OSIRIS THERAPEUTICS, INC.

FORM 10-K/A
(Amended Annual Report)

Filed 03/27/17 for the Period Ending 12/31/14

Address	7015 ALBERT EINSTEIN DRIVE COLUMBIA, MD 21046
Telephone	443-545-1819
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Symbol	OSIR
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

Amendment No. 1

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

For the fiscal year ended December 31, 2014

☐ **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 ☐ No ☒

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 ☐ No ☒

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 ☐ No ☒

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 ☐ No ☒

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. ☒

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 ☐	Accelerated filer ☒	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

On June 30, 2014, 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 $303,915,919.

The number of shares of the registrant's Common Stock outstanding as of March 6, 2017 is 34,525,886.

Documents Incorporated by Reference:

Certain sections of the Registrant's definitive proxy statement filed with the Commission on April 30, 2015 in connection with the 2015 Annual Meeting of Stockholders were incorporated by reference into Part III of the Form 10-K originally filed with the Commission on March 20, 2015.

EXPLANATORY NOTE

Osiris Therapeutics, Inc. (the "Company") is filing this amendment (this "Amendment" or "Form 10-K/A") to its Annual Report on Form 10-K for the year ended December 31, 2014, which was originally filed on March 20, 2015 (the "Original Form 10-K" or the "Original Filing"). This Amendment includes restated financial statements for the year ended December 31, 2014. This Amendment also includes restated 2014 interim financial statements in Note 16 (Quarterly Financial Data (Unaudited)) to the financial statements in Part II, Item 8 of this Form 10-K/A.

The corrections contained in these restated financial statements, which we refer to herein as the "Restatement," were prepared following an independent review by the Audit Committee (the "Audit Committee") of the Company's Board of Directors into certain accounting matters, which is further described herein.

Background

As previously described in the Company's Current Report on Form 8-K filed on March 15, 2016, the Audit Committee, in consultation with management, concluded that the Company's unaudited interim and audited annual financial statements previously issued for 2014 and its unaudited interim financial statements previously issued for the three and nine months ended September 30, 2015 should not be relied upon due to errors identified in such financial statements related to the timing of revenue recognition under contracts with distributors. In the Company's Current Report on Form 8-K filed on November 20, 2015, the Company previously disclosed its conclusion that its unaudited interim financial statements for the quarters ended March 31, 2015 and June 30, 2015 should not be relied upon for similar reasons.

The previously issued financial statements that should not be relied upon were included in the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014, the Original Form 10-K and its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015, June 30, 2015 and September 30, 2015 (the "Non-Reliance Periods").

As previously described in the Company's Current Report on Form 8-K filed on December 17, 2015, the Company's independent registered public accounting firm BDO USA, LLP ("BDO") resigned and the Company has selected Ernst & Young LLP as its independent registered public accounting firm for the fiscal year ended December 31, 2015, subject to completion of its standard client acceptance procedures, which are still ongoing. Notwithstanding the resignation, BDO has continued to work with the Company to complete its audit of the financial statements contained in Part II, Item 8 of this Form 10-K/A.

At the request of BDO, the Audit Committee commenced an independent review into these matters with the assistance of outside professionals engaged by the Audit Committee (the "Independent Review").

The scope of the Independent Review, which was determined by the Audit Committee after discussion with BDO and outside professionals engaged by the Audit Committee, focused primarily on revenue recognition related to distributor sales arrangements. In conjunction with the Independent Review, the Audit Committee reviewed these matters and determined that errors and irregularities existed in the Company's previously issued financial statements with respect to the Non-Reliance Periods, which as to the 2014 financial statements are described in more detail below. The Audit Committee also determined, in consultation with management, that certain material weaknesses in internal control over financial reporting existed at December 31, 2014. These material weaknesses are described below under "—Controls and Procedures" and in Part II, Item 9A of this Form 10-K/A. In reaching these conclusions, the Audit Committee considered information derived from the Independent Review, as well as procedures and other work performed by management.

The Audit Committee determined that errors and irregularities in the Company's previous accounting in 2014 occurred on the basis of, among other things:

1. with respect to sales transactions with two distributors that were affiliated with each other, the existence of extra-contractual or undocumented terms or arrangements initiated by former executives of the Company at the onset of the transactions and concessions agreed to by former executives of the Company subsequent to the initial transaction, such as unusually long payment terms. The existence of unusually long payment terms caused the related sales transactions to fail the "fixed and determinable" criteria required under generally accepted accounting principles in the United States ("GAAP") to recognize revenue; and

2. for one sales transaction to a third distributor previously recorded in the fourth quarter of 2014, the existence of evidence indicating the former chief financial officer of the Company created a document subsequent to filing of the Original Form 10-K. The evidence suggests that an arrangement with the distributor did not exist in 2014 so that the criteria required under GAAP to recognize revenue for this transaction in 2014 was not met.

In the Restatement, the Company will reverse revenue previously recorded in 2014 for these sales transactions with the three distributors and will thereafter recognize revenue from these transactions under the cash, rather than accrual, basis of accounting, which means that revenue arising from these transactions will be recognized in subsequent periods upon receipt of payment from the customer.

The Company assessed the information derived from the Independent Review in making determinations with respect to accounting adjustments reflected in the restated financial statements contained in this Form 10-K/A, and such determinations are consistent with the findings of the Independent Review. Certain other adjustments identified by management, including correction of errors in the valuation of inventory, accounting for consigned inventory quantities, determination of bad debt reserve and the classification of costs and expenses, were made to the financial statements in connection with the Restatement. These adjustments are described below under "—Description of the Restatement."

The Audit Committee, at the request of management and as part of the Independent Review, also evaluated certain issues related to director expense reimbursements. On the basis of that review, the Audit Committee determined that certain requests for reimbursement submitted between 2012 and 2015 by the Company's Chairman of the Board to the Company's former chief financial officer should not have been paid to him. In December 2016, the Chairman returned to the Company the full amount that the Audit Committee determined should not have been paid to him. See Note 10 (Related Party Transactions and Warrant) to the Company's financial statements in Part II, Item 8 of this Form 10-K/A for further details.

Description of the Restatement

The primary errors corrected by the Restatement include the errors determined in the Independent Review and management's internal review, and are as follows:

Recognition of revenue under distributor sales arrangements . Based on the Independent Review, the Company determined that it had erred in its application of GAAP with respect to the recognition of revenue arising from certain distributor sales arrangements as described below:

1. Certain distributor sales did not meet the criteria for recognizing revenue in 2014 . During 2014, the Company provided unusually long payment terms to two distributors that were affiliated with each other. Granting a customer unusually long payment terms can cause the related sales transactions to fail the "fixed and determinable" criteria required under GAAP to recognize revenue. Also, for one sales transaction to a third distributor in the fourth quarter of 2014, the Company determined that evidence existed which suggests that an arrangement under GAAP did not exist in 2014. Accordingly, revenue arising from these transactions did not meet the criteria for recognizing revenue under GAAP in 2014. Correction of these errors decreased 2014 revenue by $10.3 million and decreased trade accounts receivable as of December 31, 2014 by a like amount. Net of product costs and sales commission expenses arising from these transactions, correction of these errors decreased 2014 net income by $5.6 million. Under GAAP, the $10.3 million revenue reversed in 2014 may be recognized in a future period on an accrual basis upon meeting the criteria for revenue recognition or, if such criteria is not met, on a cash basis, upon receipt of payment from the customer.

2. Sales through government contracting agent. The Company utilizes a government contracting agent through which it sells to facilities of the United States Department of Veterans Affairs and the United States Department of Defense under the agent's GSA Federal Supply Schedule. The Company erred in reporting revenue from such sales net of the agent's fees, although GAAP (and the Company's policy) requires that revenue arising from contractual arrangements of this type be reported at the gross price paid by the end user, and that the related fees be reported as a sales expense. Correction of this error, with respect to these sales, increased both 2014 sales and marketing expenses and product revenue by $1.5 million and, accordingly, had no impact on net income.

Taken together, correction of the errors arising from these two types of distributor sales arrangements decreased 2014 product revenue by $8.8 million (consisting of a $10.3 million decrease described in paragraph (1) above offset by a $1.5 million increase described in paragraph (2) above). In addition, the Company corrected other revenue accounting errors unrelated to distributor sales arrangements which decreased 2014 product revenue by an additional $241,000. As a result, the correction of errors in the Restatement decreased 2014 product revenue by a total of $9.0 million.

Consistent with corrections in the Company's recognition revenue, the product costs arising from the distributor sales transactions for which revenue has been reversed have also been reversed and added back to inventory. As a result of such corrections, inventory as of December 31, 2014 increased by $852,000 and the cost of product revenue for the year then

ended decreased by the same amount. Similarly, sales commission expenses incurred during 2014 in connection with the distributor sales transactions for which revenue has been reversed have also been reversed. As a result of such corrections, prepaid expenses increased by $2.2 million, with respect to such expenses paid during 2014, and accrued expenses decreased by $1.5 million, with respect to commissions unpaid and accrued as of December 31, 2014, while 2014 sales and marketing expenses decreased by $3.8 million.

Valuation of inventory and accounting for consigned inventory quantities . Management determined that there were errors in the valuation of the Company's finished goods inventory resulting from computational errors, failure to update and apply current cost information in the calculation of unit costs, and non-timely identification and write-off of products that were no longer salable as determined by the Company's quality assurance procedures. In addition, management determined the need to establish a reserve for consigned finished goods inventory as the Company had not adequately monitored the ultimate disposition of consigned goods whereby some were returned, or scrapped, or used by the consignee. Lastly, management determined the need to establish a reserve for work-in-process inventory which largely consists of product in quarantine pending the outcome of the Company's quality assurance procedures. This process results in a reasonably consistent identification of product that is unsalable. Correction of these errors, to write-down the value of inventory as of December 31, 2014, increased 2014 cost of product revenue and decreased 2014 net income by $2.0 million.

Bad debt reserve . Management determined that it did not correctly assess the collectability of accounts receivable and determined an appropriate allowance for doubtful accounts as of December 31, 2014. Correction of this error, by increasing its 2014 bad debt expenses and allowance for doubtful accounts as of December 31, 2014, increased the Company's 2014 general and administrative expenses by $450,000 and reduced its accounts receivables as of December 31, 2014 by the same amount.

Classification of costs and expenses to income statement captions . Management determined that errors had been made in classification of costs and expenses to income statement captions. Correction of these errors reduced 2014 cost of product revenue and research and development expenses by $4.1 million and $3.6 million, respectively, and increased sales and marketing and general and administrative expenses by $7.6 million and $134,000, respectively.

Other adjustments. In addition to the errors mentioned above, adjustments were made to the 2014 financial statements for various other errors identified by management and the Audit Committee during the course of the restatement process. The net impact of such adjustments was to decrease net income by $507,000 for the year ended December 31, 2014. See Note 2 (Restatement of the Financial Statements) to the Company's financial statements included in Part II, Item 8 of this Form 10-K/A for further details.

Tax effect of Restatement adjustments. The Company reduced 2014 income tax expense by $585,000 to account for the impact of the adjustments in the Restatement described above.

In the aggregate, the Restatement decreased revenue and net income for 2014 by $9.0 million and $8.2 million, respectively. The revenue decrease arises from a $10.3 million reversal of revenue resulting from the Company's failure to meet criteria for recognizing revenue under GAAP, offset by a $1.5 million increase in revenue required to recognize the gross end-user sales value of the product sold through the Company's government contracting agent. GAAP requires the recognition of revenue when the customer payment is received if unusually long payment terms are offered. Customer payments aggregating $8.1 million and $1.2 million were received in 2015 and 2016, respectively, on distributor sales transactions for which revenue was reversed in 2014, which will be recognized as revenue in the year payment was received. In addition, the Company corrected other revenue accounting errors unrelated to distributor sales arrangements which decreased 2014 product revenue by $241,000. See Note 2 (Restatement of the Financial Statements) to the Company's financial statements included in Part II, Item 8 of this Form 10-K/A for further details.

Revision of Prior Period Financial Statements

In addition to the correction of the errors in 2014 in the Restatement, the Company also voluntarily corrected certain immaterial errors in its financial statements for the years ended December 31, 2013, 2012 and 2011 contained herein. The adjustments to correct immaterial errors only had an impact on certain captions within the Company's statements of comprehensive (loss) income and balance sheets as set forth below.

(in thousands)	For year ended December 31, 2013 Net Income Impact	2013 Stockholders' Equity Impact	2012 Net Income Impact	2012 Stockholders' Equity Impact	2011 Net Income Impact	2011 Stockholders' Equity Impact
Revenue Recognition						
Product revenue	$ 1,390	$ —	$ (685)	$ —	$ (262)	$ —
Cost of product revenue	(195)	—	131	—	64	—
Sales and marketing expenses	(443)	—	—	—	—	—
Deferred revenue	—	947	—	(685)	—	(262)
Inventory	—	(195)	—	131	—	64
Directors' Expenses						
Other receivables	—	70	—	34	—	—
Fees paid to related parties	70	—	34	—	—	—
Tax Effect of the Adjustments						
Income taxes benefit	(332)	—	—	—	—	—
Income from discontinued operations	332	—	—	—	—	—
Net increase/(decrease)	**$ 822**	**$ 822**	**$ (520)**	**$ (520)**	**$ (198)**	**$ (198)**

See "Revision of Prior Period Financial Restatements" in Note 2 (Restatement of the Financial Statements) to the Company's financial statements included in Part II, Item 8 of this Form 10-K/A for further details on these adjustments to periods prior to 2014. See also Note 10 (Related Party Transactions and Warrant) to the Company's financial statements for more details on the director's expenses adjustment.

Controls and Procedures

As previously disclosed in the Company's Currrent Report Form 8-K filed on November 20, 2015 and the Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, the Company identified a control deficiency related to revenue recognition under distributor sales arrangements that constituted a material weakness in its internal control over financial reporting. Management also identified other material weaknesses in its internal control over financial reporting as of December 31, 2014, which were not previously disclosed. As a result of the material weaknesses, management has concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2014. The Company has implemented and continues to implement measures to remediate these material weaknesses. See Part II, Item 9A, "Controls and Procedures" of this Form 10-K/A for more information about the material weaknesses and our remediation activities.

Items Amended by this Form 10-K/A

Revisions to the Original Filing have been made to the following items to reflect the Restatement and related matters (including legal proceedings and government investigations), the Company's late filings with the Securities and Exchange Commission ("SEC") and the consequences therefrom, including delisting of our common stock from trading on Nasdaq, and to correct other immaterial errors:

- Part I, Item 1A, Risk Factors
- Part I, Item 3, Legal Proceedings
- Part II, Item 6, Selected Financial Data
- Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations
- Part II, Item 8, Financial Statements and Supplementary Data
- Part II, Item 9A, Controls and Procedures
- Part IV, Item 15, Exhibits and Financial Statement Schedules

This Form 10-K/A also amends the Original Filing to restate management's report on internal control over financial reporting and its conclusion on disclosure controls and procedures to address the material weaknesses in internal control over financial reporting. This Form 10-K/A also amends the Original Filing to provide an amended opinion of BDO on the effectiveness of the Company's internal control over financial reporting as of December 31, 2014.

Subsequent to filing of the Original Form 10-K, the former chief executive officer and former chief financial officer left the Company. In accordance with applicable SEC rules, this Form 10-K/A includes certifications from our current chief executive officer and current chief financial officer dated as of the date of this filing.

The errors corrected by the Restatement are further discussed in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in Note 2 (Restatement of the Financial Statements) to the Company's financial statements included in Part II, Item 8 of this Form 10-K/A.

