as a result of the disposal transaction, and have presented the assets, liabilities, and results of the segment's operations as a discontinued operation for all periods presented. Our continuing operations now represent the portion of our business previously referred to as our Biosurgery segment.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 deferred tax assets, inventory valuation, share-based compensation and the value of the derivative obtained in connection with the sale of our former Therapeutics business.

Cash and Cash Equivalents

Amounts listed as cash on our balance sheets are maintained in depository accounts at a commercial bank. Cash and cash equivalents, which include highly liquid investments with maturities of three months or less when purchased, held in our brokerage investment accounts are classified as investments available for sale, as the amounts represent investments that have matured and are anticipated to be reinvested in debt securities in the near future, and are disclosed at fair value, which approximates cost.

Reclassifications

We have reclassified certain prior-year amounts for comparative purposes. These reclassifications did not affect our results of operations or financial positions for the years presented.

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Description of Business and Significant Accounting Policies (Continued)

Investments Available for Sale

Investments available for sale consist primarily of marketable securities with maturities less than one year. Investments available for sale are valued at their fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in accumulated other comprehensive income. All realized gains and losses on our investments available for sale are recognized in results of operations as other income.

Investments available for sale are evaluated periodically to determine whether a decline in their value is "other than temporary." The term "other than temporary" is not intended to indicate a permanent decline in value. Rather, it means that the prospects for near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. We review criteria such as the magnitude and duration of the decline, as well as the reasons for the decline, to predict whether the loss in value is other than temporary. If a decline in value is determined to be other than temporary, the carrying value of the security is reduced and a corresponding charge to earnings is recognized.

Restricted Cash

We periodically are required under the terms of various agreements to provide letters of credit which are collateralized by cash deposits. The majority of the restricted cash balance relates to a letter of credit that we caused to be issued in lieu of a security deposit under the operating lease for our Columbia, Maryland facility.

Trade Accounts Receivable

Trade accounts receivable are reported at their net realizable value. We charge off uncollectible receivables when the likelihood of collection is remote. We set credit terms with individual customers, and consider receivables outstanding longer than the time specified in the respective customer's contract, typically 45-days, to be past due. As of December 31, 2013 and 2012, accounts receivable in the accompanying balance sheet are reported net of a $78,000 and a $25,000 allowance for doubtful accounts, respectively. We believe the reported amounts are fully collectible. Trade accounts receivable balances are not collateralized. We have incurred bad debt expense of $95,000, $22,000 and $3,000 related to our biosurgery operations during fiscal 2013, 2012 and 2011, respectively.

Inventory

We began carrying inventory of our Biosurgery products on our balance sheet following commercial launch of such products. Inventory consists of raw materials, biologic products in process, and products available for distribution. We determine our inventory values using the first-in, first-out method. Inventory is valued at the lower of cost or market, and excludes units that we anticipate distributing for clinical evaluation.

Property and Equipment

Property and equipment, including improvements that extend useful lives, are valued at cost, while maintenance and repairs are charged to operations as incurred. Depreciation is calculated using the

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Description of Business and Significant Accounting Policies (Continued)

straight-line method based on estimated useful lives ranging from three to seven years for furniture, equipment and internal use software. Leasehold improvements and assets under capital leases are amortized over the shorter of the estimated useful life of the asset or the original term of the lease.

Valuation of Long-lived Assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or group of assets may not be fully recoverable. These events or changes in circumstances may include a significant deterioration of operating results, changes in business plans, or changes in anticipated future cash flows. If an impairment indicator is present, we evaluate recoverability by a comparison of the carrying amount of the assets to future undiscounted net cash flows expected to be generated by the assets. Assets are grouped 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 fiscal years 2013, 2012 or 2011.

Derivative and Securities Received in Business Disposition

As discussed in Note 2 *Discontinued Operations*, we disposed of our Therapeutics segment in October 2013. A portion of the consideration for the sale of that business was stock of Mesoblast Limited ("Mesoblast"), the parent of the purchaser. We are required to hold that stock for one year from the date of receipt. We currently intend to dispose of the Mesoblast stock as soon as we are able to do so. As such, we have reflected the investment as a current asset in Trading Securities. Mesoblast is a public company and its stock is traded on the Australian stock exchange.

The Mesoblast stock is subject to limited price protection for the one year required holding period. To the extent the value of those shares decreases during the holding period, Mesoblast is required to pay us for the decrease in value. This payment is to be made at least one half in cash and at the option of Mesoblast, up to one half in additional shares of Mesoblast stock. Any additional Mesoblast stock will also have to be held for one year during which period there is no further price protection. The price protection is accounted for as a derivative under ASC 815, Derivatives and Hedging, and, as such is recorded on the balance sheet at fair value, with changes recognized in net income. We have elected to measure the Mesoblast stock at fair value with changes in fair value reflected in net income, as permitted under ASC 825-10, Financial Instruments Fair Value Option.

All derivative instruments within the scope of ASC 815, Derivatives and Hedging, are recorded on the balance sheet at fair value. Currently, our only derivative instrument is the price guarantee regarding the payment received in restricted Mesoblast shares described in Note 12 *Derivative and Securities Received in Business Disposition* below. We do not hold derivative financial instruments for trading purposes.

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Description of Business and Significant Accounting Policies (Continued)

Investments Available for Sale

Investments available for sale consist primarily of marketable securities. Investments available for sale are valued at their fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in accumulated other comprehensive income. All realized gains and losses on our investments available for sale are recognized in results of operations as other income.

Investments available for sale are evaluated periodically to determine whether a decline in their value is "other than temporary." The term "other than temporary" is not intended to indicate a permanent decline in value. Rather, it means that the prospects for near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. We review criteria such as the magnitude and duration of the decline, as well as the reasons for the decline, to predict whether the loss in value is other than temporary. If a decline in value is determined to be other than temporary, the carrying value of the security is reduced and a corresponding charge to earnings is recognized.

Biosurgery Revenue Recognition

We recognize revenue from product distribution when title passes to the customer. Title usually passes when the product is shipped to the customer and leaves our loading dock. In some situations, we store consigned inventory on site in freezers at hospital or clinic facilities and title passes to the customer when the product is used in a surgical procedure. In these instances we recognize the revenue upon notification of the completed surgical procedure. We verify the condition and status of all consigned inventory on at least a quarterly basis. Due to the nature of our products and the need to ensure they are maintained at the proper frozen temperature, we generally do not allow product returns.

Therapeutics Revenue Recognition

In our former Therapeutics business, we evaluated revenues from agreements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting. To recognize a delivered item in a multiple element arrangement, the delivered items must have value on a standalone basis and the delivery or performance must be probable and within our control for any delivered items that have a right of return. The determination of whether multiple elements of a collaboration agreement meet the criteria for separate units of accounting requires us to exercise judgment. We account for the activities of our former Therapeutics business as discontinued operations.