Other than this Form 10-K/A, we do not intend to file any other amended reports in connection with the restatement of the annual and interim 2014 financial statements. All of our future Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q will reflect the restated information included in this Form 10-K/A. We expect to file a Form 10-K for the year ended December 31, 2015 as soon as practicable after the date hereof, which is expected to include restated financial statements for the interim periods in 2015.

Other than with respect to matters related to the Restatement and related matters (including legal proceedings, government investigations and subsequent events), the Company's late filings with the SEC and the consequences therefrom and to correct other immaterial errors, this Amendment generally does not reflect events that have occurred after March 20, 2015, the filing date of the Original Form 10-K, or modify or update the disclosures presented in the Original Form 10-K, except to reflect the effects of such matters. Accordingly, this Amendment should be read in conjunction with the Company's Current Reports on Form 8-K filed with the SEC since March 20, 2015 and with respect to all of the Company's filings after the date hereof, including the Company's Form 10-K for 2015 which will be filed as soon as practicable after the date hereof.

OSIRIS THERAPEUTICS, INC.
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CAUTIONARY STATEMENTS ABOUT FORWARD-LOOKING INFORMATION

This Form 10-K/A includes "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Statements included or incorporated herein which are not historical facts are forward looking statements. When used in this Form 10-K/A, the words "estimates", "expects", "anticipates", "projects", "plans", "intends", "believes", "forecasts", "will" 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 SEC. Examples of forward-looking statements may include, without limitation, statements regarding any of the following: risks relating to the Audit Committee's Independent Review, the Company's related ongoing work, and the Restatement and related legal proceedings; the Company's ability to recognize revenue reversed in 2014 in subsequent periods; our previous and current non-compliance with certain Nasdaq Stock Market LLC ("Nasdaq") listing rules, and related pending proceedings in connection therewith; the outcome of pending legal proceedings and government investigations; our product development efforts; our clinical trials and anticipated regulatory requirements, and our ability to successfully navigate these requirements; the success of our product candidates in development; status of the regulatory process for our products and product candidates; implementation of our corporate strategy; our financial performance; our product research and development ("R&D") activities and projected expenditures, including our anticipated timeline and commercialization strategy for our marketed products (including Grafix®, BIO $^{4\text{™}}$ and Cartiform®) and our products under development; our cash needs; patents, trademarks and other proprietary rights; the safety and ability of our products to 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, future products to meet demand; our ability to commercialize and distribute our current and any future marketed products; our relationships with collaborating partners; our ability to maintain and benefit from our collaborative arrangements; 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, and the ability of our customers and end users to obtain, reimbursement for our commercially available products from Medicare and other third-party payors; 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 are made only as of March 20, 2015, the date on which the Original Form 10-K was filed, unless it is specifically otherwise stated to be made as of a different date, or refers to matters related to the Restatement (including consequences of the Company's delay in filing its Annual Report on Form 10-K for the year ended December 31, 2015 and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016, June 30, 2016 and September 30, 2016) and are expressly qualified in their entirety by the cautionary statements included herein. Except as otherwise required by law, 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.

PART I

ITEM 1A. Risk Factors.

We are subject to numerous risks and uncertainties in the course of our business. In addition to the other information contained in this report and the exhibits hereto, you should carefully consider the risks and uncertainties described below as. These risks are not the only ones that we may face. Additional risks not presently known to us or that we currently consider immaterial may also impair our business operations. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below or elsewhere in this report.

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 in the future. As of December 31, 2014, we had an accumulated deficit of $211.6 million. These losses resulted principally from costs incurred in our R&D 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:

- complete our confirmatory Phase III quality random clinical trial with Grafix® for complex diabetic foot wounds with exposed tendon or bone;
- continue other studies and initiate and pursue additional studies and possible clinical trials for our Biosurgery products, including Grafix® for venous leg ulcers, which we have begun, 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 U.S. Food and Drug Administration ("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 risks affecting our business.

We rely upon third parties for certain aspects of our business, including collaboration partners, wholesale distributors, contract clinical trial providers, contract 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. 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 which could harm our business and might significantly delay or prevent the achievement of research, development or business objectives.

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;
- ethical controversies that may arise regarding the use of human tissue of any kind, including tissues derived from deceased donors, 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, which could have 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®, Cartiform® and BIO $^{4™}$ 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 our customers to obtain adequate reimbursement from third-party payors for our products and the procedures in which they are used, particularly if we cannot demonstrate a favorable cost-benefit relationship. Third-party payors may also deny coverage 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 from that for BIO $^{4™}$ —which we expect to be used more often in an in-patient hospital setting as part of a surgical procedure.

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. Payors' reimbursement policies also are subject to change, and the policies in effect at the time a product is marketed may be different from the policies in place when a reimbursement strategy was developed.

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, or they may not provide reimbursement for our products separately from the procedures in which they are used to encourage providers to select products based on cost-effectiveness. Cost-control initiatives could decrease the price for products that we may develop, which would result in lower product revenue to us.

We and our distributor sales representatives must comply with U.S. federal and state fraud and abuse laws, including anti-kickback and false claims laws and equivalent foreign rules.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors or third-party distributors may engage in fraudulent or other illegal activity. Misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that

violates FDA regulations, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete and accurate reporting of financial information or data, other commercial or regulatory laws or requirements and equivalent foreign rules. We have policies and procedures intended to prohibit and deter such conduct, including, a Code of Ethics for Interactions with Healthcare Professionals, a Code of Conduct, an Anticorruption Policy, and a Whistleblower Policy, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws. Our relationships and our distributors' relationships with physicians, other healthcare professionals and hospitals are subject to scrutiny under these laws.

Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs. There can be both criminal and civil penalties for violations;

- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting a false or fictitious or fraudulent claim to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created federal criminal laws that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program including private third-party payors;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually (with certain exceptions) to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" to such physician owners;

- the federal Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions, which generally prohibit companies and their intermediaries from making improper payments to government officials and/or other persons for the purpose of obtaining or retaining business; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug and device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Violations of any of the laws described above or any other governmental regulations are punishable by significant civil, criminal and administrative penalties, damages, fines and exclusion from government-funded healthcare programs, such as Medicare and Medicaid. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

We are in a highly competitive and evolving field and face competition from well-established tissue processors and medical device manufacturers, as well as new market entrants.

Our business is in a very competitive and evolving field. Competition from other tissue processors, medical device companies and from research and academic institutions is intense, expected to increase, subject to rapid change and could be significantly affected by new product introductions. The presence of this competition in our market may lead to pricing pressure, which would make it more difficult to sell our products at a price that will make us profitable or prevent us from selling our products at all. Our success will depend on our ability to perfect and protect our intellectual property rights related to our technologies as well as to develop new technologies and new applications for our technologies. Our failure to compete effectively would have a material and adverse effect on our business, results of operations and financial condition.

Rapid technological change could cause our products to become obsolete.

The technologies underlying our products are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop services, products or processes with significant advantages over the products, services and processes that we offer or are seeking to develop. Any such occurrence could have a material and adverse effect on our business, results of operations and financial condition.

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® is processed from human placental tissue. BIO $^{4\text{™}}$ 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 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, (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 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 R&D 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 or commercialized 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;
- the ability of a collaborator to successfully market and promote our products;
- 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.

Our most significant collaborative arrangement is with a subsidiary of Stryker Corporation, and our success may depend upon performance on the part of Stryker and the success of this collaboration. We are also dependent upon our exclusive partnership with Arthrex, Inc. for the commercial distribution of Cartiform®, and may enter into and become dependent upon additional collaborations in the future.

We are party to an Exclusive Service Agreement with Howmedica Osteonics Corp., also referred to as Stryker Orthopaedics, a subsidiary of Stryker Corporation ("Stryker"), for the commercialization of our viable bone matrix allograft under the name BIO $^{4™}$. Pursuant to the agreement, Stryker is the exclusive worldwide marketer and promoter of allograft services for BIO $^{4™}$ for use in surgical applications, including spine, trauma, extremity, cranial, and foot and ankle surgery. This collaboration is subject to all of the risks and uncertainties applicable to collaborative arrangements generally, including those described above. In addition, this collaboration is subject to a number of risks and uncertainties specific to the transaction and the parties.

The agreement with Stryker provides for an initial four-year exclusive term, commencing in 2015. The term may be extended by Stryker for an additional exclusive period of four years or an additional non-exclusive period of two years. If Stryker extends the term on an exclusive basis, it has the option to further extend the term on an exclusive basis for two years. Osiris received an initial exclusivity fee of $5.0 million and is entitled to receive additional fees upon any exercise by Stryker of its right to extend the initial term, whether on an exclusive or non-exclusive basis. These additional fees are reduced on a sliding scale if Stryker meets certain revenue thresholds during the initial term, or if revenue goals are not met as a result of Osiris not fulfilling its supply obligations. Stryker is entitled to a certain percentage of sales of allograft services for BIO $^{4™}$ and has limited early termination rights. The success of this collaboration for us will in part be dependent upon Stryker, including its success in marketing and promoting BIO $^{4™}$.

Stryker has significantly greater resources that we do, and this collaboration is not as core to its business as it is to ours. We are dependent upon Stryker's continued performance under this collaboration, and any determination by Stryker not to proceed or perform, or any material adverse event that affects Stryker's ability or desire to perform may have a material adverse effect on our business.

We are also dependent upon Arthrex, Inc. ("Arthrex") for the commercial distribution of Cartiform®. We have granted Arthrex exclusive commercial distribution rights for Cartiform®, and any determination by Arthrex not to proceed or perform, or any material adverse event that affects Arthrex's ability or desire to perform may have a material adverse effect on our business.

We may also enter into additional collaborations in the future. If we fail to maintain our existing or any future collaborative relationships for any reason, we would need to undertake on our own and at our own expense, or find other collaborators, to perform the activities we currently anticipate will be performed by our collaborators. This may substantially increase our cash requirements. We may not have the capability or financial capacity to undertake these activities on our own, or we may not be able to find other collaborators on acceptable terms, or at all. This may limit the programs we are able to pursue and result in significant delays in the development, sale and manufacture of our products, and may have a material adverse effect on our business.

We distribute products through distribution arrangements that sometimes involve the consignment of inventory to third parties, which results in additional risk and uncertainty as to the viability of consigned inventory and as to inventory accounting.

We have historically distributed our Biosurgery products either ourselves or through third-party distributors who sometimes take possession of our inventory on a consignment basis, or through a combination of both methods. In some situations, we store consigned inventory on site in freezers at hospital or clinic facilities. We commercialize Grafix® through the efforts of our own focused direct distribution and marketing staff, as well as through a network of specialty distributors for certain target markets. Like Ovation®, BIO $^{4™}$ (formerly branded as OvationOS®) will sometimes be commercialized through a consignment arrangement, and our agreement with Stryker includes consignment terms, as does our agreement with Arthrex for Cartiform®. Because our consigned inventory must be stored at –80° C, it is at risk of thawing, resulting in the loss of that inventory. That risk of loss of is borne by us, although we believe that we maintain adequate insurance to cover the risk. Inventory management is complicated by a consignment arrangement, as is revenue recognition and inventory and receivables accounting. Thus, for example, no revenue is recognized upon the placement of inventory into consignment, as we retain title and maintain the inventory on our balance sheet. For these products, revenue is recognized when we receive appropriate notification that the product has been used in a surgical procedure. The Restatement corrects, among other things, errors in our prior revenue recognition related to various distributor agreements, including several with consigned inventory. If we are unable to track and maintain proper controls related to consigned inventory, we could experience difficulty in accurately managing and accounting for these consignment arrangements.

We monitor and verify the condition and status of all consigned inventory on at least a quarterly basis, at additional expense to us. As a result of the Restatement, we will likely incur additional expenses in connection with our planned improvements in our controls related to consigned inventory. In addition, FDA, The American Association of Tissue Banks and other accrediting agency rules, regulations or standards require that we monitor our consigned inventory, and require tracking of human tissue and inventory as it moves through the supply chain. Moreover, as is the case with all of our inventory, should the FDA or any other regulatory authority determine that we are unable for any reason to continue to distribute consigned inventory, either on account of the viability of that inventory or because of the withdrawal of necessary approvals or other qualifications allowing for the distribution and sale of that inventory, the value of that inventory may have to be written off and our balance sheet adjusted accordingly. The complexity of our inventory management, or the application

of rules, regulations and standards to our product inventory, or the occurrence of any of these negative events, could have an adverse effect on our business, financial condition and results of operations.

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 FDA Current Good Manufacturing Practice ("cGMP") regulations. 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.

Our dependence on third parties 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 a material adverse 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 suppliers, distributors and other third parties with which we contract are subject to many or all of the risks and uncertainties that we are subject to. 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 with these regulations and standards by our suppliers, distributors and other third parties with which we contract. They might not be able to comply with these regulatory requirements. If they fail to comply with applicable regulations, the FDA or other regulatory authorities could impose sanctions on us, including fines, injunctions, civil penalties, denial of any required marketing approval, 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 the supply of our products and could have a material adverse effect on our business, financial condition and results of operations.

If our processing and storage facility is 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 $22.8 million against damage to our property and equipment, an additional $5.0 million to cover business interruption and extra expenses and $7.3 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, legal 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 therapies and technologies. Competitors competing with our Biosurgery products include, but are not limited to: Organogenesis, the manufacturer of Apligraf® and Dermagraft®, and MiMedx, the manufacturer of EpiFix® which competes with Grafix®. BIO ^{4}™ competes with bone tissue products such as Osteocel® and Trinity®, while Cartiform® competes with cartilage allografts. In addition to those listed above, we have other existing and 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 cellular regenerative 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 R&D 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.

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 is 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:

- continue to develop, expand and support our distribution network of third-party distributors and independent sales professionals for the distribution of Grafix®, BIO $^{4™}$ and other Biosurgery products;
- continue to expand and support 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, 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.

To be commercially successful, we must convince physicians that our products are safe and effective alternatives to existing treatments and that our products should be used in their procedures.

We believe physicians will only adopt our products if they determine, based on experience, clinical data and published peer reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to conventional methods. Physicians may be slow to change their medical treatment practices for the following reasons, among others:

- their lack of experience with prior procedures in the field using our products;
- lack of evidence supporting additional patient benefits and our products over conventional methods;
- perceived liability risks generally associated with the use of new products and procedures;
- limited availability of reimbursement from third-party payers; and
- the time that must be dedicated to training.

In addition, hospital acquisition decisions often are affected by physicians' assessments of products. If physicians do not support adoption of our products or if we are unable to demonstrate favorable long-term clinical data, hospitals may not use our products, which would significantly reduce our ability to achieve expected revenue and would prevent us from sustaining profitability.

We may implement a product recall or voluntary market withdrawal, which could significantly increase our costs, damage our reputation and disrupt our business.

The manufacturing, marketing and processing of our tissue products involves an inherent risk that our tissue products or processes do not meet applicable quality standards and requirements. In that event, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority. A recall or market withdrawal of one of our products would be costly and would divert management resources. A recall or withdrawal of one of our products, or a similar product processed by another entity, also could impair sales of our products as a result of confusion concerning the scope of the recall or withdrawal, or as a result of the damage to our reputation for quality and safety.

Significant disruptions of information technology systems or breaches of information security could adversely affect our business.

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we have invested significantly in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they could use to trade in our securities.

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 allograft for the treatment of acute and chronic wounds, including diabetic foot ulcers, does not require pre-marketing approval by the FDA because we believe that this product meets the regulatory definition of human cells, tissues and cellular and tissue-based products, or so-called 361 HCT/Ps (meaning that they comply with section 361 of the Public Health Service Act (PHSA) and with 21 CFR Part 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 allergenic 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 allograft 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® (rebranded by Stryker as BIO $^{4™}$ in 2015) by no later than the second half of 2014, which we did. In August 2014, we stopped distributing promotional materials for Ovation® and ceased manufacturing the product. In October 2014, we stopped shipping Ovation® from our Columbia, MD facilities. At December 31, 2014, we owned some units of Ovation® located in the field for use in procedures by the end users. We believe that commercial distribution of BIO $^{4™}$, a viable bone matrix for bone growth, and Cartiform®, a viable chondral allograft, does not require pre-marketing approval by the FDA because we believe that these products meet the regulatory definition of HCT/Ps.

We engage in ongoing discussion and communication with FDA representatives regarding the applicable regulatory requirements and pathways for our products and product candidates. The analysis and determination of compliance of a

product with these regulatory requirements and pathways is complex and dependent upon numerous factors, and is readily subject to varying interpretations and conclusions. The FDA may not agree with our views on these matters. Should the FDA decide that Grafix®, BIO $^{4™}$ 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 require clinical trials and could take years to obtain, at significant expense. This or any other determination by the FDA that adversely affects our ability to produce or to market any of our products or product candidates would have a material adverse effect on our business, financial condition and results of operations.

Our ability to expand the marketing claims for Grafix® and BIO $^{4™}$ 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. 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 section 361 of the PHSA and 21 CFR Part 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 R&D, financial resources and personnel to obtain the necessary regulatory approvals, if required.

For the current label indications, for Grafix® and BIO $^{4™}$, we rely upon the exception to the BLA requirement afforded 361 HCT/Ps. However, compliance with these requirements limits our activities with 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 1271.3(f). These and other limitations applicable to HCT/Ps limit the uses 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. In addition, later discovery of previously unknown problems with a product, a manufacturer or a 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 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 are currently pursuing and in the future 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, Current 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 revenue.

Tissue-based products are regulated differently in different countries. We believe that commercial distribution of Grafix® as a wound allograft for the treatment of acute and chronic wounds, including diabetic foot ulcers, and the commercial distribution of BIO $^{4\text{™}}$, a viable bone matrix for bone 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 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, either to enhance our ability to successfully market these products, or because 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 is a requirement in order to become a licensed tissue bank. In addition, some states have their own tissue banking regulations. We are licensed 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 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 business, financial condition and 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 and 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 R&D activities. In the United States, these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. We cannot assure you that accidental contamination or injury to our employees and third parties from hazardous materials will not occur. We do not have insurance to cover claims arising from our use and disposal of these hazardous substances other than limited clean-up expense coverage for environmental contamination due to an otherwise insured peril, such as fire.

We face significant uncertainty in the industry due to Government healthcare reform.

There have been and continue to be proposals by the Federal Government, State Governments, regulators and third-party payers to control healthcare costs, and generally, to reform the healthcare system in the United States. There are many programs and requirements for which the details have not yet been fully established or the consequences are not fully understood. These proposals may affect aspects of our business. We also cannot predict what further reform proposals, if any, will be adopted, when they will be adopted, or what impact they may have on us.

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 or confidential know-how. In an effort to protect this proprietary information, 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 trade secrets or confidential information, and these agreements may be breached. For example, a portion of the processing methodology and know-how for Grafix® is protected by trade secret or through

confidentiality arrangements. 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 or know-how.

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 revenue 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 or know-how 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 United States 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. Even if we hold patents or have patent rights through licenses or otherwise with respect to a particular product, third parties may challenge, narrow, invalidate, design around or circumvent any patents now or hereafter owned, assigned or licensed to us. Patents with broader 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.

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 or proprietary know-how. In an effort to protect these trade secrets and know-how, 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 or know-how 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 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 United States 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; be early entrants to the market; and 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 Asset Purchase Agreement (the "Purchase Agreement") with Mesoblast International SARL ("Mesoblast"), a wholly owned subsidiary of Mesoblast Limited ("Mesoblast Limited"), for the sale of our culture-expanded mesenchymal stem cell ("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 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.

We have received all of the $50 million in initial consideration, consisting of $35 million in cash and $15 million in Mesoblast Limited ordinary shares. The shares received were subject to a one-year holding period that initially ended in December 2014 and was ultimately extended through May 2015. Mesoblast Limited provided the Company limited downside protection against a decline in the market value of these shares during this holding period. The Mesoblast Limited shares are classified as Trading Securities in the Company's balance sheets as of December 31, 2014 and 2013 and accounted for on a marked-to-market basis. In May 2015 Mesoblast Limited paid the Company $6.2 million upon expiration of the limited downside market value protection provided during the designated holding period. Later in 2015 the Company sold all of its Mesoblast Limited shares for $6.5 million.

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 Limited ordinary shares, based on a then current valuation of such shares.

Any portion of the second $50 million in consideration paid in Mesoblast Limited ordinary shares will also be, is subject to a one year holding period, with limited downside protection for a drop in the Mesoblast Limited share price over the holding period. Therefore, any such payment, if made, will be are subject to investment risk, and because the Mesoblast Limited ordinary shares are traded on the Australian Stock Exchange and the per share price is denominated in Australian Dollars, will also be subject to foreign currency exchange risk.

Accordingly, not only do we have no assurances that any of the second $50 million in consideration will ever be paid to or received by us, but also we may be unable to liquidate on favorable terms any amounts paid to us in Mesoblast Limited ordinary shares. As a result, we may 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.

Risks Related to Our Common Stock

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

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

- our recent suspension from trading and upcoming delisting of our common stock from Nasdaq;
- loss of investor confidence in us due to the Restatement, the delisting and related matters;
- the lack of a trading market in our common stock as a result of not trading on Nasdaq;
- the recent changes in our senior management team, and any delays or difficulties in identifying permanent members of the team to replace interim officers;
- 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.

As a result of the Restatement and our failure to file SEC reports, we have not been in compliance with Nasdaq Stock Market LLC's requirements for continued listing and, as a result, our common stock was suspended from trading on Nasdaq on March 14, 2017, which could have a material effect on us and our stockholders. We expect that our common stock will be delisted from Nasdaq promptly after Nasdaq files a Form 25 with the SEC. See "We have not been in compliance with Nasdaq Stock Market LLC's requirements for continued listing and, as a result, our common stock has been suspended from trading on Nasdaq, which we expect to have a material effect on us and our stockholders."

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 to 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:

- authorization of the board of directors to issue shares of preferred stock generally without stockholder approval;
- 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 Exchange Act, and with at least three independent directors to elect to be subject to any or all of five provisions:

- a two-thirds vote requirement to remove a director;
- 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, 2015. 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, 2015. 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.

Risks Related to the Restatement of our Financial Statements

We have restated our prior financial statements, which may lead to additional risks and uncertainties, including loss of investor confidence and negative impacts on our stock price.

As discussed in the Explanatory Note and Note 2 to the Company's financial statements included in Part II, Item 8 of this Form 10-K/A, we have restated our audited financial statements for the year ended December 31, 2014, and our unaudited financial statements for all interim periods in 2014 (the "Restated Periods"). The determination to restate the financial statements for the Restated Periods was made by our Audit Committee upon management's recommendation to address discovered errors. Due to the errors, our Audit Committee concluded that our previously issued financial statements for the Restated Periods should no longer be relied upon. We have filed this Form 10-K/A to, among other things, reflect the restatement of our financial statements for the Restated Periods.

As a result of these events, we have become subject to a number of additional costs and risks, including unanticipated costs for accounting and legal fees in connection with or related to the Restatement and the remediation of our ineffective disclosure controls and procedures and material weakness in internal control over financial reporting. In addition, the attention of our management team has been diverted by these efforts. We are subject to shareholder, governmental and other actions in connection with the Restatement and related matters. In addition, the Restatement and related matters could impair our reputation or could cause our counterparties to lose confidence in us. Each of these occurrences could have a material adverse effect on our business, financial condition, results of operations and stock price.

Our management has identified material weaknesses in the Company's internal control over financial reporting which could, if not remediated, result in additional material misstatements in our consolidated financial statements. We may be unable to develop, implement and maintain appropriate controls in future periods.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, and the Sarbanes-Oxley Act of 2002 and SEC rules require that our management report annually on the effectiveness of the Company's internal control over financial reporting. Among other things, our management must conduct an assessment of the Company's internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to audit, the effectiveness of the Company's internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. As disclosed in Part II, Item 9A, "Controls and Procedures" of this Form 10-K/A, our management, with the participation of our current president and chief executive officer and our current chief financial officer, has determined that we have material weaknesses in the Company's internal control over financial reporting as of December 31, 2014 related to the Company's control environment and specific control activities. Some of these material weaknesses contributed to the material misstatements in our previously filed annual audited and interim unaudited consolidated financial statements.

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 our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. We are actively engaged in developing and implementing a remediation plan designed to address such material weaknesses. However, additional material weaknesses in the Company's internal control over financial reporting may be identified in the future. Any failure to implement or maintain required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses, or could result in material misstatements in our consolidated financial statements. These misstatements could result in a further restatement of our consolidated financial statements, cause us to fail to meet our reporting obligations, reduce our ability to obtain financing or cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

Although we are working to remedy the ineffectiveness of the Company's internal control over financial reporting, there can be no assurance as to when the remediation plan will be fully developed, when it will be fully implemented or the aggregate cost of implementation. Until our remediation plan is fully implemented, our management will continue to devote significant time and attention to these efforts. If we do not complete our remediation in a timely fashion, or at all, or if our remediation plan is inadequate, there will continue to be an increased risk that we will be unable to timely file future periodic reports with the SEC and that our future consolidated financial statements could contain errors that will be undetected. Further and continued determinations that there are material weaknesses in the effectiveness of the Company's internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain and require additional expenditures of both money and our management's time to comply with applicable

requirements. For more information relating to the Company's internal control over financial reporting, the material weaknesses that existed as of December 31, 2014 and the remediation activities undertaken by us, see Part II, Item 9A, "Controls and Procedures" of this Form 10-K/A.

We and certain of our current and former directors and executive officers have been named as defendants in litigation actions that could result in substantial costs and divert management's attention.

We are currently party to legal and other proceedings which are described under Part II, Item 3, "Legal Proceedings", of this Form 10-K/A. We, and certain of our executive officers, have been named as defendants in purported class action lawsuits that allege, among other things, that the defendants made materially false or misleading statements and material omissions in the Company's SEC filings in violations of federal securities laws. Further, shareholder derivative complaints have been filed in Maryland against individual members of the Company's board of directors and certain executive officers alleging, among other things, that the defendants (i) violated their fiduciary duties to the Company's shareholders; (ii) abused their ability to control and influence the Company; (iii) engaged in gross mismanagement of the assets and business of the Company; and (iv) were unjustly enriched at the expense of, and to the detriment of, the Company. These matters may involve substantial expense to us, which could have a material adverse impact on our financial position and our results of operations. We can provide no assurances as to the outcome of any litigation.

In addition, the volatility in our stock price may make us more vulnerable to future litigation.

Any adverse judgment in or settlement of the pending or any future litigation could require payments that exceed the limits of our available directors' and officers' liability insurance, which could have a material adverse effect on our operating results or financial condition.

We face risks related to ongoing SEC and U.S. Attorney investigations.

As previously disclosed on March 15, 2016, the Company received a subpoena from the SEC, which is conducting a non-public investigation relating to the Company's historic accounting practices (the "SEC Investigation"). As previously disclosed on May 27, 2016, the Company has been advised by the United States Attorney's Office for the Southern District of New York (the "U.S. Attorney") that a criminal investigation has been opened by that office into what the Company understands to be the matters of the SEC Investigation (together with the SEC Investigation, the "Investigations"). See Part II, Item 3, "Legal Proceedings", of this Form 10-K/A, for a discussion of the Investigations. The Company is cooperating fully with the Investigations. At this point, we are unable to predict what the outcomes of the Investigations may be or what, if any, consequences the Investigations may have with respect to the Company or any current or former Company personnel. However, the Investigations could result in considerable legal expenses, divert management's attention from other business concerns and harm our business. If the SEC or U.S. Attorney were to determine that legal violations occurred, we could be required to pay significant civil and/or criminal penalties and/or other amounts and we could become subject to a cease and desist order and/or other remedies or conditions imposed as part of any resolution. The filing of our restated financial statements in this Form 10-K/A to correct the discovered accounting errors will not resolve the Investigations. We can provide no assurances as to the outcome of the Investigations.

Our failure to prepare and timely file our periodic reports with the SEC limits our access to the public markets to raise debt or equity capital.

We did not file an Annual Report on Form 10-K for the year ended December 31, 2015 or Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016, June 30, 2016 and September 30, 2016 within the timeframe required by the SEC. Because we have not remained current in our reporting requirements with the SEC, we are limited in our ability to access the public markets to raise debt or equity capital. Our limited ability to access the public markets could prevent us from pursuing transactions or implementing business strategies that we might otherwise believe are beneficial to our business. Even if we maintain compliance with our SEC reporting obligations prospectively, until one year from the date we regain and maintain status as a current filer, we will be ineligible to use shorter and less costly filing forms, such as Form S-3, to register our securities for sale. We may use Form S-1 to register a sale of our stock to raise capital or complete acquisitions, but doing so would likely take longer that using a shorter and less costly form, increase transaction costs and adversely impact our ability to raise capital or complete acquisitions of other companies in a timely manner.

We have not been in compliance with Nasdaq Stock Market LLC's requirements for continued listing and, as a result, our common stock has been suspended from trading on Nasdaq, which we expect to have a material effect on us and our stockholders.

As a result of the Restatement, we are delinquent in the filing of our Annual Report on Form 10-K for the year ended December 31, 2015 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016, June 30, 2016 and September 30, 2016, which has caused us to be out of compliance with the rules of Nasdaq. On November 10, 2016, we participated in a hearing before the Nasdaq Hearings Panel, which granted our request that we be provided through March 10, 2017 to become a current filer without being delisted. However, we were not able to file all delinquent filings by March 10, 2017 and our common stock was suspended from trading on Nasdaq on March 14, 2017. Nasdaq will file a Form 25 to formally delist our common stock. There can be no assurance whether or when our common stock will again be listed for trading on Nasdaq or any other national securities exchange. Further, the market price of our shares might decline and become more volatile, and our shareholders may find that their ability to trade in our stock would be adversely affected. Furthermore, institutions whose charters do not allow them to hold securities in unlisted companies might sell our shares, which could have a further adverse effect on the price of our stock.

ITEM 3. Legal Proceedings

As previously disclosed in the Company's Current Report on Form 8-K filed on March 15, 2016, various shareholder lawsuits have been filed against the Company and certain of its officers and directors since the disclosure of the Company's accounting review and intention to restate certain prior period financial statements.

On November 23, 2015, a putative class action lawsuit was filed in the United States District Court for the District of Maryland by a single plaintiff, individually and on behalf of other persons similarly situated, against the Company and three current or former executive officers of the Company. The action, captioned *Kiran Kumar Nallagonda v. Osiris Therapeutics, Inc. et al.* , Case 1:15-cv-03562 (the "Nallagonda Action"), alleges, among other things, that the defendants made materially false or misleading statements and material omissions in the Company's SEC filings in violation of the federal securities laws. The complaint seeks certification as a class action, unspecified damages and reimbursement of attorneys' fees. On March 21, 2016, the Court entered an order appointing Dr. Raffy Mirzayan as lead plaintiff and the firm of Hagens Berman Sobol Shapiro LLP as lead counsel. Subsequently, on August 15, 2016, the Court entered an order providing that the lead plaintiff shall file an amended complaint no later than 15 days after the Company files amended financial statements with the SEC.