Revenues from research licenses associated with our former Therapeutics business were 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 agreement. Payments received in advance of research performance were designated as deferred revenue. Non-refundable upfront license fees and certain other related fees associated with our former Therapeutics business were recognized on a straight-line basis over the development periods of the contract deliverables. Fees associated with substantive at risk performance based milestones [are]

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Description of Business and Significant Accounting Policies (Continued)

recognized as revenue upon their completion, as defined in the respective agreements. Incidental assignment of technology rights [were] recognized as revenue when and if it was earned and received.

In October 2008, we entered into a Collaboration Agreement with Genzyme Corporation, then an independent and now a Sanofi company ("Genzyme"), for the development and commercialization of our biologic drug candidates, Prochymal and Chondrogen . Under this agreement, Genzyme made non-contingent, non-refundable cash payments to us, totaling $130 million. The agreement provided Genzyme with certain rights to intellectual property developed by us, and required that we continue to perform certain development work related to the subject biologic drug candidates. In February 2012, Sanofi issued a press release which included an update on their R&D pipeline, stating that it had discontinued its project with Prochymal for GvHD. In September 2012, we reached agreement with Sanofi to conclude the Collaboration Agreement without either party having any continuing obligation to the other.

We evaluated the deliverables related to the upfront payments made to us under the Genzyme collaboration agreement, and concluded that the various deliverables represent a single unit of accounting. For this reason, we deferred the recognition of revenue related to the upfront payments, and amortized these amounts to revenue on a straight-line basis over the estimated delivery period of the required development services, which extended through January 2012.

Research and Development Costs

We expense internal and external research and development ("R&D") costs, including costs of funded R&D arrangements and the manufacture of clinical batches of Biosurgery products used in clinical trials, in the period incurred.

Internal resources are applied interchangeably across several product candidates due to the potential applicability of our biologic drug candidates for multiple indications.

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.

We recognize in our financial statements the impact of a tax position, if that position is more likely than not to be sustained upon an examination, based on the technical merits of the position. Interest and penalties related to income tax matters are recorded as income tax expense. At December 31, 2013 and 2012, we had no accruals for interest or penalties related to income tax matters.

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Description of Business and Significant Accounting Policies (Continued)

Income per Common Share

Basic income per common share is calculated by dividing net income by the weighted average number of common shares outstanding during the period. Diluted income per common share adjusts basic income per share for the potentially dilutive effects of common share equivalents, using the treasury stock method, and includes the incremental effect of shares that would be issued upon the assumed exercise of stock options and warrants.

Diluted loss from continuing operations for the year ended December 31, 2013 excluded all 1,233,767 shares issuable upon the exercise of options, as their impact on our loss from continuing operations is anti-dilutive. As a result, basic and diluted weighted average common shares outstanding are identical.

Diluted loss per common share for the year ended December 31, 2012 excludes the 1,000,000 shares issuable upon the exercise of an outstanding "out-of the money" warrant, and all 1,826,114 of our outstanding options as of December 31, 2012, as their impact on our net loss is anti-dilutive. As a result, basic and diluted weighted average common shares outstanding are identical.

Diluted income per common share for 2011 excludes 1,311,686 "out-of the money" stock options and the 1,000,000 shares issuable upon the assumed exercise of our outstanding warrant, discussed in Note 8 below, as their effect is anti-dilutive.

Share-Based Compensation

We account for share-based payments using the fair value method.

We recognize all share-based payments to employees and non-employee directors in our financial statements based on their grant date fair values, calculated using the Black-Scholes option pricing model. Compensation expense related to share-based awards is recognized on a straight-line basis for each vesting tranche based on the value of share awards that are expected to vest on the grant date, which is revised if actual forfeitures differ materially from original expectations.

Comprehensive Income

Comprehensive income consists of net income and all changes in equity from non-stockholder sources, which consist of changes in unrealized gains and losses on investments.

Concentration of Risk

We maintain cash and short-term investment balances in accounts that exceed federally insured limits, although we have not experienced any losses on such accounts. We also invest excess cash in investment grade securities, generally with maturities of one year or less.

We have historically provided credit in the normal course of business to contract counterparties and to the distributors of our product. Trade accounts receivable in the accompanying balance sheets consist primarily of amounts due from distributors of our Biosurgery products within the United States. During fiscal 2013, revenues from one of the distributors of our Biosurgery products, Stability Biologics, comprised approximately 50% of our total Biosurgery revenues. As of December 31, 2013, receivables

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Description of Business and Significant Accounting Policies (Continued)

from this distributor comprised 6% of our total receivables. We expect all of our reported receivables to be fully collected. As discussed under "*Trade Accounts Receivable*" above, we have not incurred material bad debt expense for the three years ended December 31, 2013.

Recent Accounting Guidance Not Yet Adopted at December 31, 2013

In July 2013, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards Update ("ASU") related to the presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The ASU requires an unrecognized tax benefit, or a portion of an unrecognized tax benefit, to be presented in the financial statements as either a reduction to a deferred tax asset or separately as a liability depending on the existence, availability and/or use of an operating loss carryforward, a similar tax loss, or a tax credit carryforward. This ASU will be effective for us beginning the first quarter of 2014. We do not expect that this ASU will have an impact on our consolidated financial statements as we currently do not have any unrecognized tax benefits in the same jurisdictions in which we have tax loss or credit carryovers.

In February 2013, the FASB issued an ASU related to the reporting and disclosure of amounts reclassified out of accumulated other comprehensive income by component. An entity is required to present either on the face of the statement of operations or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income, but only if the amount reclassified is required to be reclassified to net income in its entirety in the same reporting period. For amounts not reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional detail about those amounts. This ASU was effective for our annual and interim periods beginning in fiscal 2013. The ASU had no effect on our consolidated financial statements as we have a single component of other comprehensive income, currency translation adjustments, which is not reclassified to net income.

2. Discontinued Operations

As reported on our Current Report on Form 8-K, dated October 10, 2013, we entered into a Purchase Agreement with Mesoblast, pursuant to the terms of which the we sold our culture expanded mesenchymal stem cell (ceMSC) business, including Prochymal and other related assets. The Purchase Agreement provides for payment to us of $50 million in initial consideration, and payment of up to an additional $50 million upon the achievement by Mesoblast of certain clinical and regulatory milestones. Additionally, we will be entitled to earn low single to double digit cash royalties on future sales by Mesoblast of Prochymal and other products utilizing the acquired ceMSC technology.

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

2. Discontinued Operations (Continued)

The Purchase Agreement provides for the $50.0 million of initial payments and up to $50.0 million of contingent additional payments to us upon our achievement of milestone events, as follows:

Milestone	Amount ($000)
Initial consideration	
Letter of intent payments	$ 3,500
Initial closing payment	16,500
Additional closing payment, 6 months after closing date	15,000
Delivery of all scheduled assets under the Transfer Agreement	15,000
Total initial consideration	50,000
Contingent Consideration	
First marketing authorization received in the U.S.	20,000
First marketing authorization received from France, Germany, or European Union.	10,000
Completion of the enrollment of the Phase 3 Crohn's Trial or Mesoblast's election to discontinue the trial	10,000
Receipt of final data for the Crohn's trial or first marketing approval for Crohn's	10,000
Total conditional consideration	50,000
Total possible purchase price	$ 100,000

Of the $50 million in total initial consideration, we had received at December 31, 2013, payment of $20 million in cash, and $15 million in Mesoblast ordinary shares, which were delivered to us upon completed delivery of the ceMSC assets. The remaining $15 million of the initial consideration is scheduled for payment to us in cash on April 10, 2014. The Mesoblast shares received by us are subject to a one year holding period from the date of receipt, but are afforded limited downside protection for a drop in the Mesoblast share price over the holding period. We have evaluated this downside protection, and determined that it meets the criteria of a derivative instrument. The fair value of the protection at the time of the disposition of our Therapeutics business was $1.7 million. We recognized the price protection derivative as an asset at year end at its then fair value of $1.7 million, which has been reflected in the calculation of the gain on sale of the Therapeutics business.

Our ability to receive the second $50 million is subject to satisfaction of the milestones indicated above all of which are largely dependent upon the clinical and regulatory success of Mesoblast and other factors not in our control. These include many if not all of the risks and uncertainties that our ceMSC business was subject to prior to its sale to Mesoblast, including product development, efficacy and regulatory risks. We have received no such payments thus far, nor do we have any expectation of receiving any such payments in the foreseeable future. Our ability to earn royalties from Mesoblast is subject to these same risks and will require performance by Mesoblast that results in its meeting some or all of the milestones referred to above, and is thereafter also dependent upon the commercial success of Mesoblast's ceMSC business. Royalties, if any, are payable to us in cash. Any portion of the second $50 million that becomes payable to us will be payable, at the discretion of Mesoblast, in Mesoblast ordinary shares, based on a then current valuation of such shares. Any such Mesoblast

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

2. Discontinued Operations (Continued)

ordinary shares that we receive will also be subject to a one year holding period, with the same limited downside protection described above.

We eliminated the Therapeutics segment from our continuing operations as a result of the disposal transaction and have presented the assets, liabilities, and results of the segment's operations as a discontinued operation for all periods. Our continuing operations now represent the portion of our business previously referred to as our Biosurgery segment.

As noted above, we eliminated the Therapeutics business from our continuing operations as a result of the disposal transaction and have presented the assets, liabilities, and results of the segment's operations as a discontinued operation for all periods presented. We have no continuing involvement with Therapeutics business, and the only continuing cash flows to us related to the Therapeutics business will be the contingent consideration and royalties provided for under the purchase agreement, as described above. We received no such contingent payments or royalties in 2013.

We recognized a gain of approximately $49.4 million of the sale of discontinued operations during the year ended December 31, 2013, representing the $50.0 million in initial payments received under the Purchase Agreement and the $1.7 million fair value of the derivative instrument received, net of transaction costs of $0.6 million, including legal, accounting and advisory fees, and income tax expense of $1.7 million.

The net assets allocable to the Therapeutics business at December 31, 2013 and 2012 were as follows:

	2013 ($000s)	2012 ($000s)
Current assets:		
Accounts receivable	$ 91	$ 204
Current liabilities:		
Accounts payable and accrued expenses	$ 57	$ 2,903

Summarized operating results of the Therapeutics segment are as follows:

	Year ended December 31, ($000s)		
	2013	2012	2011
Revenue from collaborative research agreements and royalties	$ 639	$ 3,955	$ 41,140
Operating expenses:			
Research and development	$ 6,426	8,607	14,816
Selling, general and administrative	881	666	712
	7,307	9,273	15,528

(Loss) income from discontinued operations before income tax expense	(6,668)	(5,318)	25,612
Income tax expense			(818)
(Loss) income from discontinued operations	$ (6,668)	$ (5,318)	$ 24,794

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

2. Discontinued Operations (Continued)

Revenues for our Therapeutics segment have historically consisted primarily of collaborative research agreements and royalties. Because of the disposition of our Therapeutics business in 2013, we will no longer incur related research and development expenses related to these discontinued operations. Our Therapeutics segment also earned royalty revenues and cost reimbursement under our adult expanded access program. Royalties are earned on the sale of human mesenchymal stem cells sold for research purposes. We recognize this revenue as sales are made. Revenues from our former Therapeutics business include approximately $215,000 of royalty revenue in 2013, $305,000 of royalty revenue in 2012, and $65,000 of royalty revenue in 2011. Revenues from our former Therapeutics business also include approximately $424 000, $296,000, and $115,000, in cost reimbursement for Prochymal used in our adult expanded access program during 2013, 2012, and 2011, respectively.

3. Segment Reporting

Historically, we have managed our business in two operating segments: our Biosurgery segment and our Therapeutics segment.

Our Biosurgery segment is focused on the development, manufacture and distribution of biologic products for wound healing, cartilage repair, and orthopedics to harness the ability of cells and novel constructs to promote the body's natural healing. We launched Grafix for commercial distribution in 2010, began distribution of Ovation in early fiscal 2011, and began distribution of Cartiform and OvationOS during 2013. We have continued to increase our distribution volume of these products since their respective commercial launches and are developing additional products for future commercialization.

Our Therapeutics segment focused on developing and marketing products to treat medical conditions in the inflammatory and cardiovascular disease areas. Its operations have focused on clinical trials and discovery efforts. As disclosed in Note 2 *Discontinued Operations*, we entered into a Purchase Agreement with Mesoblast, pursuant to the terms of which we sold our culture expanded mesenchymal stem cell business, including Prochymal and other related assets.

Given the sale of our former Therapeutics segment, we now have only one operating segment in the United States of America. As such, our financial statements present the assets, liabilities, and results of the former Therapeutics segment as discontinued operations for all periods presented, the rest of our balance sheets and statements of comprehensive (loss) income present information of the remaining Biosurgery segment.

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

4. Property and Equipment

Property and equipment at December 31, 2013 and 2012 are as follows:

	2013 ($000)	2012 ($000)
Laboratory and manufacturing equipment	$ 663	$ 492
Computer hardware, furniture and fixtures	899	567
Leased assets	228	228
Leasehold improvements	4,260	4,234
	6,050	5,521
Accumulated depreciation and amortization	(4,154)	(3,410)
Property and equipment, net	$ 1,896	$ 2,111

5. Inventory

We began carrying inventory of our Biosurgery products on our balance sheet following commercial launch of such products.