On March 2, 2016, a shareholder derivative complaint was filed in the Circuit Court for Howard County in the State of Maryland (Case No. 13C16106811) by a single plaintiff, derivatively and on behalf of the Company, against individual members of the Company's board of directors and certain executive officers. This action, captioned *Kevin Connelley v. Lode Debrabandere et al* ., alleges that each of the individual directors and officers named as defendants (i) violated their fiduciary duties to the Company's shareholders; (ii) abused their ability to control and influence the Company; (iii) engaged in gross mismanagement of the assets and business of the Company; and (iv) was unjustly enriched at the expense of, and to the detriment of, the Company. The alleged claims generally relate to the matters that are the subject of the Nallagonda Action. The plaintiff seeks, among other things, unspecified monetary damages, reimbursement of attorneys' fees and shareholder votes on amendments to the Company's Articles of Incorporation and Bylaws with respect to various corporate governance policies. On June 2, 2016, the Court entered an order that, subject to certain qualifications, stayed the action until 30 days after the entry of an order either: (1) denying all motions to dismiss in the Nallagonda Action, or (2) finally dismissing the Nallagonda Action with prejudice.

As disclosed in the March 15 Form 8-K, the Company has received a subpoena from the SEC relating to a non-public investigation relating to its historic accounting practices, which have been under independent review by the Audit Committee of the Company's Board of Directors, with the assistance of outside professionals. Counsel to the Audit Committee also has voluntarily advised the SEC about the Independent Review. The Company is cooperating fully with the SEC in this matter.

As disclosed in the Company's Current Report on Form 8-K filed on May 27, 2016, the Company was contacted by the United States Attorney, and was notified that a criminal investigation had been opened by that office, which to the Company's knowledge is considering the same issues that are under review by the SEC. The Company is cooperating fully with the U.S. Attorney in this matter.

On July 26, 2016, an alleged shareholder of the Company filed a complaint in the Circuit Court for Howard County in the State of Maryland (Case 13C16108356) against the Company and certain directors captioned *Brian C. Lee v. Osiris Therapeutics, Inc., et al* . The plaintiff alleged that the Company and its directors failed to schedule or hold an annual meeting within the time period allegedly required by the Company's bylaws and Maryland law. On March 1, 2017, the parties executed a settlement agreement that will resolve the litigation if the Company provides shareholders with certain additional information on or before March 30, 2017. The Company intends to fulfill its obligations pursuant to the settlement agreement and expects this complaint to be voluntarily dismissed with prejudice.

On February 9, 2017, a shareholder derivative complaint was filed in the United States District Court for the District of Maryland (Case No. 1:17-cv-00381-JKB) by a single plaintiff, derivatively and on behalf of the Company, against individual members of the Company's board of directors. This action, captioned *Recupero v. Friedli et al.,* alleges, among other things, that each of the individual directors named as defendants (i) violated their fiduciary duties to the Company's shareholders, including that such violations constituted constructive fraud; (ii) engaged in gross mismanagement of the assets and business of the Company; and (iii) was unjustly enriched at the expense of, and to the detriment of, the Company. The plaintiff seeks, among other things, unspecified monetary damages, reimbursement of attorneys', accountants' and experts' fees, and that the Company take all necessary actions to improve and comply with corporate governance, internal procedures and existing laws.

PART II

ITEM 6. Selected Financial Data.

The following tables of selected financial data of the Company have been prepared in accordance with GAAP. As discussed in the Explanatory Note to this Form 10-K/A, the Company has (i) restated its audited financial statements for the year ended December 31, 2014 and the Restatement has been reflected in the 2014 information provided below, and (ii) revised its financial statements for the years ended December 31, 2013, 2012 and 2011 to correct immaterial errors and those revisions are reflected in the 2013, 2012 and 2011 information provided below. For more information, see Note 2 to the Company's financial statements included in Part II, Item 8 of this Form 10-K/A. The financial data as of December 31, 2014, 2013 and 2012 and for the years ended December 31, 2014, 2013 and 2012 should be read in conjunction with, and are qualified in their entirety by, reference to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and notes thereto included in this Form 10-K/A.

	Year ended December 31,				
(in thousands)	**2014**	**2013**	**2012**	**2011**	**2010**
	(Restated)				
Product revenue	$ 50,835	$ 25,698	$ 7,164	$ 1,001	$ 183
Cost of product revenue	9,886	6,851	2,420	467	62
Gross profit	40,949	18,847	4,744	534	121
Operating expenses:					
Research and development	3,414	4,330	4,059	4,340	4,399
Sales and marketing	36,384	13,810	2,836	—	—
General and administrative and other	8,135	2,718	4,202	7,169	6,450
Total operating expenses	47,933	20,858	11,097	11,509	10,849
Loss from operations	(6,984)	(2,011)	(6,353)	(10,975)	(10,728)
Other (expense) income, net	(1,771)	414	49	100	175
Loss from continuing operations, before income taxes	(8,775)	(1,597)	(6,304)	(10,875)	(10,553)
Income tax (expense) benefit	(97)	994	37	775	(241)
Loss from continuing operations	(8,852)	(603)	(6,267)	(10,100)	(10,794)
(Loss) income from discontinued operations	(1,118)	43,063	(5,318)	24,794	23,919
Net (loss) income	$ (9,970)	$ 42,460	$ (11,585)	$ 14,694	$ 13,125
Basic loss per share from continuing operations	$ (0.26)	$ (0.02)	$ (0.19)	$ (0.31)	$ (0.33)
Basic and diluted (loss) income per share	$ (0.29)	$ 1.27	$ (0.35)	$ 0.45	$ 0.40
Weighted average common shares (basic and diluted)	34,263	33,307	32,859	32,820	32,784

	At December 31,				
(in thousands)	**2014**	**2013**	**2012**	**2011**	**2010**
	(Restated)				
Balance Sheet Data:					
Cash and investment securities	$ 50,104	$ 59,010	$ 34,092	$ 47,391	$ 67,608
Working capital(1)	77,096	73,420	33,275	43,195	27,423
Total assets	88,450	92,201	41,693	54,337	77,784
Long-term liabilities	3,589	355	531	430	3,798
Accumulated deficit	(211,620)	(201,650)	(244,110)	(232,525)	(247,219)
Total stockholders' equity	75,681	81,053	35,172	45,620	27,457

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

The effect of the Restatement of the Company's selected financial data are as follows:

	Year ended December 31, 2014		
	Previously Reported	Adjustments	Restated
	(In thousands, except per share data)		
Operating data:			
Product revenue	$ 59,867	$ (9,032)	$ 50,835
Cost of product revenue	13,171	(3,285)	9,886
Gross profit	46,696	(5,747)	40,949
Operating expenses	44,978	2,955	47,933
Other (expense) income	(1,771)	—	(1,771)
Income taxes (expense) benefit	(193)	96	(97)
Net (loss) income from continuing operations	(246)	(8,606)	(8,852)
Net (loss) income from discontinued operations	(1,543)	425	(1,118)
Net (loss) income	$ (1,789)	$ (8,181)	$ (9,970)
		—	
Basic net (loss) income per share from continuing operations	$ (0.01)	$ (0.25)	$ (0.26)
Basic and diluted net (loss) income per share	$ (0.05)	$ (0.24)	$ (0.29)

	Year ended December 31, 2014		
	Previously Reported	Adjustments	Restated
	(In thousands)		
Balance Sheet Data:			
Cash and investment securities	$ 50,104	$ —	$ 50,104
Working capital	85,370	(8,274)	77,096
Total assets	98,118	(9,668)	88,450
Long-term liabilities	3,589	—	3,589
Accumulated deficit	(203,543)	(8,077)	(211,620)
Total stockholders' equity	83,963	(8,282)	75,681

(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 Form 10-K/A. 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 Form 10-K/A under the heading "Cautionary Statements About Forward-Looking Information" above.

The accompanying Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") gives effect to the Restatement. For additional information on the restatement, see Note 2 in the Company's financial statements included in Part II, Item 8 of this Form 10-K/A.

The following is a discussion and analysis of our financial condition, results of operations, liquidity and capital resources for each of the three years ended December 31, 2014, 2013 and 2012 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 Part II, Item 8, "Financial Statements and Supplementary Data", of this Form 10-K/A.

In October 2013, we sold our Therapeutics segment for up to $100 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 segment's 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 3, “Discontinued Operations” in the accompanying financial statements for further discussion of these discontinued operations.

Business Overview

Osiris Therapeutics, Inc., based in Columbia, Maryland, is a world leader in researching, developing and marketing cellular regenerative medicine products that improve the health and lives of patients, and lower overall healthcare costs. We continue to advance our R&D in biotechnology by focusing on innovation in regenerative medicine—including bioengineering, stem cell research and viable tissue-based products. We have achieved commercial success with products in orthopedics, sports medicine and wound care, including Ovation®, OvationOS® (now the subject of exclusive distribution rights held by Stryker under the brand BIO $^{4™}$), Cartiform® and Grafix®.

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

From May 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, including Prochymal and related assets, to a wholly-owned subsidiary of Mesoblast Limited, in a transaction worth up to $100 million plus royalties. The agreement with Mesoblast provides for the receipt by us of $50 million in initial consideration at 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 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 Limited stock. We received the remainder of the initial consideration, $15 million in cash, in April 2014. The Mesoblast Limited stock was subject to a holding period which was ultimately extended to May 2015. During this holding period, Mesoblast Limited provided the Company limited protection against a decline in the market value of the stock. In May 2015, concurrent with expiration of holding period, Mesoblast Limited paid the Company $6.2 million representing the decline in the market value of the stock through that date. Later in 2015, the Company sold all of its Mesoblast Limited shares for $6.5 million. A $2.3 million loss was recognized in 2015 in connection with these transactions.

In December 2014, the Company executed commercial partnership agreements with the Orthopedics Unit with Stryker and the Sports Medicine Unit of Arthrex for the distribution of BIO $^{4™}$ and Cartiform $^{®}$, respectively. Sales under these exclusive distribution arrangements commenced in 2015.

In September 2013, the Company received an “untitled letter” from the FDA regarding the qualification of its Ovation® and Grafix® products as HCT/Ps (human cells, tissues, and cellular and tissue-based products). In October 2013, the Company reached agreement with the FDA to cease its production and sale of Ovation® and the FDA confirmed the continuing status of Grafix® as a HCT/P regulated under section 361 of the Public Health Services Act. In addition, the Company announced plans to submit a BLA covering expanded indications for Grafix®. A clinical trial supporting the BLA began in 2015 with a target enrollment of 224 patients. In October 2016, the Company announced plans to terminate further enrollment in the trial and complete treatment of the 53 patients then enrolled. The decision to terminate further enrollment in the trial reflects the Company’s desire to allocate more of its research and development resources to other clincial programs, including its new cellular drug platform technology.

Production of Ovation® was discontinued in the third quarter of 2014 and the Company sold or shipped to consignees all of its remaining Ovation® inventory by the end of October 2014. As described further in Note 2 to the Company’s financial statements included in Part II, Item 8 of this Form 10-K/A, recognition of a substantial portion of these sales in 2014 are not recorded as revenue in 2014 but rather will be recorded as revenue in the period that payment is received. In the first quarter of 2014, the Company launched OvationOS® (rebranded as BIO $^{4™}$ in 2015) as a therapeutic substitute for Ovation® in many of clinical protocols to which Ovation® has historically been applied.

Since 2013, the Company has built a substantial direct sales force dedicated exclusively to the sale of Grafix®. As a result, Grafix® sales in 2014 were nearly five times that achieved in 2013. However, the contribution of Grafix® to the Company’s operating income has been limited due the heavy investment in sales and marketing. We operate in a competitive and challenging business environment and recognize that our execution of product development and market penetration

strategy will face a number of challenges. As a result, we may experience variability in our overall results, and in our quarter to quarter revenue.

We are a fully integrated company, having developed capabilities in R&D, manufacturing, marketing and sales of stem cell products.

Restatement

All amounts set forth in this MD&A have been adjusted to reflect the Restatement.

Financial Operations Overview

Product Revenue

We manufacture human tissue-based products in our Columbia, Maryland facility. Commercial sales of our first placenta-based Biosurgery product, Grafix®, began in 2010. In 2011, we launched our second placenta-based Biosurgery product, Ovation®. In 2013, we launched the first of our two cadaver-based products, Cartiform®, followed in 2014 by OvationOS® (rebranded by Stryker as BIO ^{4}™ in 2015).

The Company's products are sold through its direct sales force as well as independent distributors. All of these products are cryopreserved and stored in special freezers at - 80 degrees Celsius. Our products are shipped to customers on dry ice in thermo-cooler boxes.

Some of our direct sales customers provide purchase orders in advance of our shipment and take title to our products as shipped, while others take title to our products only after the products have been implanted in their patients. Some of our direct sales customers purchase our products under a consignment sales arrangement and store our products on site in approved freezers, which are in most instances provided at no charge by our Company. Revenue is recognized upon shipment when a customer provides a purchase order in advance of shipment and in all other instances revenue is recognized when we receive notice that our product has been implanted.

Sales to and through distributors are made under various arrangements.

- **Direct Sales Distributor - Distributor buys products from the Company and resells the products directly to end-use (clinical provider) customers at mark-up from its purchase cost:** Revenue arising from direct sales arrangements with distributors is reported at the Company's sales price to the distributor.

- **Commissioned Sales Agent - Distributor serves as the Company's commissioned sales agent, selling to end-use customers at agreed upon prices:** Revenue arising from commissioned sales agent arrangements is reported at the sales price paid by the end-use customer and commissions paid to the distributor as a percentage of sales are reported as a sales expense.

- **Government Contracting Agent — Company sells product under the government procurement contract of the contracting agent:** Revenue arising from government contract sales arrangements is reported at the sales price paid by the end-use customer (primarily Veterans Administration hospitals) and service fees paid to the agent as a percentage of sales are reported as a sales expenses.

Cost of Product Revenue

All of the Company's products are produced at its Columbia, Maryland headquarters facility. Cadaveric and placental tissue is purchased from independent tissue banks and processed in the Company's production clean room. Other production costs include chemical solutions applied during the production process, packaging materials and quality control testing and quality assurance services.

Research and Development Costs

Our R&D costs consist of expenses incurred in identifying, developing and testing biologic tissue-based products and protecting the resulting intellectual property. These expenses consist primarily of salaries and related expenses for

personnel, fees paid to professional service providers for independent monitoring and analysis of our clinical trials, costs of contract research, costs of facilities, and costs of manufacturing clinical trial materials, quality control supplies and the costs of filing, maintaining and defending patents designed to protect the Company's intellectual property. Our historic R&D 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 R&D costs on a project-by-project basis.

R&D expenses were $4.1 million in 2012, $4.3 million in 2013, and $3.4 million in 2014, which includes costs incurred for Protocol 302, which began during the second quarter of 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. R&D expenses declined from 2013 to 2014 due to the completion of the Protocol 302 trials.

We expect our R&D 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 R&D projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of the costs of building, developing, training and maintaining our direct sales force and marketing teams including salaries, commissions and travel expenses as well as commissions and fees paid to our distributors and our federal contracting agent. The cost of establishing and maintaining reimbursement coverage for our products and advising our customers regarding reimbursement issues, together with regulatory oversight of our sales and marketing and distribution operations are also classified as sales and marketing expenses.

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. Bad debt arising from uncollectible trade accounts receivable are also classified as general and administrative expenses. We expect general and administrative expenses to increase as a result of hiring additional operational, financial, accounting, facilities engineering and information systems personnel as the scope our business activities grows. 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 (Expense), 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

The total tax provision for 2014 is a combination of $97,000 from continuing operations and $516,000 from the portion of the proceeds from the sale of discontinued operations received in 2014, which is reflected as a component of discontinued operations. The tax expense from continuing operations is due to federal alternative minimum taxes and state taxes.