As of December 31, 2013 and 2012, inventory for our Biosurgery segment consists of the following:

	2013 ($000)	2012 ($000)
Inventory		
Raw materials and supplies	$ 387	$ 284
Work-in-process	22	135
Finished goods	1,520	859
Total Biosurgery inventory	$ 1,929	$ 1,278

Prior to the transaction described in Note 2 *Discontinued Operations*, we did not carry any inventory for our Therapeutics products, as we had yet to launch Prochymal for commercial distribution.

6. Capital Lease

In July 2012, we leased equipment under a capital lease at an effective interest rate of approximately 5%, with 60 monthly payments of $4,000 starting July 2012. The capital lease is recorded

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

6. Capital Lease (Continued)

at the present value of the future minimum lease payments. Future minimum lease payments under the capital lease agreement at December 31, 2013 are as follows:

	Amount (000s)
December 31,	
2014	$ 48
2015	48
2016	48
2017	24
	168
Less: Amount representing interest	(6)
Present value of minimum lease payments	162
Less: Current portion of capital lease obligations	(45)
Long-term portion of capital lease obligations	$ 117

7. Share-Based Compensation

In April 2006, we adopted our 2006 Omnibus Plan. We amended and restated this plan in 2008 and 2010, and amended it further in 2012, in each case to, among other things, increase the number of shares available for grant. In addition, we had previously established our Amended and Restated 1994 Stock Incentive Plan. Both Plans authorize the issuance of various forms of stock-based awards, including incentive and non-qualified stock options, stock purchase rights, stock appreciation rights and restricted and unrestricted stock awards. A total of 2,250,000 shares of our common stock have been reserved for issuance under the Amended and Restated 2006 Omnibus Plan, and 736,378 shares were reserved under our Amended and Restated 1994 Stock Incentive Plan. We ceased all grants under the Amended and Restated 1994 Stock Incentive Plan concurrent with our initial public offering in August 2006. As a result, no shares are currently available for future awards under the Amended and Restated 1994 Stock Incentive Plan. At December 31, 2013, there were approximately 369,781 shares available for future awards under the Amended and Restated 2006 Omnibus Plan.

We generally issue stock option awards that vest over four years and have a ten-year contractual life. We estimate the fair value of stock options using the Black-Scholes option-pricing model. Estimates of fair value are not intended to predict actual future events or the value ultimately realized

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

7. Share-Based Compensation (Continued)

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,		
	2013	**2012**	**2011**
Assumptions:			
Weighted average risk-free interest rate	1.00-1.50%	2.00%	2.00%
Dividend yield	0.0%	0.0%	0.0%
Expected life of option grants	5.0-6.5 yrs	6.0-6.3 yrs	5.5 yrs
Weighted average expected stock price volatility	52-61%	52-54%	53-55%

The expected life of stock options granted was based on the our historical option exercise experience and post vesting forfeiture experience using the historical expected term from the vesting date. The expected volatility of the options granted was determined using historical volatilities based on stock prices over a look-back period corresponding to the expected life. The risk-free interest rate was determined using the yield available for zero-coupon United States government issues with a remaining term approximating the expected life of the options. The forfeiture rate was determined based on historical pre-vesting forfeitures. We have never paid a dividend and have no intention to pay a dividend, and as such, the dividend yield is zero.

In connection with the stock options exercised during the year ended December 31, 2013, we received cash proceeds of $2.2 million. At December 31, 2013, there was $1.3 million of total unrecognized compensation costs related to non-vested stock options, which is expected to be recognized through fiscal 2017.

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

7. Share-Based Compensation (Continued)

A summary of stock option activity for the years ended December 31, 2013, 2012, and 2011 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2011	1,349,261	$ 9.75	7.0-years	
Granted	450,000	$ 6.82		
Exercised	(9,064)	$ (2.42)		$ 36
Forfeited or canceled	(88,125)	$ (8.89)		
Balance, December 31, 2011	1,702,072	$ 9.06	6.8-years	
Granted	302,000	$ 5.50		
Exercised	(28,708)	$ (3.05)		$ 114
Forfeited or canceled	(149,250)	$ (7.20)		
Balance, December 31, 2012	1,826,114	$ 8.72	6.1-years	$ 4,754
Granted	452,000	$ 9.03		
Exercised	(642,514)	$ (6.50)		$ 6,983
Forfeited or canceled	(401,833)	$ (6.79)		
Balance, December 31, 2013	1,233,767	$ 10.61	6.3-years	$ 7,992
Exercisable at December 31, 2013	541,142	$ 14.22	2.6-years	$ 2,224

A summary of stock options outstanding at December 31, 2013, 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
$ 0.01 to $ 1.00	18,201	1.4	$ 0.40	18,201	$ 0.40
1.01 to 5.00	2,500	8.2	4.78	625	4.78
5.01 to 6.75	233,377	7.9	5.36	44,127	5.73
6.76 to 7.50	180,064	6.4	7.06	72,564	6.98

7.51 to 8.50	327,750	8.2	7.75	65,125	7.74
8.51 to 12.25	114,875	7.6	10.50	36,500	11.93
12.26 to 15.00	74,500	6.4	13.67	44,500	13.40
15.01 to 17.50	24,000	4.4	17.04	21,000	17.10
17.51 to 20.00	140,500	4.0	18.52	120,500	18.60
$20.01 to $23.62	118,00	0.6	23.62	118,000	23.62
	1,233,767	6.3	$ 10.62	541,142	14.22

The weighted fair value of options granted during the years ended December 31, 2013, 2012, and 2011 were $4.68, $2.82, and $3.50, respectively.

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

7. Share-Based Compensation (Continued)

The table below reflects the total share-based compensation expense (including share-based payments to our non-employee directors, but excluding the non cash expense related to the extension of the expiration date of an outstanding warrant as discussed in Note 8 below) recognized in our statements of comprehensive (loss) income for the years ended December 31, 2013, 2012, and 2011.

	Year Ended December 31,		
	2013	2012	2011
	(000s)	(000s)	(000s)
Research and development	335	283	432
Selling, general and administrative	248	209	462
Discontinued operations	658	598	790
Total	1,241	1,090	1,684

8. Related Party Transactions and Warrant

Peter Friedli. Peter Friedli, the Chairman of our Board of Directors, or entities with which he is affiliated, have been responsible for procuring since 1993, an aggregate of approximately $270 million in debt and equity financing for us and our predecessor company. Mr. Friedli is the beneficial owner of approximately 43% of our common stock as of December 31, 2013. Of the shares beneficially owned by Mr. Friedli at December 31, 2013, 75,000 shares were received by him as Board compensation since 1996, 12,500 shares were granted in recognition of his fundraising efforts, as discussed below, 567,610 shares were received by him upon his net exercise of a warrant to purchase 1,000,000 shares of our common stock at $11.00 per share, as described below, and the remaining shares were acquired through investment or through purchase from third parties.