Because realization of deferred tax assets is dependent upon future earnings, a full valuation allowance has been recorded on the net deferred tax assets as of December 31, 2013 and 2014, which relate primarily to net operating loss and various business tax credit carryforwards. In the event that we become profitable, we have general business credits (before a 100% valuation allowance) of approximately $71.1 million that may be utilized to reduce our federal tax but not below the alternative minimum tax threshold. 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 reduce income taxes payable on a with-and-without basis.

The total tax provision for 2013 is a combination of the income tax benefit of $994,000 from continuing operations and the gain from sale of discontinued operations, which is reflected net of income taxes of $1.3 million. The tax provision for 2013 reflects an effective tax rate benefit for continuing operations of 64.4% and was greater than the U.S. statutory tax rate of 35% due primarily to the tax benefit from disqualifying dispositions of incentive stock options (excluding windfall tax benefits). The Company was also subject to the alternative minimum tax of $388,000 in 2013, which was included in the income taxes allocated to the gain from the sale of discontinued operations.

In October 2013, we entered into an agreement with a wholly owned subsidiary of Mesoblast Limited for the sale of our 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 2013. The remaining $15 million payment was received 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 2013 and the balance of the initial consideration of $15 million was recognized in 2014 for income tax purposes. The tax effect of the $15 million consideration received in 2014 was reported as a deferred tax liability in the amount of $6.1 million in 2013. This deferred payment also required that interest be accrued in the amount of $103,000 that increased the income taxes payable in 2013.

Amended income tax returns were filed for 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

recovery in the amount of $79,000. The inventory of deferred tax assets has been updated for these income tax amendments. Those refunds were received in 2014.

In 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 and the impact of the restatement as discussed in Note 2 to the Company's financial statements included in Part II, Item 8 of this Form 10-K/A.

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 GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue 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 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 production of our first Biosurgery segment product, Grafix®, a regenerative wound care product, during the first quarter of 2010. We launched the product for limited commercial distribution during the third quarter of 2010. We began distribution of another Biosurgery product, Ovation®, in early 2011. During 2013, we launched Cartiform®, a viable cartilage mesh for cartilage repair and in 2014 we introduced OvationOS® (rebranded by Stryker as BIO ^{4}™ in 2015) a viable bone matrix. We recognized revenue of $50.8 million, $25.7 million and $7.2 million on sales of our Biosurgery products in 2014, 2013 and 2012, respectively.

We recognize revenue from the sales of our products when title and the risk of loss pass to the customer; when persuasive evidence of an arrangement exists; when sales amounts are fixed and determinable; and when collectability is reasonably assured. Due to the nature of the products and the manufacturing process, we generally do not allow sales returns or refunds unless the product is returned in the original shipping container and is determined to be salable.

For sales generated by our direct sales force, we recognize revenue upon shipment of our products to end-use customers (clinical providers), provided the customer has provided a purchase order or other documentation evidencing acceptance of the risks of ownership in advance of shipment. For products shipped before the customer has accepted the risks of ownership, we recognize revenue upon receipt of notice that our product has been used (implanted). Prior to receipt of such notice, the cost of products shipped is classified as consignment inventory.

We also sell our products through our distributors. Some of our distributors act as principals and sell products purchased from us to their clinical provider customers at a marked-up price. Revenue from sales to such distributors is reported at our selling price to the distributor. Other distributors act as commissioned sales agent for the Company. Revenue from sales to such distributors are reported at the price paid by the clinical provider. Revenue from distributor sales is recognized upon shipment if risk of ownership passes to the distributor at that time, or upon receipt of notice of product use if risk of ownership passes only upon clinical use of the product. Prior to receipt of such notice, the cost of products shipped is classified as consignment inventory.

In certain circumstances, our distributors and/or their clinical end-use customers may require the Company to maintain consignment inventory at their locations. For inventory held at consignment locations, no revenue is recognized as we retain title and maintain the inventory on our balance sheet. We recognize revenue when we receive notification from the distributor that the consigned product has been used (implanted) or when a purchase order for the consigned product has been received from the distributor's end-use customer for which, at that point, the title and risk of loss has passed to the customer. As of December 31, 2014 consigned inventory was valued at $1.8 million, of which $1.3 million was held by distributors and $0.5 million held by end-use customers.

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" in the accompanying financial statements.

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.

Trading Securities

The Mesoblast Limited ordinary shares the Company received as initial consideration for the sale of its Therapeutics business are classified as Trading Securities on our balance sheets as of December 31, 2014 and 2013 since it is our intention to sell such securities following expiration of the agreed upon holding period. These shares were sold for $6.5 million in the second half of 2015. In addition, Mesoblast Limited paid the Company $6.2 million in May 2015, representing the decline in the market value of the shares from the date received through the expiration of the holding period during which Mesoblast had agreed to provide the Company protection against a decline in the market value of such shares.

Trade Accounts Receivable

Accounts receivable has grown as a result of our revenue increasing from $7.5 million in the fourth quarter of 2013 to $15.1 million in the fourth quarter of 2014 and slower collections. Trade accounts receivable are reported at the Company's estimate of 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 to be past due. As of December 31, 2014 and 2013, trade accounts receivable in the accompanying balance sheets are reported net of an allowance for doubtful accounts of $1.7 million and $78,000, respectively. We incurred bad debt expense of $1.6 million, $80,000, and $22,000 during 2014, 2013 and 2012, 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, product quarantined pending clearance by quality assurance and released products available for sale. We determine our inventory values using the first-in, first-out method. Inventory is valued at the lower of standard cost or market.

As discussed further in Note 2 to the Company's financial statements included in Part II, Item 8 of this Form 10-K/A, the Company's 2014 financial statements have been restated to correct errors in the valuation of inventory. Such errors include computation errors in the valuation of the Company's finished goods inventory; inaccurate unit cost calculations of the Company's finished goods inventory resulting from the use of non-current cost information; non-timely identification and write-off of known unsalable finished goods inventory as determined by the Company's quality assurance procedures; the need for a reserve for consigned finished goods inventory due to inadequate monitoring of the ultimate disposition of consigned product; and the need for a reserve for work-in-process inventory which largely consists of product in quarantine pending the completion of the Company's quality assurance procedures which results in a reasonably consistent identification of a portion of the product as unsalable.

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 years 2014, 2013 or 2012.

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 Accounting Standards Codification ("ASC") 815, Derivatives and Hedging. We do not trade derivative instruments as a part of our normal continuing operations. We held a derivative instrument for the price protection of the value of the Mesoblast Limited stock held from falling below $15.0 million for a one year period, which was included in trading securities on the balance sheet as of December 31, 2013. The fair value of the price protection instrument was $1.7 million at December 31, 2013. The price protection ended in December 2014 and, therefore, as of December 31, 2014, we no longer had a derivative instrument.

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 R&D costs in the period incurred.

R&D expenses were $3.4 million, $4.3 million, and $4.1 million, in 2014, 2013 and 2012 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 carryforwards. Temporary differences are primarily the result of the differences between the tax bases of assets and liabilities and their financial reporting values. Deferred tax liabilities and assets are measured by applying the enacted statutory tax rates applicable to the future years in which deferred tax liabilities or assets are expected to be settled or realized. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense, if any, consists of the taxes payable for the current period and the change during the period in deferred tax assets and liabilities.

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, 2014 and 2013, we had no accruals for interest or penalties related to income tax matters.

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, 2014 excludes all 1,608,557 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 from continuing operations for the year ended December 31, 2013 excludes 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.

Results of Operations

The following tables of selected financial data of the Company have been prepared in accordance with GAAP:

(in thousands)	Year ended December 31, 2014 (Restated)	2013	2012
Product revenue	$ 50,835	$ 25,698	$ 7,164
Cost of product revenue	9,886	6,851	2,420
Gross profit	40,949	18,847	4,744
Operating expenses:			
Research and development	3,414	4,330	4,059
Sales and marketing	36,384	13,810	2,836
General and administrative	7,563	2,538	2,282
Related parties	572	180	1,920
Total operating expenses	47,933	20,858	11,097
Loss from operations	(6,984)	(2,011)	(6,353)
Other (expense) income, net	(1,771)	414	49
Loss from continuing operations, before income taxes	(8,775)	(1,597)	(6,304)
Income tax (expense) benefit	(97)	994	37
Loss from continuing operations	(8,852)	(603)	(6,267)
(Loss) income from discontinued operations	(1,118)	43,063	(5,318)
Net (loss) income	$ (9,970)	$ 42,460	$ (11,585)

Year ended December 31, 2014 compared to December 31, 2013 and December 31, 2012

	Year Ended December 31,							
	2014		2013		2012		% Change	
Product	Product Revenue (Restated)	Percent of Total	Product Revenue	Percent of Total	Product Revenue	Percent of Total	14 vs 13	13 vs 12
Grafix	$ 36,069	71.0%	$ 8,154	31.7%	$ 2,572	35.9%	342.3%	217.0%
Ovation	12,370	24.3%	16,694	65.0%	4,592	64.1%	(25.9)%	263.5%
Other	2,396	4.7%	850	3.3%	—	—%	181.9%	—%
Total	**$ 50,835**	**100.0%**	**$ 25,698**	**100.0%**	**$ 7,164**	**100.0%**	**97.8%**	**258.7%**

Product Revenue and Gross Profit

Product revenue recognized in 2014 was more than double that realized in 2013, reflecting the ramp-up of the Company's direct sales force and the rapid expansion of reimbursement coverage for our Grafix® product. Grafix® is sold primarily through our direct sales force, while Ovation® and our other products are sold through our distributor network. Revenue from sale of Ovation® declined 25.9% from 2013 to 2014. The decline in revenue from the sale of Ovation® was primarily due to the timing of revenue recognition of several transactions initiated in 2014 which did not meet the applicable revenue recognition criteria in the period. As described in Note 2 to the Company's financial statements included in Part II, Item 8 of this Form 10-K/A, Ovation® sales were adversely impacted in 2014 by the reversal of approximately $10.3 million of previously reported revenue arising from distributor sales arrangements under which the Company had granted three distributors unusually long payment terms. GAAP requires the recognition of revenue when the customer payment is received if unusually long payment terms are offered. Customer payments aggregating $8.1 million and $1.2 million were received in 2015 and 2016, respectively, on distributor sales transactions for which revenue was reversed in 2014, which will be recognized as revenue in the year payment was received.

The Company agreed to end its production and sale of Ovation® as part of its previously announced agreement with the FDA. The Company discontinued its production of Ovation® in the third quarter of 2014, and shipped its remaining Ovation® inventory to distributors or consignees in the fourth quarter of 2014.

Our gross profit margin increased in 2014 to 80.6% compared to 73.3% in 2013, primarily as the result of operational efficiencies gained as we increased the utilization of our production facilities.

Research and Development Expenses

R&D expenses in 2014 were $3.4 million compared to $4.3 million in 2013. Just over half of our 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 2013 R&D costs were spent on both new product development and product improvements. These efforts resulted in the introduction of OvationOS® (rebranded by Stryker as BIO(4)™ in 2015) and Cartiform®, and in novel packaging and application improvements to our Grafix® product line. R&D expenses declined in 2014, primarily due to the completion of Protocol 302 in the first quarter of 2014. While no new clinical trials were started in 2014, the Company continued R&D work focused on the expansion of Grafix to venous leg ulcers and other clinical applications. The Company is also developing new placenta-based products as well as new product platforms.

Sales and Marketing Expenses

Sales and marketing expenses increased to $36.4 million in 2014 from $13.8 million in 2013, primarily due to the increase in our Grafix® sales force from 10 at the end of 2013 to approximately 100 at the end of 2014. Compensation of our sales force, including sales-based commissions, increased commensurate with these additions to our sales force and the $28 million increase in Grafix® sales. We also expanded our market access and reimbursement group in 2014 and opened a reimbursement hotline for our customers. As a result, health insurance coverage available to patients using our Grafix® product expanded from 100 million at December 31, 2013 to 200 million at December 31, 2014.

General and Administrative Expenses

General and administrative expenses increased to $7.6 million during 2014 compared to $2.5 million in 2013. This increase was primarily due to the hiring of addition personnel required to support the Company's rapidly expanding operations. The $1.6 million increase in our bad debt reserve was also a major contributor to the growth of the Company's general and administrative expenses. A substantial portion of general and administrative expenses incurred in 2013 were allocated to discontinued operations.

Other Income (Expense), net

Other expense, net in 2014 was $1.8 million compared to other income, net of $414,000 million in 2013. Other expense, net in 2014 was comprised of a $401,000 unrealized loss on the decline in the market value of Mesoblast Limited stock we received in connection with the sale of our Therapeutics business and $1.7 million loss on the price protection, offset by $400,000 million of net investment income earned on our investments available for sale. We carry the Mesoblast Limited stock as trading securities on the balance sheets as of December 31, 2014 and 2013. Other income, net in 2013 was comprised principally of a $400,000 million of unrealized gain on the increase in the market value of Mesoblast Limited stock.

Income Taxes

The total tax provision for 2014 is a combination of $97,000 from continuing operations and $516,000 from the portion of the proceeds from the sale of discontinued operations received in 2014, which is reflected as a component of discontinued operations in the accompanying financial statements. The tax expense from continuing operations is due to federal alternative minimum taxes and state taxes.

Because realization of deferred tax assets is dependent upon future earnings, a full valuation allowance has been recorded on the net deferred tax assets as of December 31, 2013 and 2014, which relate primarily to net operating loss and various business tax credit carryforwards. In the event that we become profitable, we have general business credits (before a 100% valuation allowance) of approximately $71.1 million that may be utilized to reduce our federal tax but not below the alternative minimum tax threshold. In addition, windfall equity based compensation deductions in the amount of $5.4 million are tracked but not recorded to the balance sheets until they are reduce income taxes payable on a with-and-without basis.

The total tax provision for 2013 is a combination of the income tax benefit of $994,000 from continuing operations and the gain from sale of discontinued operations, which is reflected net of income taxes of $1.3 million. The tax provision for 2013 reflected an effective tax rate benefit for continuing operations of 64.4% and was greater than the U.S. statutory tax rate of 35%, due primarily to the tax benefit from disqualifying dispositions of incentive stock options (excluding windfall tax benefits). We were also subject to the alternative minimum tax of $388,000 in 2013, arising from the sale of discontinued operations.

In October 2013, we entered into an agreement with a wholly owned subsidiary of Mesoblast Limited for the sale of our 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 2013. The remaining $15 million payment was received 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 2013 and the balance of the initial consideration of $15 million was recognized in 2014 for income tax purposes. The tax effect of the $15 million consideration received in 2014 was reported as a deferred tax liability in the amount of $6.1 million in 2013. This deferred payment also required that interest be accrued in the amount of $103,000 that increased the income taxes payable in 2013.

Amended income tax returns were filed for 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 income tax recoverable in the amount of $79,000. We have recorded a full valuation allowance against our net deferred tax assets as of December 31, 2014 and 2013. The inventory of deferred tax assets has been updated for these income tax amendments. Such refunds were received in 2014.

In 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.

Fees Paid to Related Parties, Including Share-Based Payments

In 2014 and 2013, we compensated non-employee members of our Board of Directors by grants of stock ranging from 2,500 to 10,000 shares annually, and we permit the directors to take their payments in either cash or stock or a combination thereof. During 2014, our non-employee directors were awarded the value of 35,000 shares of our common stock which had a fair market value of $14.93 per share. This was paid with $119,400 of cash and 27,000 shares of stock valued at $403,100. During 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.

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

Product Revenue and Gross Profit

Product revenue recognized in 2013 was more than three times that realized in 2012. Our sales growth leader was Ovation® which gained commercial traction in 2013. Grafix® also achieved a high rate of sales growth reflecting the launch of our direct sales force and progress in obtaining reimbursement coverage.