Of the 75,000 shares received by Mr. Friedli as board compensation since 1996, 10,000 shares, then valued at approximately $77,000, were issued to Mr. Friedli in 2013, 10,000 shares, then valued at approximately $51,000, were issued to Mr. Friedli in 2012, and 10,000 shares, then valued at approximately $71,000, were issued to Mr. Friedli in 2011.

In response to Mr. Friedli's successful efforts in procuring for us accommodations relative to financing transactions that had occurred prior to our initial public offering, we issued to Mr. Friedli in 2006, in connection with and just prior to our initial public offering, a warrant 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 was scheduled to expire in May 2011. In light of Mr. Friedli's unwavering support of the Company over a period of many years, and in recognition of his invaluable contributions to us, as founder, as a director and as Chairman of our Board, and to encourage his continued support, our Board of Directors and Compensation Committee, by the unanimous vote of all independent and disinterested members of each, approved the extension of the expiration date of the warrant until May 24, 2015, subject to the approval of our stockholders. Our stockholders approved the extension of the warrant at our 2011 Annual Meeting of Stockholders, on May 26, 2011.

We incurred a non cash charge against earnings on account of the extension of the warrant expiration date, based on its increase in fair value of approximately $1.7 million. This amount was

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

8. Related Party Transactions and Warrant (Continued)

recorded within general and administrative expenses. The increase in value was computed using the Black-Scholes option pricing model with a risk free interest rate of 1.50%, a four year increase in the expected life of the warrant, and a historical volatility of approximately 51%.

Mr. Friedli exercised this warrant on August 14, 2013 using the Net Exercise Method, resulting in the net issuance of 567,610 shares of our common stock. As of December 31, 2013, we no longer have any outstanding warrants.

Prolexys Pharmaceuticals, Inc. During the third quarter of fiscal 2011 we entered into a contract research agreement with Prolexys Pharmaceuticals, Inc. under which we are conducting for Prolexys an early stage clinical trial investigating a novel compound as a product candidate for cancer therapeutics. This contract was filed as an exhibit to and discussed in a Current Report on Form 8-K filed by us with the SEC primarily because of the related nature of the management and ownership of Prolexys with us and our management and with certain of our significant stockholders, and not because our rights or obligations under the contract research agreement with Prolexys are otherwise material to us. We are not incurring any third party costs related to our work with Prolexys and are primarily contributing only the efforts of employees. All third party costs associated with the Prolexys study are paid directly by Prolexys. As of December 31, 2013, the amount of internal resources we have devoted to Prolexys is not material to our operations as a whole.

Prolexys is 35.7% owned by BIH SA, which owns 7.8% of our outstanding common stock; 24.3% owned by Peter Friedli who is the Chairman of our Board of Directors and direct owner of 29.3% of our common stock; and 13.8% owned by Venturetec, Inc., which holds 12.5% of our common stock. Peter Friedli is the President and an approximately 2% owner of Venturetec, Inc. Mr. Friedli has also recently reported the acquisition of a convertible bond that would entitle him, upon conversion, to acquire an additional approximately 19% interest in Venturetec, Inc. Lode Debrabandere, our Chief Executive Officer, serves on the Board of Directors of Prolexys, but has no other interest therein.

This arrangement is part of our ongoing efforts to expand our portfolio of product candidates, but we do not consider this arrangement to be material to us at this time.

Our Board of Directors and Audit Committee, including all of our independent directors, but with Mr. Friedli abstaining, unanimously approved this transaction.

9. Income Taxes

For income tax reporting purposes, we reported taxable income in fiscal 2013, compared to a loss in fiscal 2012 and 2011. The income in 2013 was primarily attributable to the gain from sale of discontinued operations which are reflected in the statement of comprehensive (loss) income, net of income taxes. Continuing operations below reflect a tax benefit in the amount of $1.3 million generated during fiscal 2013. Included in this amount is $79,000 of taxes recoverable from a prior period.

The loss in 2011 was primarily because we recognized the entire $130.0 million up-front payment made to us by Genzyme as of the end of fiscal 2010 for tax purposes. For financial reporting purposes, we recognized $40.0 million in revenue from the Genzyme payments during fiscal 2011. The $37,000 income tax benefit recognized during fiscal 2012 resulted from the true-up of our tax asset accounts upon filing our 2011 income tax returns. In fiscal 2011, we recorded an income tax benefit of $775,000

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

9. Income Taxes (Continued)

from continuing operations and an income tax expense of $818,000, which was offset against the income from discontinued operations.

In 2013 we are subject to the alternative minimum tax in the amount of $388,000. This is reported in gain from sale of discontinued operations. In 2012 and 2011, we were not subject to the alternative minimum tax due to having a net loss for tax purposes. In the future, we may be subject to the alternative minimum tax regardless of our tax attributes. The gain from sale of discontinued operations includes interest to be accrued in the amount of $70,000 which increases income taxes payable.

The effective tax rate benefit (expense) varies from the U.S. Federal Statutory tax rate principally due to the following:

	2013	2012	2011
U.S. Federal Statutory tax rate	35.0%	35.0%	35.0%
State taxes, net of federal benefits	7.0	0	3.7
Permanent differences	10.7	(5.6)	(10.6)
Change in valuation allowance		(29.4)	(20.4)
Other	2.1	0.6	(0.4)
Effective tax rate	54.8%	0.6%	7.3%

Permanent differences represent primarily the exercise of incentive stock options, net of windfall benefits attributable to disqualifying dispositions, for the year ended December 31, 2013, and research and development expenses for which we claimed the orphan drug credit and non-cash share based compensation for each of the two years ended prior to December 31, 2013.

The components of our net deferred tax assets and liabilities at December 31 are as follows:

	2013 ($000)	2012 ($000)
Deferred Tax Assets:		
Credits	$ 76,023	$ 76,491
Net Operating loss carry-forward	0	9,243
Stock options NQSO	1,689	1,638
Fixed assets	811	798
Accrued Expenses	101	57
Allowance for doubtful accounts	31	10
Contribution carry-forward		5
	78,655	88,243
Valuation allowance	(72,601)	(88,243)
Net deferred tax assets	$ 6,054	$
Deferred Tax Liabilities:		
Gain on installment sale	$ (6,054)	$

We presently have available for federal income tax purposes, approximately $74.6 million of general business credit carry-forwards, which expire beginning in 2025 through 2031. In addition, we

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

9. Income Taxes (Continued)

have approximately $3.5 million of net operating loss and $2.1 million alternative minimum tax credit carry forwards as of December 31, 2013. The net operating losses will begin to expire in 2031 and the alternative minimum tax credits do not expire. In addition, the windfall equity-based compensation deductions are tracked, but will not be recorded to the balance sheet until Management determines that such amounts will be utilized. During 2013, the Company had $5.4 million, of windfall stock compensation deductions. When realized, the tax benefit associated with these deductions will be credited to additional paid-in capital.

The Company's ability to realize its deferred tax assets depends primarily upon the generation of sufficient future taxable income to allow for the utilization of the Company's deductible temporary differences and upon tax planning strategies. Realization of net deferred tax assets is dependent on the Company's ability to generate future taxable income, which is uncertain. The Company has recorded a valuation allowance of $72.6 million and $88.2 million, against the Company's net deferred tax assets as of December 31 2013 and December 31 2012, respectively, as Management believes it is more likely than not that the assets will not be realized.

Utilization of the net operating loss carryforwards and credits may be subject to an annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The Company has not performed a detailed analysis to determine whether an ownership change under Section 382 of the Internal Revenue Code occurred. The effect of an ownership change would be the imposition of an annual limitation on the use of net operating loss carryforwards and credits attributable to periods before the change and could result in a reduction in the total net operating losses and credits available.

The Company is subject to income taxes in the United States and State of Maryland. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company had tax net operating losses and credit carryforwards that are subject to examination for a number of years beyond the year in which they are generated for tax purposes. Since a portion of these carryforwards may be utilized in the future, many of these attribute carryforwards remain subject to examination.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2013 and December 31, 2012, the Company had no accruals for interest or penalties related to income tax matters.

Effective January 1, 2007, we adopted the provisions of the accounting pronouncement clarifying the accounting for uncertain tax positions. The pronouncement prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The pronouncement also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. We have evaluated our tax positions in the tax returns filed, as well as un-filed tax positions and the amounts comprising our deferred tax assets. We have determined that the pronouncement does not have a material impact on our financial condition, results of operations or cash flows.

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

10. 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.

11. Commitments and Contingencies

Contract Research Organizations. We utilize independent contract research organizations ("CROs") to perform many of the tasks required under our clinical trials. We rely on CROs for their testing expertise and to ensure the objectivity of our clinical results. Under the terms of these agreements, we design the protocol regarding the testing to be performed, and the CRO assists in the enrollment of the patients and testing sites, administers the trial, performs statistical analysis of the results, and compiles the final report.

We pay fees directly to the CROs for their professional services, which may be payable upon specified trial milestones or as they provide services, depending on the structure of the contract. We are also responsible for reimbursing the CROs for certain pass thru expenses they incur in administering the trial. The timing of our payments to the CROs is dependent upon the progress of the various trials, which is highly variable dependent upon the speed with which the CROs are able to enroll patients and testing sites. As such, we are unable to specifically predict the timing of future payments to CROs.

As of December 31, 2013, we had one active contract with a CRO. The total contracted payments were $3.2 million, of which we had incurred approximately $3.0 million as of that date. We expect to pay our remaining obligations under this contract during 2014.

We may utilize CROs for future clinical trials.

Leases. 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 was effective as of June 1, 2009 upon the expiration of the sublease and expires in July 2016. During 2009, following the expiration of the sublease agreement, we increased an outstanding letter of credit, which was used in lieu of a security deposit for this lease, to $591,000 according to the terms of the direct lease with the owner of the facility. At each of July 1, 2013, 2012, and 2011, the security deposit required under this lease decreased to $223,000, $298,000, and $372,000, respectively. We reduced our outstanding letter of credit accordingly, and the reduced letter of credit of $223,000 remained outstanding as of December 31, 2013, and has been fully collateralized by restricted cash.

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

11. Commitments and Contingencies (Continued)

The future minimum lease payments due under the operating lease for this facility are as follows:

	Columbia Facility ($000)
2014	$ 1,165
2015	1,194
2016	709
	$ 3,068

Our expenses under this lease were $1.3 million, $1.3 million, and $1.2 million, during 2013, 2012, and 2011, respectively.

Historically, 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.

As discussed in Note 6 *Capital Lease*, in July 2012, we leased an additional $228,000 of equipment under a capital lease, which was included in our balance sheet at December 31, 2013 along with $68,000 of accumulated depreciation.

Legal. We are subject to certain litigation, claims and assessments which occur in the normal course of business. Based on consultation with our legal counsel, management is of the opinion that there are no matters that are probable or reasonably possible that require accrual or disclosure.

12. Derivative and Securities Received in Business Disposition

The only derivative instrument to which the company is a party is the price protection related to the shares received from Mesoblast as part of the disposition of our Therapeutics business. As discussed in Note 2 *Discontinued Operations,* the $15 million milestone for completed delivery of the ceMSC assets was payable in either cash or stock, at Mesoblast's election. Because Mesoblast made that payment in stock, the Purchase Agreement provides that these shares are subject to a one year holding period, during which time we are afforded limited protection for any drop in the Mesoblast share price. In the event that the shares decrease in value during the holding period, we will be compensated for 100% of the decrease in value, with 50% of the decrease payable to us in cash, and the remaining 50% again payable in either cash or ordinary shares, at Mesoblast's election. Any additional shares issued would be subject to an additional one year holding period, but will not be afforded price protection.

The price protection was recorded as a part of the initial consideration received under the Purchase Agreement at its fair value as of that date of $1.7 million. We have evaluated this downside protection, and determined that it meets the criteria of a derivative instrument under ASC 815. As such, the price protection derivative is being remeasured at its fair value with change in fair value being recorded in net income as a component of "Other income".

As of December 31, 2013, the price protection derivative has a fair value of $1.7 million, which is included as a component of "Trading Securities" as of December 31, 2013. From the closing of the sale

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

12. Derivative and Securities Received in Business Disposition (Continued)

of the Therapeutics business through December 31, 2013, we recorded a loss of $52,000 on the price protection, which is included as a component of "Other income":

The shares of Mesoblast to which the price protection relates were received by the Company on December 18, 2013 and are required to be held for one year from the date of receipt. The fair value of the shares when they were received was $15 million. The Company has elected to remeasure the Mesoblast shares at fair value, with changes in fair value being recorded as a component of "Other income". As such, the statement of comprehensive (loss) income impact of changes in the fair value of the Mesoblast shares and the statement of comprehensive (loss) income impact of changes in the fair value of the price protection derivative will largely offset each other during the mandatory holding.

The fair value of the Mesoblast shares as of December 31, 2013, determined by reference to the trading price of identical Mesoblast ordinary shares on the Australian Securities Exchange, was $15.4 million. The gain during the period from December 18, 2013 through December 31, 2013 was $401,000 and is included as a component of "Other income".

13. Fair Value

Fair value is defined as the price at which an asset could be exchanged or a liability transferred (an exit price) in an orderly transaction between knowledgeable, willing parties in the principal or most advantageous market for the asset or liability. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or inputs are not available, valuation models are applied.

Financial assets recorded at fair value in the accompanying financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The levels are directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities, and are as follows:

Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets at the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The fair valued assets we hold that are generally included in this category are money market securities and the Mesoblast shares received in the disposition of the Therapeutics business, where fair value is based on publicly quoted prices.

Level 2 Inputs are other than quoted prices included in Level 1, which are either directly or indirectly observable for the asset or liability through correlation with market data at the reporting date and for the duration of the instrument's anticipated life.