Our gross profit increased in 2013 to 73.3% compared to 66.2% in 2012, primarily as the result of operational efficiencies as we more heavily utilized our production facilities.

Research and Development Expenses

R&D expenses in 2013 were $4.3 million compared to $4.1 million in 2012. A little over half of our 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® (rebranded by Stryker as BIO(4)™ in 2015) and Cartiform®, and in novel packaging and application improvements to our Grafix® product line. In 2012, the Company's R&D efforts were directed primarily to improving processes applied in the manufacturing and packaging of existing products and the enrollment of patients in clinical trials required to obtain cost reimbursement for Grafix®.

Sales and Marketing Expenses

Sales and marketing expenses increased to $13.8 million during 2013 as compared to $2.8 million in 2012. This increase was due to additional sales commissions paid to the Company's distributors commensurate with the growth of the Company's revenue. We also made a substantial investment in our marketing and reimbursement infrastructure which was essential to increasing the Company's exposure to the nation's public and private health care providers and insurers. During 2013, we launched our own in-house direct sales force, primarily for Grafix®, and invested in training and more extensive product support capabilities.

General and Administrative Expenses

General and administrative expenses increased to $2.5 million during 2013 compared to $2.3 million in 2012. This increase was primarily due to the hiring of addition personnel required to support the Company's rapidly expanding operations. A substantial portion of the general and administrative expenses incurred in 2013 were allocated to discontinued operations.

Other Income (Expense), net

Other income, net in 2013 was comprised principally of $414,000 million of unrealized gain arising from the increase in the market value of the Mesoblast Limited stock we received in connection with the sale of our Therapeutics business. We carried the Mesoblast stock as trading securities. Other income, net in 2012 was comprised solely of the net investment gains on our investments available for sale.

Income Taxes

In 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, $35 million of the initial consideration was taxable in 2013, and the additional $15 million was taxable in 2014 when we received the payment.

The total tax provision for 2013 is a combination of the income tax benefit of $994,000 from continuing operations and the gain from sale of discontinued operations, which is reflected net of income taxes of $1.3 million. The tax provision for 2013 reflects an effective tax rate benefit for continuing operations of 64.4% and was greater than the U.S. statutory tax rate of 35% due primarily to the tax benefit from disqualifying dispositions of incentive stock options (excluding windfall tax benefits). We were also subject to the alternative minimum tax of $388,000, arising from the sale of discontinued operations.

In 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.

We 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

In 2013 and 2012, we compensated non-employee members of our Board of Directors by grants of stock ranging from 2,500 to 10,000 shares annually, and we permitted the directors to take their payments in either cash or stock or a combination thereof. During 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 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.

Liquidity and Capital Resources

Liquidity

At December 31, 2014, we had $2.2 million in cash and $37.3 million in investments available for sale. Other receivables at December 31, 2014 included the $5.0 million initial payment from Stryker and the $4.4 million difference

between the market value at December 31, 2014 of the Mesoblast Limited shares held by us and the $15 million Mesoblast Limited was then obligated pay the Company in the event we chose to sell such shares. As of December 31, 2014, the trading securities of $10.6 million consists of the fair value of the Mesoblast stock held by us.

As a result of the Restatement and related legal proceedings and government investigations, we have and will continue to incur significant legal, accounting and other professional fees, well beyond historical levels. We expect this trend to continue until these matters are resolved.

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,		
(In thousands)	**2014**	**2013**	**2012**
	(Restated)		
Net cash used in operating activities of continuing operations	$ (18,756)	(3,309)	$ (4,783)
Net cash used in operating activities	(3,155)	(13,601)	(13,271)
Net cash provided by investing activities	1,059	11,940	13,324
Net cash provided by financing activities	1,888	2,223	140

Net cash used in operating activities of continuing operations was $18.8 million during 2014, and primarily reflects our net loss of $8.9 million and net increases in our current assets partially offset by non-cash charges and increase in current liabilities.

Net cash used in operating activities of continuing operations during 2013 was $3.3 million, and primarily reflects our net loss of $603,000 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 2012 was $4.8 million, and reflects our net loss of $6.3 million, partially offset by $1.1 of non-cash charges and net unfavorable changes in working capital.

Net cash provided by investing activities was $1.1 million, $11.9 million, and $13.3 million, respectively, during years 2014, 2013 and 2012, 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 $1.9 million and $2.2 million in 2014 and 2013, respectively, and was insignificant in 2012. The 2014 cash provided by financing activities is primarily the net proceeds from the exercise of stock options by our employees to purchase our common stock.

The adjustments had an impact on certain captions within the condensed statements of cash flows for the restated quarterly periods as discussed further in Note 2 to the Company’s financial statements included in Part II, Item 8 of this Form 10-K/A.

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;

- the costs of enlarging our work force consistent with expanding our business and operations and distribution of our Biosurgery products; and

- the costs incurred for professional fees and any legal liabilities related to the Restatement and related legal matters described under Part I, Item 3, "Legal Proceedings".

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, 2014. The information in the table reflects future unconditional payments and is based on the terms of the relevant agreements, appropriate classification of item under GAAP 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	$ 10,610	$ 1,194	$ 2,153	$ 2,306	$ 4,957
Capital lease obligations	120	48	72	—	—
Total contractual cash obligations	$ 10,730	$ 1,242	$ 2,225	$ 2,306	$ 4,957

Contract Research Organizations. We contract with independent contract research organizations ("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 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.

We have active contracts with a CRO related to on-going clinical trials. Although we cannot directly control the timing of the remaining payments, based on our estimates and assumptions as of February 27, 2015, we expect to pay approximately $10.7 million to the CRO between 2015 and 2017.

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 originally expired in July 2016. According to the terms of the lease agreement, we were required to provide a letter of credit which was fully collateralized by restricted cash and as of December 31, 2013, the letter of credit of $224,000 remained outstanding. In September 2014, we entered into an amendment to the operating lease for our Columbia, Maryland facilities, extending the term of the lease through October 2023 and increasing the future minimum lease commitment by $9.0 million. The lease amendment includes an allowance for tenant improvements of approximately $1.5 million that we expect to utilize in 2015 to expand our manufacturing facilities and adjust our office space to accommodate our additional employees. Under the amended lease agreement, we also replaced the $224,000 letter of credit with a $96,000 cash deposit and eliminated all 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

OSIRIS THERAPEUTICS, INC.
FINANCIAL STATEMENTS
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FINANCIAL STATEMENT SCHEDULES

* 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.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING F IRM

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, 2014 and 2013 and the related statements of comprehensive (loss) income, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014. In connection with the 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 also 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 financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Osiris Therapeutics, Inc. at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, 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.

As discussed in Note 2 to the financial statements, the 2014 financial statements have been restated to correct certain misstatements.

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, 2014, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 27, 2017 expressed an adverse opinion thereon.

/s/ BDO USA, LLP

McLean, Virginia

March 27, 2017

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, 2014, based on criteria established in *Internal Control — Integrated Framework (2013)* 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 "Management's Report on Internal Control Over Financial Reporting" included in Item 9A of the accompanying report. 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.

In our report dated March 20, 2015, we expressed an unqualified opinion on the effectiveness of internal control over financial reporting as of December 31, 2014. Subsequent to March 20, 2015, Osiris Therapeutics, Inc. identified material misstatements in its annual and quarterly financial statements for 2014, requiring restatement of such financial statements. Management revised its assessment of internal control over financial reporting due to the identification of material weaknesses in connection with the financial statement restatement. Accordingly, our opinion on the effectiveness of Osiris Therapeutic, Inc.'s internal control over financial reporting as of December 31, 2014 expressed herein is different from that expressed in our previous report. 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. Material weaknesses have been identified and described in management's assessment. These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2014 financial statements (as restated).

In our opinion, Osiris Therapeutics, Inc. did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We do not express an opinion or any other form of assurance on management's statements referring to any corrective actions taken by the company after the date of management's assessment.

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, 2014 and 2013, and the related statements of comprehensive (loss) income, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014, and our report dated March 27, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

McLean, Virginia

March 27, 2017

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

	December 31, 2014 (Restated)	December 31, 2013
Assets		
Current assets		
Cash	$ 2,208	$ 2,416
Investments available for sale	37,305	39,508
Trading securities	10,591	17,086
Trade accounts receivable, net of reserves	13,373	7,459
Other receivables	10,081	15,369
Inventory	9,824	1,929
Prepaid expenses and other current assets	2,894	355
Current assets of discontinued operations	—	91
Total current assets	86,276	84,213
Property and equipment, net	2,079	1,896
Deferred tax asset	—	5,849
Restricted cash	—	243
Other assets	95	—
Total assets	$ 88,450	$ 92,201
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$ 7,468	$ 4,842
Capital lease obligations, current portion	45	45
Deferred exclusivity fee revenue, current portion	1,667	—
Deferred tax liability	—	5,849
Current liabilities of discontinued operations	—	57
Total current liabilities	9,180	10,793
Other long-term liabilities	3,589	355
Total liabilities	12,769	11,148
Commitments and contingencies		
Stockholders' equity		
Common stock, $.001 par value, 90,000 shares authorized, 34,346 shares outstanding - 2014, 34,115 shares outstanding - 2013	35	34
Additional paid-in-capital	287,320	282,702
Accumulated other comprehensive loss	(54)	(33)
Accumulated deficit	(211,620)	(201,650)
Total stockholders' equity	75,681	81,053
Total liabilities and stockholders' equity	$ 88,450	$ 92,201

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

OSIRIS THERAPEUTICS, INC
STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(amounts in thousands, except per share data)

	Year ended December 31,		
	2014 (Restated)	2013	2012
Product revenue	$ 50,835	$ 25,698	$ 7,164
Cost of product revenue	9,886	6,851	2,420
Gross profit	40,949	18,847	4,744
Operating expenses			
Research and development	3,414	4,330	4,059
Sales and marketing	36,384	13,810	2,836
General and administrative	7,563	2,538	2,282
Fees paid to related parties	169	—	2
Share-based payments to related parties	403	180	1,918
Total operating expenses	47,933	20,858	11,097
Income (loss) from operations	(6,984)	(2,011)	(6,353)
Other (expense) income, net	(1,771)	414	49
Loss from continuing operations, before income taxes	(8,775)	(1,597)	(6,304)
Income tax (expense) benefit	(97)	994	37
Loss from continuing operations	(8,852)	(603)	(6,267)
Discontinued operations			
Loss from operations of discontinued operations, net of income taxes of $516 in 2014, $0 in 2013, and $0 in 2012	(1,118)	(6,668)	(5,318)
Gain from sale of discontinued operations, net of income taxes of $1,374 in 2013	—	49,731	—
(Loss) income from discontinued operations	(1,118)	43,063	(5,318)
Net (loss) income	(9,970)	42,460	(11,585)
Other comprehensive loss			
Unrealized loss on investments available for sale	(21)	(13)	(40)
Comprehensive (loss) income	$ (9,991)	$ 42,447	$ (11,625)
Basic and diluted income (loss) per share			
Income (loss) from continuing operations	$ (0.26)	$ (0.02)	$ (0.19)
Income (loss) from discontinued operations	(0.03)	1.29	(0.16)
Basic income (loss) per share	$ (0.29)	$ 1.27	$ (0.35)
Weighted average common shares (basic and diluted)	34,263	33,307	32,859

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

OSIRIS THERAPEUTICS, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(amounts in thousands, except for share and per share data)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
Balance at January 1, 2011	**32,827,521**	**$ 33**	**$ 278,092**	**$ 20**	**$ (232,327)**	**$ 45,818**
Revision to prior period financial statements (see Note 2)	—	—	—	—	(198)	(198)
Balance at January 1, 2011 as revised	**32,827,521**	**$ 33**	**$ 278,092**	**$ 20**	**$ (232,525)**	**$ 45,620**
Exercise of options to purchase common stock ($.40- $7.74 per share)	28,708	—	87	—	—	87
Share-based payment-director services ($5.08 per share)	25,000	—	127	—	—	127
Share-based payment-employee compensation	—	—	963	—	—	963
Net loss	—	—	—	—	(11,585)	(11,585)
Unrealized gain on investments available for sale	—	—	—	(40)	—	(40)
Balance at December 31, 2012	**32,881,229**	**$ 33**	**$ 279,269**	**$ (20)**	**$ (244,110)**	**$ 35,172**
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 ($11.00 per share)	567,610	1	(1)	—	—	—
Share-based payment-employee compensation	—	—	1,061	—	—	1,061
Net income	—	—	—	—	42,460	42,460
Unrealized loss on investments available for sale	—	—	—	(13)	—	(13)
Balance at December 31, 2013	**34,114,603**	**$ 34**	**$ 282,702**	**$ (33)**	**$ (201,650)**	**$ 81,053**
Exercise of options to purchase common stock ($0.40 - $14.19 per share)	204,085	1	1,684	—	—	1,685
Share-based payment-director services ($14.93 per share)	27,000	—	403	—	—	403
Share-based compensation - employees	—	—	2,526	—	—	2,526
Net loss (Restated)	—	—	—	—	(9,970)	(9,970)
Unrealized loss on investments available for sale	—	—	—	(21)	—	(21)
Windfall tax benefit from stock-based compensation	—	—	5	—	—	5
Balance at December 31, 2014 (Restated)	**34,345,688**	**$ 35**	**$ 287,320**	**$ (54)**	**$ (211,620)**	**$ 75,681**

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

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

	Year ended December 31,		
	2014 (Restated)	2013	2012
Cash flows from operating activities:			
Continuing operations			
Loss from continuing operations	$ (8,852)	$ (603)	$ (6,267)
Adjustments to reconcile loss from continuing operations to net cash used in operations of continuing operations:			
Unrealized loss (gain) on trading securities	401	(401)	—
Depreciation and amortization	940	587	552
Non cash share-based payments	2,929	583	492
Provision for bad debts	1,628	80	22
Changes in operating assets and liabilities:			
Accounts receivable	(7,542)	(4,685)	(2,185)
Inventory	(7,895)	(456)	(642)
Prepaid expenses, and other current assets	(2,832)	88	(293)
Tax receivable	(10)	(160)	2,188
Other assets	(95)	—	—
Deferred revenue	—	(947)	685
Accounts payable, accrued expenses, and other liabilities	2,572	2,605	665
Net cash used in operating activities of continuing operations	(18,756)	(3,309)	(4,783)
Discontinued operations			
Loss from discontinued operations	(1,118)	(6,668)	(5,318)
Adjustments to reconcile loss from discontinued operations to net cash used in operations of discontinued operations:			
Expiration of price protection derivative related to trading securities	1,685	(1,705)	—
Depreciation and amortization	—	156	156
Non cash share-based payments	—	658	598
Changes in operating assets and liabilities:			
Accounts receivable and other current assets	15,091	113	(172)
Accounts payable and accrued expenses	(57)	(2,846)	(419)
Deferred revenue	—	—	(3,333)
Net cash provided by (used in) operations of discontinued operations	15,601	(10,292)	(8,488)
Net cash used in operating activities	(3,155)	(13,601)	(13,271)
Cash flows from investing activities:			
Purchases of property and equipment	(1,123)	(528)	(128)
Proceeds from sale of discontinued operations, net	—	19,751	—
Proceeds from sale of investments available for sale	114,374	55,357	217,185
Purchases of investments available for sale	(112,192)	(62,640)	(203,733)
Net cash provided by investing activities	1,059	11,940	13,324
Cash flows from financing activities:			
Principal payments on capital lease obligations	(45)	(44)	(22)
Restricted cash	243	74	75
Proceeds from the exercise of options to purchase common stock	1,685	2,193	87
Windfall benefit from stock-based compensation	5	—	—
Net cash provided by financing activities	1,888	2,223	140
Net (decrease) increase in cash	(208)	562	193
Cash at beginning of period	2,416	1,854	1,661
Cash at end of period	$ 2,208	$ 2,416	$ 1,854
Supplemental disclosure of cash flows information:			
Cash paid for income taxes	$ 619	$ 539	$ —
Supplemental disclosure of non cash activities:			
Deferred compensation related to Stryker agreement	5,000	—	—
Equipment acquired under a capital lease	—	—	228
Trading securities from the sales of discontinued operations	—	15,000	—
Guaranteed payment related to trading securities	4,409	—	—
Purchase price guarantee related to trading securities	—	1,685	—
Proceeds receivable due from sale of discontinued operations	—	15,000	—
Unrealized loss on investments available for sale	21	13	40

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

OSIRIS THERAPEUTICS, INC.
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2014, 2013 AND 2012

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 the approval of our stockholders, we reincorporated as a Maryland corporation on May 31, 2010. We are a world leader in researching, developing and marketing cellular regenerative medicine products that improve the health and lives of patients and lower overall healthcare costs. We continue to advance research and development ("R&D") in biotechnology by focusing on innovation in regenerative medicine, including bioengineering, stem cell research and viable tissue-based products. Osiris has achieved commercial success with products in orthopedics, sports medicine and wound care.