The fair valued assets we hold that are generally included in this category are investment grade short-term securities and our derivative instrument.

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

13. Fair Value (Continued)

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities and which reflect management's best estimate of what market participants would use in pricing the asset or liability at the reporting date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

The only asset we hold that is included in this category is the price protection derivative related to the Mesoblast shares received in the disposition of our Therapeutics business.

When quoted prices in active markets for identical assets are available, we use these quoted market prices to determine the fair value of financial assets and classify these assets as Level 1. In other cases where a quoted market price for identical assets in an active market is either not available or not observable, we obtain the fair value from a third party vendor that uses pricing models, such as matrix pricing, to determine fair value. These financial assets would then be classified as Level 2. In the event quoted market prices were not available, we would determine fair value using broker quotes or an internal analysis of each investment's financial statements and cash flow projections. In these instances, financial assets would be classified based upon the lowest level of input that is significant to the valuation. Thus, financial assets might be classified in Level 3 even though there could be some significant inputs that may be readily available. There have been no transfers between level 1 and 2.

The price protection derivative related to the Mesoblast shares is classified in Level 3. Its fair value was determined through use of the Black-Scholes valuation method, a standard industry methodology for valuing equity options, because the price protection is economically equivalent to a put option on the Mesoblast shares at a price of $15 million. Significant inputs to the model include the following:

Fair value of underlying Mesoblast stock: $15,000,000
Contractual life: 1.0 year
Volatility: 40%
Risk-free interest rate: 0.13%
Expected dividends: $0

There have been no other transfers in and out of Level 3. The following table represents a rollforward of the fair value of Level 3 instruments, comprised solely of the limited price protection derivative related to the Mesoblast stock issued to us in connection with the sale of our former Therapeutics business:

	December 31, 2013 ($000s)
Balance at beginning of period	$
Fair value upon receipt of Mesoblast stock	1,737
Change in Fair Value	(52)
Balance at end of period	$ 1,685

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

13. Fair Value (Continued)

Assets and liabilities measured at fair value on a recurring basis are summarized below as of December 31, 2013 and 2012:

	December 31, 2013 ($000s)			
	Level I	Level II	Level III	Total
Assets				
Investments available for sale				
Cash & Cash Equivalents	$ 655	$	$	$ 655
Investments: Available for Sale Securities				
Government Obligations	$	$ 9,244	$	$ 9,244
Mutual Funds		4,076		4,076
Agency Obligations	$	$ 6,675	$	$ 6,675
Corporate Debt Securities & Commercial Paper		6,367		6,367
Municipal Securities	$	$ 12,491	$	$ 12,491
Investments available for sale	**$ 655**	**$ 38,853**	**$**	**$ 39,508**
Derivative and securities received in business disposition				
Restricted shares of Mesoblast common stock	$ 15,401	$	$	$ 15,401
Price protection on restricted Mesoblast shares			1,685	1,685
Derivative and securities received in business disposition	**$**	**$**	**$ 1,685**	**$ 17,086**
Total assets	**$ 16,056**	**$ 38,853**	**$ 1,685**	**$ 56,594**

	December 31, 2012 ($000s)			
	Level I	Level II	Level III	Total
Assets				
Money market funds and certificates of deposit	$ 2,478	$	$	$ 2,478
U.S. and international government agencies		200		200
Agency obligations		14,856		14,856
Corporate debt securities & commercial paper		4,937		4,937

Municipal securities		9,767		9,767
Investments available for sale	**$ 2,478**	**$ 29,760**	**$**	**$ 32,238**

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OSIRIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

14. Quarterly Financial Data (Unaudited)

Following is a summary of our unaudited quarterly results for the years ended December 31, 2013 and 2012:

	First Quarter (000s)	Second Quarter (000s)	Third Quarter (000s)	Fourth Quarter (000s)
2013				
Product revenues	$ 4,055	$ 5,291	$ 6,882	$ 8,080
Gross profit	2,920	3,810	5,024	5,898
Research and development expenses	957	1,132	913	1,950
Selling, general and administrative expenses and fees	2,646	4,157	4,602	4,128
Income (loss) from continuing operations	(654)	(1,454)	(466)	1,481
(Loss) income from discontinued operations	(2,081)	(2,302)	(1,211)	48,325
Net (loss) income	(2,735)	(3,756)	(1,677)	49,806
**Loss from continuing operations per share, basic	$ (0.02)	$ (0.04)	$ (0.01)	$ 0.03
**Loss from continuing operations per share, basic diluted	(0.02)	(0.04)	(0.01)	0.03
**(Loss) income from discontinued operations per share, basic	$ (0.06)	$ (0.07)	$ (0.04)	$ 1.46
**(Loss) income from discontinued operations per share, diluted	(0.06)	(0.07)	(0.04)	1.43
**Net (loss) income per share, basic	$ (0.08)	$ (0.11)	$ (0.05)	$ 1.49
**Net (loss) income per share, diluted	(0.08)	(0.11)	(0.05)	1.46
2012				
Product revenues	$ 1,137	$ 1,626	$ 2,151	$ 2,935
Gross profit	750	1,074	1,419	2,055
Research and development expenses	1,454	1,434	1,413	1,200
Selling, general and administrative expenses and fees	1,353	1,253	1,369	1,655
Loss from continuing operations	(2,039)	(1,560)	(1,345)	(803)
Income (loss) from discontinued operations	767	(2,705)	(1,569)	(1,811)
Net loss	(1,272)	(4,265)	(2,914)	(2,614)
**Loss from continuing operations per share, basic and diluted	$ (0.06)	$ (0.05)	$ (0.04)	$ (0.02)
**Income (loss) from discontinued operations per share, basic and dilute	$ 0.02	$ (0.08)	$ (0.05)	$ (0.05)
**Net loss per share, basic and diluted	$ (0.04)	$ (0.13)	$ (0.09)	$ (0.07)

**

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

15. Subsequent Events

We evaluated our December 31, 2013 financial statements for subsequent events through the date the financial statements were issued. We are not aware of any subsequent events which would require recognition or disclosure in the financial statements.

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OSIRIS THERAPEUTICS, INC.

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

FOR THE YEARS ENDED DECEMBER 31, 2013, 2012 and 2011

(in thousands)

	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Accounts Receivable Reserve:				
2013	$ 25	$ 80	$ (27)	$ 78
2012	3	22		25
2011		3		3
Inventory Reserve:				
2013	$ 112	$	$ (112)	$
2012	274		(162)	112
2011	300		(26)	274
Net Deferred Tax Asset Valuation Allowance:				
2013	$ 88,243	$	$ (15,642)	$ 72,601
2012	84,134	4,109		88,243
2011	77,317	6,817		84,134

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ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

ITEM 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures. An evaluation of the effectiveness of the design and operation of our "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Annual Report on Form 10-K was made under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that due to the material weakness in our internal control over financial reporting that is described in Management's Report on Internal Control over Financial Reporting referred to below and included in "Item 8. Financial Statements and Supplementary Data," and in light of the delay in our filing of our Annual Report on Form 10-K beyond its normal due date, our disclosure controls and procedures were not effective as of December 31, 2013.

Notwithstanding the identified material weakness described above, management has determined that the financial statements and other financial information included in this report present fairly in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with accounting principles generally accepted in the United States (GAAP).

Management's Report on Internal Control over Financial Reporting. Management's report on internal control over financial reporting is included in "Item 8. Financial Statements and Supplementary Data."

Attestation Report of Registered Public Accounting Firm. BDO USA, LLP's attestation report on our internal control over financial reporting is included in "Item 8. Financial Statements and Supplementary Data."

Changes in Internal Control over Financial Reporting. There has occurred a change in our internal control over financial reporting during the fourth quarter of the fiscal year ended December 31, 2013, as discussed above, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information.

Our Chief Financial Officer, Philip R. Jacoby, Jr., has, with the filing of this Annual Report on Form 10-K, assumed on an interim basis the function of or similar to that of principal accounting officer (a position he formerly held), due to the illness of Mathew Neumayer, who regularly serves as our Corporate Controller and principal accounting officer. Biographical information regarding Mr. Jacoby appears in Part I Item 1 of this Annual Report on Form 10-K.

PART III

Certain information required in Part III is omitted from this report, but is incorporated by reference from our definitive proxy statement for the 2013 Annual Meeting of Stockholders anticipated to be filed within 120 days after the end of our fiscal year ended December 31, 2013, pursuant to Regulation 14A with the Securities and Exchange Commission.

ITEM 10. Directors, Executive Officers and Corporate Governance.

The information required by this item and not set forth below is incorporated herein by reference to the information contained in the Proxy Statement.

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We have adopted the Osiris Therapeutics, Inc. Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers and the Osiris Therapeutics, Inc. Code of Conduct which applies to all our employees and members of the Board of Directors. These policies are publicly available on our website at http://www//investor.osiris.com/documents.cfm.

ITEM 11. Executive Compensation.

The information required by this item is incorporated herein by reference to the information contained in the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the information contained in the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated herein by reference to the information contained in the Proxy Statement.

ITEM 14. Principal Accounting Fees and Services.

The information required by this item is incorporated herein by reference to the information contained in the Proxy Statement.

PART IV

ITEM 15. Exhibits, Financial Statement Schedules.

(a)

The following documents are filed as part of this report:

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

Management's Report on Internal Control Over Financial Reporting
Reports of Independent Registered Public Accounting Firm
Balance Sheets at December 31, 2013 and 2012
Statements of Comprehensive Income (Loss) for the years ended December 31, 2013, 2012 and 2011
Statements of Changes in Stockholders' Equity for the years ended December 31, 2013, 2012 and 2011
Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011
Notes to Financial Statements

FINANCIAL STATEMENT SCHEDULES

SCHEDULE II Valuation and Qualifying Accounts

2. Exhibits:

Exhibit Number	Description of Exhibit
3.1	Articles of Restatement of the Registrant as filed with the State Department of Assessments and Taxation of Maryland on June 4, 2010 (Incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 6, 2010).

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Exhibit Number	Description of Exhibit
3.2	Articles of Merger between Osiris Therapeutics, Inc., a Delaware corporation, and Osiris Maryland, Inc., a Maryland corporation, as survivor, changing the name of "Osiris Maryland, Inc." to "Osiris Therapeutics, Inc," as filed with the State Department of Assessments and Taxation of Maryland on May 27, 2010, and effective May 31, 2010 (Incorporated herein by reference to Exhibit 3.2 to the Current Report on Form 8-K filed by the Registrant with the SEC on June 2, 2010).
3.3	Bylaws of the Registrant (Incorporated herein by reference to Exhibit 3.3 to the Current Report on Form 8-K filed by the Registrant with the SEC on June 2, 2010).
4.1	Form of Common Stock Certificate.
10.1	Amended and Restated 1994 Stock Incentive Plan, as amended.
10.2.1	Amended and Restated 2006 Omnibus Plan, effective as of May 27, 2010. (Incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant with the SEC on June 2, 2010).
10.2.2	First Amendment to Amended & Restated 2006 Omnibus Plan, effective as of June 11, 2012 (Incorporated herein by reference to Exhibit 4.4 to the Registration Statement on Form S-8 filed by the Registrant with the SEC on November 9, 2012).
10.3	Director Compensation Policy.
10.4	Employment Agreement, dated July 31, 2006, by and between the Registrant and Lode Debrabandere.
10.5	Lease Agreement by and between Gateway S-8, LLLP and Nova Telecommunications, Inc., dated August 11, 1998, as amended.
10.6	Agreement of Lease by and between the Registrant and Columbia Gateway S-28, L.L.C., dated June 6, 2006.
10.7	Asset Purchase Agreement by and between the Registrant and Mesoblast International SARL, dated as of October 10, 2013 (filed herewith).
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 BDO USA, LLP (filed herewith).
31.1.1	Rule 15d-14(a) Certification of Lode Debrabandere, President and Chief Executive Officer (filed herewith).
31.2.1	Rule 15d-14(a) Certification of Philip R. Jacoby, Jr., Chief Financial Officer (filed herewith).
32.1.1	Section 1350 Certification of Lode Debrabandere, Chief Executive Officer, and Philip R. Jacoby, Jr., Chief Financial Officer (filed herewith).
101	*The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013, formatted in Extensible Business Reporting Language (XBRL), include: (i) the Statements of Income, (ii) the Balance Sheets, (iii) the Statements of Cash Flows, and (iv) related notes (furnished herewith).*

Incorporated herein by reference to corresponding Exhibit to the Registrant's Registration Statement on Form S-1, which was declared effective by the SEC on August 3, 2006.

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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 31, 2014 By: /s/ LODE DEBRABANDERE

Lode Debrabandere, Ph.D.
President & Chief Executive Officer

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

/s/ LODE DEBRABANDERE Lode Debrabandere, Ph.D.	President and Chief Executive Officer (principal executive officer)	March 31, 2014
/s/ PHILIP R. JACOBY, JR. Philip R. Jacoby, Jr.	Chief Financial Officer (principal financial officer and performing the function of or similar to that of principal accounting officer)	March 31, 2014
/s/ PETER FRIEDLI Peter Friedli	Director	March 31, 2014
/s/ FELIX GUTZWILLER Felix Gutzwiller M.D., Dr.P.H.	Director	March 31, 2014
/s/ HANS KLINGEMANN Hans Klingemann, M.D., Ph.D.	Director	March 31, 2014
/s/ JAY M. MOYES Jay M. Moyes	Director	March 31, 2014