From 2010 to 2013, we operated our business in two segments, Biosurgery and Therapeutics. 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. 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 3— *Discontinued Operations* below, on October 10, 2013, we entered into an Asset Purchase Agreement (the "Purchase Agreement") with Mesoblast International SARL ("Mesoblast"), a wholly owned subsidiary of Mesoblast Limited ("Mesoblast Limited"), to sell our Therapeutics segment, including all of our culture expanded mesenchymal stem cell ("ceMSC") 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 generally accepted accounting principles in the United States ("GAAP") 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 instrument obtained in connection with the sale of our former Therapeutics business.

Restatement and Revisions to Prior Financial statements

We have restated our audited financial statements for the year ended December 31, 2014. For more information about the restatement, see Note 2 below. Note 16 below includes restated unaudited interim financial statements for 2014. In addition to the restatement of the annual and interim periods in 2014, we have also corrected immaterial errors in our financial statements for the years ended December 31, 2013, 2012 and 2011. See "Revision of the Prior Period Financial Statement" in Note 2 for a description of the revisions to correct the immaterial errors in the years ended December 31, 2013, 2012, and 2011.

Reclassifications

The previously reported columns of the Company's Statements of Comprehensive Income (Loss) for the years ended December 31, 2014, 2013 and 2012 reflect the reclassification of operating expenses between captions in the operating expense section of such financial statements in order to report such expenses consistently over the three years then ended. These reclassifications did not affect our results of operations or financial positions for the years presented.

Cash

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.

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 to be past due. As of December 31, 2014 and 2013, accounts receivable in the accompanying balance sheets are reported net of a $1.7 million and an $78,000 allowance for doubtful accounts, respectively. We have incurred bad debt expense of $1.6 million, $80,000 and $22,000 related to our Biosurgery operations during 2014, 2013 and 2012, respectively.

Inventory

We begin 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, finished goods available for sale and products held by customers under consignment sales arrangements. 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 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 2014, 2013 or 2012.

Derivative and Securities Received in Business Disposition — Trading Securities

All derivative instruments within the scope of Accounting Standards Codification ("ASC") 815, Derivatives and Hedging, are recorded on the balance sheet at fair value. As of December 31, 2013 our only derivative instrument was the price guarantee regarding the payment received in restricted Mesoblast Limited shares described in Note 14— *Derivative and Securities Received in Business Disposition* below. We do not hold derivative financial instruments for trading purposes.

As discussed in Note 3— *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, the parent of the purchaser, Mesoblast. We were required to hold that stock for one year from the date of receipt. This agreed upon holding period was later extended to May 31, 2015. Mesoblast Limited is a public company and its stock is traded on the Australian Stock Exchange. As of December 31, 2014 and 2013, we reflect the investment as a current asset in Trading Securities, at market value as of the balance sheet dates, since it was our intent to sell our Mesoblast Limited shares following the expiration of the agreed upon holding period. In December 2014, the price protection on these shares expired, but Mesoblast Limited agreed to pay us $15 million in cash for the stock in the first half of 2015 and the holding period of the shares was extended to May 2015. Accordingly, this $15 million is shown as $10.6 million in Trading Securities and $4.4 million in Other Receivables on our balance sheets as of December 31, 2014.

The Mesoblast Limited stock was previously subject to limited price protection for the one year required holding period. To the extent the value of those shares decreased during the holding period, Mesoblast was required to pay us for the decrease in value. This payment was to be made at least one half in cash and at the option of Mesoblast, up to one half in additional shares of Mesoblast Limited stock. Any additional Mesoblast Limited stock would also have to be held for one year during which period there was no further price protection. In 2013, the price protection was accounted for as a derivative under ASC 815, Derivatives and Hedging, and, as such was recorded on the balance sheets at fair value, with changes recognized in net income. We 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. The price protection ended in December 2014 and we no longer have a derivative instrument.

Revenue Recognition

We sell our products through our direct sales force and our distributor network. Some of our distributors act as principals buying our product at a stipulated price and selling to their end-use (clinical provider) customers at a marked-up price. Other distributors act as agents selling to end-use customers in exchange for earning sales commissions and/or administrative support fees. Revenue from sales to distributors who are principals is recorded at our sales price to the distributor, while revenue from sales to distributors who function as agents to Osiris is recorded at the sales price to the end-use customer.

We recognize revenue from sales of our products when title and the risk of loss pass to the customer, persuasive evidence of an arrangement exists, sales amounts are fixed and determinable and collectability is reasonably assured.

We recognize revenue upon shipment when a customer provides a purchase order or other documentation evidencing their acceptance of ownership risks in advance of shipment. Many of our customers accept the risks of ownership only when they use (implant) our product. For these customers, we recognize revenue upon our receipt of notice of product use and classify products shipped to these customers as consignment inventory pending receipt of such notice.

With regard to a number of transactions in 2014, the Company granted unusually long payment terms to certain of its distributors. As further described in Note 2, the Company has determined that these unusually long payment terms caused these transactions to fail the "fixed and determinable" criteria required under GAAP to recognize revenue. Accordingly, the accompanying 2014 financial statements have been restated to reverse revenue from sales initiated under these unusually long payment terms and will recognize such transactions as revenue in a future period only when cash payment is received from the distributor.

In December 2014, we entered into exclusive distribution agreements with a subsidiary of Stryker Corporation ("Stryker") for the marketing and distribution of BIO(4)™, formerly branded by the Company as OvationOS®, our viable bone matrix allograft. Pursuant to the agreement, Stryker has been granted worldwide distribution rights to the product and any improvements, for all surgical applications. We will be responsible for supply, manufacturing, inventory management, shipments to customers, continued research and product improvement activities. We will recognize as revenue the amounts charged to customers for the allografts and related services. Commissions and administrative fees paid to Stryker will be accounted for as selling expenses, as Stryker is acting as outside sales and marketing agent for Osiris. We are entitled to receive an initial exclusivity fee of $5 million and additional fees upon any exercise by Stryker of its right to extend the initial term, whether on an exclusive or non-exclusive basis. The exclusivity fee and any extension fees subsequently received are considered to be adjustments of the selling

expenses. As such, we recognize the $5 million exclusivity fee as deferred revenue to be amortized over the related exclusivity period in proportion to the expected fees to be paid to Stryker, as an offset to selling expenses. At December 31, 2014, Osiris recorded a $5 million receivable included in other receivables with the offset to short-term deferred exclusivity fee revenue of $1.67 million and long-term deferred exclusivity fee revenue of $3.33 million included in other long term liabilities.

In October 2014, we entered into an exclusive commercial and development partnership for our cartilage product, Cartiform®, with Arthrex, Inc. ("Arthrex"). The agreement provides Arthrex with exclusive commercial distribution rights to Cartiform® beginning in 2015. We will be responsible for manufacturing, continued research and product improvement activities. The responsibilities related to the design and conduct of future clinical development programs will be shared between both organizations. Pursuant to the agreement, Arthrex is entitled to a certain commission on Cartiform® sales. We will recognize the full sales price as revenue and account for the payment to Arthrex as commission expense.

Therapeutics Revenue Recognition

In our former Therapeutics business, we evaluated revenue 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.

Revenue 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 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 Graft versus Host Disease. 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 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.

Income Taxes

Deferred tax liabilities and assets are recognized for the estimated future tax consequences of temporary differences, income tax credits and net operating loss carryforwards. Temporary differences are primarily the result of the differences between the tax bases of assets and liabilities and their financial reporting values. Deferred tax liabilities and assets are measured by applying the enacted statutory tax rates applicable to the future years in which deferred tax liabilities or assets are expected to be settled or realized. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense, if any, consists of the taxes payable for the current period and the change during the period in deferred tax assets and liabilities.

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, 2014 and 2013, we had no accruals for interest or penalties related to income tax matters.

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, 2014 excludes all 1,608,557 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 from continuing operations for the year ended December 31, 2013 excludes 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.

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 to reflect actual forfeitures.

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 products. Trade accounts receivable in the accompanying balance sheets consist primarily of amounts due from distributors and end-user customers of our products within the United States. For the year ended and as of December 31, 2014, we had two customers that comprised 51% of our revenue and 31% of our trade net receivables. For the year ended and as of December 31, 2013, we had three customers that comprised 60% of our revenue and 39% of our trade net receivables. As discussed under "Trade Accounts Receivable" above, we incurred bad debt expense of $1.6 million, $80,000 and $22,000 related to our Biosurgery operations during 2014, 2013 and 2012, respectively.

Recent Accounting Guidance Not Yet Adopted at December 31, 2014

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09, "Revenue from Contracts with Customers," which requires an entity to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services.

The new standard will replace most of the existing revenue recognition standards in GAAP when it becomes effective on January 1, 2017. Early adoption is not permitted. The new standard can be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of the change recognized at the date of the initial application. We are currently assessing the impact the adoption of ASU 2014-09 will have on our financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements - Going Concern," which require management to evaluate, at each reporting period, whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financial statements are issued and provide related disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. We are currently assessing the impact the adoption of ASU 2014-15 will have on our financial statements.

2. Restatement of the Financial Statements

This Note 2 to the Company's financial statements discloses the impact on the restated financial statements for the year ended December 31, 2014 and the nature and derivation of the associated adjustments. The impact of the restatement on interim periods in 2014 is described in Note 16 (unaudited). The corrections contained in these restated financial statements are referred to herein as the "Restatement." See also "Revision of the Prior Period Financial Statements" in this Note 2 for a description of certain immaterial errors in the years ended December 31, 2013, 2012 and 2011.

Restatement Background

As previously described in the Company's Current Report on Form 8-K filed on March 15, 2015, the Audit Committee, in consultation with management, concluded that the Company's unaudited interim and audited annual financial statements previously issued for 2014 and its unaudited interim financial statements previously issued for the three and nine months ended September 30, 2015 should not be relied upon due to errors identified in such financial statements related to the timing of revenue recognition under contracts with distributors. In the Company's Current Report on Form 8-K filed on November 20, 2015, the Company previously disclosed its conclusion that its unaudited interim financial statements for the quarters ended March 31, 2015 and June 30, 2015 should not be relied upon for similar reasons. The corrections contained in these restated financial statements were prepared following an independent review by the Audit Committee (the "Audit Committee") of the Company's Board of Directors into certain accounting matters (the "Independent Review") as described in the Explanatory Note.

Impact of the Restatement

Based on the Independent Review, the Audit Committee concluded, among other things, that there were both material and immaterial misstatements in the financial statements for the year ended December 31, 2014. The correction of these material and other immaterial errors decreased product revenue by $9.0 million for the year ended December 31, 2014. The correction of these errors decreased net income for the year ended December 31, 2014 by $8.2 million.

The primary material errors corrected in the restatement relate to recognition of revenue under distributor sales arrangements and valuation of inventory.

Recognition of revenue under distributor sales arrangements

Based on the Audit Committee's Independent Review, the Company determined that it had erred in its application of GAAP with respect to the recognition of revenue arising from the two types of distributor sales arrangements described below:

1. Certain distributor sales did not meet the criteria for recognizing revenue in 2014 . During 2014, the Company provided unusually long payment terms to two distributors that were affiliated with each other. Granting a customer unusually long payment terms can cause the related sales transactions to fail the "fixed and determinable" criteria required under GAAP to recognize revenue. Also, for one sales transaction to a third distributor in the fourth quarter of 2014, the Company determined that evidence existed which suggests that an arrangement under GAAP did not exist in 2014. Accordingly, revenue arising from these transactions did not meet the criteria for recognizing revenue under GAAP in 2014. Correction of these errors decreased 2014 revenue by $10.3 million and decreased trade accounts receivable as of December 31, 2014 by the same amount. Net of product costs and sales commission expenses arising from these transactions, correction of these errors decreased 2014 net income by $5.6 million. Under GAAP, the $10.3 million revenue reversed in 2014 may be recognized in a future period on an accrual basis upon meeting the criteria for revenue recognition or, if such criteria is not met, on a cash basis, upon receipt of payment from the customer.

2. Sales through government contracting agent. The Company utilizes a government contracting agent through which it sells to facilities of the United States Department of Veterans Affairs and the United States Department of Defense under the agent's GSA Federal Supply Schedule. The Company erred in reporting revenue from such sales net of the agent's fees, although GAAP (and the Company's policy) requires that revenue arising from contractual arrangements of this type be reported at the gross price paid by the end user, and that the related fees be reported as a sales expense. Correction of this error, with respect to these sales, increased both 2014 sales and marketing expenses and product revenue by $1.5 million and, accordingly, had no impact on net income.

Taken together, correction of the errors arising from these two types of distributor sales arrangements decreased 2014 product revenue by $8.8 million (consisting of a $10.3 million decrease described in paragraph (1) above offset by a $1.5 million increase described in paragraph (2) above). In addition, the Company corrected other revenue accounting errors unrelated to distributor sales arrangements which decreased 2014 product revenue by an additional $241,000. As a result, the correction of errors in the Restatement decreased 2014 product revenue by a total $9.0 million.

Consistent with corrections in the Company's recognition revenue, the product costs arising from the distributor sales transactions for which revenue has been reversed have also been reversed and added back to inventory. As a result of such corrections, inventory as of December 31, 2014 increased by $852,000 and the cost of product revenue for the year then ended decreased by the same amount. Similarly, sales commission expenses incurred during 2014 in connection with the distributor sales transactions for which revenue has been reversed have also been reversed. As a result of such corrections, prepaid expenses increased by $2.2 million, with respect to such expenses paid during 2014, and accrued expenses decreased by $1.5 million, with respect to commissions unpaid and accrued as of December 31, 2014, while 2014 sales and marketing expenses decreased by $3.8 million.

Valuation of inventory and accounting for consigned inventory quantities

Management determined that there were errors in the valuation of the Company's finished goods inventory resulting from computational errors, failure to update and apply current cost information in the calculation of unit costs, and non-timely identification and write-off of products that were no longer salable as determined by the Company's quality assurance procedures. In addition, management determined the need to establish a reserve for consigned finished goods inventory as the Company had not adequately monitored the ultimate disposition of consigned goods whereby some were returned, or scrapped, or used by the consignee. Lastly, management determined the need to establish a reserve for work-in-process inventory which largely consists of product in quarantine pending the outcome of the Company's quality assurance procedures. This process results in a reasonably consistent identification of product that is unsalable. Correction of these errors, to write-down the value of inventory as of December 31, 2014, increased 2014 cost of revenue and decreased 2014 net income by $2.0 million.

Bad debt reserve

Management determined that it did not correctly assess the collectability of accounts receivable and determined an appropriate allowance for doubtful accounts as of December 31, 2014. Correction of this error, by increasing its 2014 bad debt expenses and allowance for doubtful accounts as of December 31, 2014, increased the Company's 2014 general and administrative expenses by approximately $450,000 and reduced its accounts receivables as of December 31, 2014 by the same amount.

Classification of costs and expenses to income statement captions

Management determined that errors had been made in classification of costs and expenses to income statement captions. Correction of these errors reduced 2014 cost of product revenue and research and development expenses by $4.1 million and $3.6 million, respectively, and increased sales and marketing and general and administrative expenses by $7.6 million and $134,000, respectively.

Other adjustments

In addition to the error corrections mentioned above, adjustments were made to the financial statements for various immaterial errors identified by management and the Audit Committee during the course of the restatement process. The net impact of such adjustments was to decrease net income by $507,000 for the year ended December 31, 2014.

Tax effect of restatement adjustments

The Company reduced 2014 income tax expense by $585,000 to account for the impact of the adjustments in the Restatement described above.

The financial reporting impact of the error correction adjustments described above is as follows:

(a) Revenue Recognition Error Corrections (in thousands)	Year ended December 31, 2014 Net Income Impact	Stockholders' Equity Impact
Product revenue	$ (9,032)	$ —
Cost of product revenue	852	—
Sales and marketing expenses	2,323	—
Trade accounts receivable	—	(10,484)
Inventory	—	852
Prepaids and other current assets	—	2,244
Accounts payable and accrued expenses	—	1,531
Net (decrease)/increase	**$ (5,857)**	**$ (5,857)**

(b) Inventory Valuation Error Corrections (in thousands)	Year ended December 31, 2014 Net Income Impact	Stockholders' Equity Impact
Cost of product revenue	$ (1,952)	$ —
Inventory	—	(1,952)
Net (decrease)/increase	**$ (1,952)**	**$ (1,952)**

(c) Bad Debt Reserve (in thousands)	Year ended December 31, 2014 Net Income Impact	Stockholders' Equity Impact
General and administrative expenses	$ (450)	$ —
Trade accounts receivable	—	(450)
Net (decrease)/increase	**$ (450)**	**$ (450)**

(d) Expense Caption Classification Error Corrections (in thousands)	Year ended December 31, 2014 Net Income Impact	Stockholders' Equity Impact
Cost of product revenue	$ 4,134	$ —
Research and development expenses	3,619	—
Sales and marketing expenses	(7,619)	—
General and administrative expenses	(134)	
Net (decrease)/increase	**$ —**	**$ —**

(e) Other Immaterial Error Corrections (in thousands)	Year ended December 31, 2014 Net Income Impact	Stockholders' Equity Impact
Cost of product revenue	$ 251	$ —
Research and development expenses	(171)	—
Sales and marketing expenses	(518)	
General and administrative expenses	(117)	—
Related party fees	112	—
Income tax expense	(64)	—
Other receivables	—	216
Property and equipment	—	(8)
Accounts payable and accrued expenses	—	(814)
Additional paid-in capital	—	203
Beginning retained earnings		(104)
Net (decrease)/increase	**$ (507)**	**$ (507)**

(f) Tax effect of restatement adjustments (in thousands)	Year ended December 31, 2014 Net Income Impact	Stockholders' Equity Impact
Income tax expense	$ 160	$ —
Loss from discontinued operations	425	—
Other receivables	—	(86)
Accounts payable and accrued expenses	—	669
Additional paid-in capital		2
Net (decrease)/increase	**$ 585**	**$ 585**

Summary of Restatement Adjustments (in thousands)	Year ended December 31, 2014 Net Income Impact	Stockholders' Equity Impact	Restatement Ref
Product revenue	$ (9,032)	$ —	(a)
Cost of product revenue	3,285	—	(a), (b), (d), (e)
Research and development expenses	3,448	—	(d), (e)
Sales and marketing expenses	(5,814)	—	(a), (d), (e)
General and administrative expenses	(701)	—	(c), (d), (e)
Related party fees	112	—	(e)
Income tax expense	96	—	(e), (f)
Loss from discontinued operations	425	—	(f)
Trade accounts receivable	—	(10,934)	(a), (c)
Other receivables	—	130	(e), (f)
Inventory	—	(1,100)	(a), (b)
Prepaids and other current assets	—	2,244	(a)
Property and equipment	—	(8)	(e)
Accounts payable and accrued expenses	—	1,386	(a), (e), (f)
Additional paid-in capital	—	205	(e), (f)
Beginning retained earnings	—	(104)	(e)
Net (decrease)/increase	**$ (8,181)**	**$ (8,181)**	

The following table presents the effects of the Restatement on the Company's Balance Sheet as of December 31, 2014.

(in thousands, except per share data)	December 31, 2014 (Previously Reported)	Restatement Adjustments	2014 (Restated)	Restatement Ref
Assets				
Current assets:				
Cash	$ 2,208	$ —	$ 2,208	
Investments available for sale	37,305	—	37,305	
Trading securities	10,591	—	10,591	
Trade accounts receivable, net of reserves	24,307	(10,934)	13,373	(a), (c)
Other receivables	9,951	130	10,081	(e), (f)
Inventory	10,924	(1,100)	9,824	(a), (b)
Prepaid expenses and other current assets	650	2,244	2,894	(a)
Total current assets	95,936	(9,960)	86,276	
Property and equipment, net	2,087	(8)	2,079	(e)
Other assets	95	—	95	
Total assets	$ 98,118	$ (9,668)	$ 88,450	
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	$ 8,854	$ (1,386)	$ 7,468	(a), (e), (f)
Capital lease obligations, current portion	45	—	45	
Deferred exclusivity fee revenue, current portion	1,667	—	1,667	
Total current liabilities	10,566	(1,386)	9,180	
Other long-term liabilities	3,589	—	3,589	
Total liabilities	14,155	(1,386)	12,769	
Commitments and contingencies				
Stockholders' equity				
Common stock, $.001 par value, 90,000 shares authorized, 34,346 shares outstanding	35	—	35	
Additional paid-in-capital	287,525	(205)	287,320	(e), (f)
Accumulated other comprehensive loss	(54)	—	(54)	
Accumulated deficit	(203,543)	(8,077)	(211,620)	
Total stockholders' equity	83,963	(8,282)	75,681	
Total liabilities and stockholders' equity	$ 98,118	$ (9,668)	$ 88,450	

The following table presents the effects of the Restatement on the Company's Statement of Comprehensive Income (Loss) for the year ended December 31, 2014.

	Year ended December 31,			
(in thousands, except per share data)	2014 (Previously Reported)	Restatement Adjustments	2014 (Restated)	Restatement Ref
Product revenue	$ 59,867	$ (9,032)	$ 50,835	(a)
Cost of product revenue	13,171	(3,285)	9,886	(a), (b), (d), (e)
Gross profit	46,696	(5,747)	40,949	
Operating expenses				
Research and development	6,862	(3,448)	3,414	(d), (e)
Sales and marketing	30,570	5,814	36,384	(a), (d), (e)
General and administrative	6,862	701	7,563	(c), (d), (e)
Fees paid to related parties	281	(112)	169	(e)
Share based payments to related parties	403	—	403	
Total operating expenses	44,978	2,955	47,933	
Income (loss) from operations	1,718	(8,702)	(6,984)	
Other (expense) income, net	(1,771)	—	(1,771)	
Loss from continuing operations, before income taxes	(53)	(8,702)	(8,755)	
Income tax (expense) benefit	(193)	96	(97)	(e), (f)
Loss from continuing operations	(246)	(8,606)	(8,852)	
Discontinued operations				
Loss from operations of discontinued operations, net of income taxes of $516 in 2014	(1,543)	425	(1,118)	(f)
(Loss) income from discontinued operations	(1,543)	425	(1,118)	
Net (loss) income	(1,789)	(8,181)	(9,970)	
Other comprehensive loss				
Unrealized loss on investments available for sale	(21)	—	(21)	
Comprehensive (loss) income	$ (1,810)	$ (8,181)	$ (9,991)	
Basic and diluted loss per share				
Loss from continuing operations	$ (0.01)	$ (0.25)	$ (0.26)	
Loss from discontinued operations	(0.04)	0.01	(0.03)	
Basic and diluted loss per share	$ (0.05)	$ (0.24)	$ (0.29)	
Weighted average common shares (basic and diluted)	34,263		34,263	

The following table presents the effects of the Restatement on the Company's Statement of Cash Flows for the year ended December 31, 2014.

(in thousands)	Year ended December 31, 2014 (Previously Reported)	Restatement Adjustments	2014 (Restated)	Restatement Ref
Cash flows from operating activities:				
Continuing operations				
Loss from continuing operations	$ (246)	$ (8,606)	$ (8,852)	
Adjustments to reconcile loss from continuing operations to net cash used in operations of continuing operations:				
Unrealized loss on trading securities	401	—	401	
Depreciation and amortization	940	—	940	
Non cash share-based payments	3,132	(203)	2,929	(e)
Provision for bad debts	1,178	450	1,628	(c)
Changes in operating assets and liabilities:				
Accounts receivable	(18,026)	10,484	(7,542)	(a)
Inventory	(8,995)	1,100	(7,895)	(a), (b)
Prepaid expenses, and other current assets	(572)	(2,260)	(2,832)	(a), (e),
Tax receivable	—	(10)	(10)	(f)
Other assets	(95)	—	(95)	
Accounts payable, accrued expenses, and other liabilities	3,958	(1,386)	2,572	(a), (e), (f)
Net cash used in operating activities of continuing operations	(18,325)	(431)	(18,756)	
Discontinued operations				
Loss from discontinued operations	(1,543)	425	(1,118)	(f)
Adjustments to reconcile loss from discontinued operations to net cash used in operations of discontinued operations:				
Expiration of price protection derivative related to trading securities	1,685	—	1,685	
Changes in operating assets and liabilities:				
Accounts receivable and other current assets	15,091	—	15,091	
Accounts payable and accrued expenses	(57)	—	(57)	
Net cash provided by operations of discontinued operations	15,176	425	15,601	
Net cash used in operating activities	(3,149)	(6)	(3,155)	
Cash flows from investing activities:				
Purchases of property and equipment	(1,131)	8	(1,123)	(e)
Proceeds from sale of investments available for sale	114,374	—	114,374	
Purchases of investments available for sale	(112,192)	—	(112,192)	
Net cash provided by investing activities	1,051	8	1,059	
Cash flows from financing activities:				
Principal payments on capital lease obligations	(45)	—	(45)	
Restricted cash	243	—	243	
Proceeds from the exercise of options to purchase common stock	1,685	—	1,685	
Windfall benefit from stock-based compensation	7	(2)	5	(f)
Net cash provided by financing activities	1,890	(2)	1,888	
Net (decrease) in cash	(208)	—	(208)	
Cash at beginning of period	2,416	—	2,416	
Cash at end of period	$ 2,208	$ —	$ 2,208	
Supplemental disclosure of cash flows information:				
Cash paid for income taxes	$ 619	—	$ 619	
Supplemental disclosure of non cash activities:				
Deferred compensation related to Stryker agreement	5,000	—	5,000	
Guaranteed payment related to trading securities	4,409	—	4,409	
Unrealized loss on investments available for sale	21	—	21	

Revision of Prior Period Financial Statements

In addition to the correction of the errors in 2014 in the Restatement described above, the Company also corrected certain immaterial errors in its financial statements for years ended December 31, 2013, 2012 and 2011 contained herein. In accordance with ASC 650-10-S99 and S55 (formerly Staff Accounting Bulletins ("SAB") No. 99 and No. 108), *Accounting Changes and Error Corrections,* the Company concluded that these errors were, individually, and in the aggregate, not material, quantitatively or qualitatively, to the financial statements in these periods. The adjustments to correct the immaterial errors only had an impact on certain captions within the comprehensive statement of income (loss) and balance sheets as set forth below.

	For year ended December 31,					
	2013		2012		2011	
(in thousands)	Net Income Impact	Stockholders' Equity Impact	Net Income Impact	Stockholders' Equity Impact	Net Income Impact	Stockholders' Equity Impact
Revenue Recognition						
Product revenue	$ 1,390	$ —	$ (685)	$ —	$ (262)	$ —
Cost of product revenue	(195)	—	131	—	64	—
Sales and marketing expenses	(443)	—	—	—	—	—
Deferred revenue	—	947	—	(685)	—	(262)
Inventory	—	(195)	—	131	—	64
Directors' Expenses						
Other receivables	—	70	—	34	—	—
Fees paid to related parties	70	—	34	—	—	—
Tax Effect of the Adjustments						
Income taxes benefit	(332)	—	—	—	—	—
Income from discontinued operations	332	—	—	—	—	—
Net increase/(decrease)	**$ 822**	**$ 822**	**$ (520)**	**$ (520)**	**$ (198)**	**$ (198)**

Adjustments related to periods prior to January 1, 2012 are reflected as an adjustment to beginning retained earnings for the year ended December 31, 2012.

The immaterial errors to product revenue in the table above were identified during the Independent Review and relate to a type of distributor sales arrangement under which the distributor agrees to be billed in advance of the Company's shipment of ordered products, commonly referred to as "bill and hold" arrangements. Historically, the Company had recognized product revenue upon shipment provided a purchase order or other documentation evidencing the customer's acceptance of the risks of ownership had been received before shipment, or upon receipt of notification of product use (implantation) if no such documentation was provided in advance. However, a limited number of distributor sales transactions in 2012 and 2011 were accounted for as bill and hold arrangements, which were initially deemed to qualify under GAAP for revenue recognition upon invoicing of the customer even though shipment was expected to take place at an unspecified future date. In the Independent Review, the Audit Committee determined that these transactions had failed to meet all of the GAAP criteria required to recognize revenue in advance of shipment and concluded that recognition of such revenue should be reversed and recognized in a subsequent period when the product had been shipped to the distributors or their end-use (clinical provider) customers. Correction of these errors, to recognize revenue when the shipment is completed, decreased 2012 and 2011 revenue by $685,000 and $262,000, respectively. Recognition of such revenue upon completion of shipment increased 2013 revenue by $947,000. Net of product costs arising from these transactions, correction of these errors decreased 2012 and 2011 net income by $554,000 and $198,000, respectively, and increased 2013 net income by $752,000.

The Company utilizes a government contracting agent through which it sells to the United States Department of Veterans Affairs and the United States Department of Defense facilities under the agent's GSA Federal Supply Schedule. The Company erred in reporting revenue from such sales net of the agent's contracting fees, although GAAP (and the Company's policy) requires that revenue arising from contractual arrangements of this type be reported at the gross price paid by the end user, and that the related fees be reported as a sales expense. Correction of this error, with respect to these sales, increased both 2013 sales and marketing expenses and product revenue by $443,000 and, accordingly, had no impact on net income.

The Company has also recorded adjustments reducing related party expenses by $70,000 and $34,000 for the years ended December 31, 2013 and 2012, respectively, which represent the amounts of expenses that the Audit Committee determined should not have reimbursed to the Chairman of the Board in those years. See Note 10, *Related Party Transactions and Warrant,* for more details.

The following table presents the effects of the revision of the Company's previously issued Balance Sheet as of December 31, 2013.

(in thousands, except per share data)	December 31, 2013 (Previously Reported)	Adjustments	2013 (Revised)
Assets			
Current assets:			
Cash	$ 2,416	$ —	$ 2,416
Investments available for sale	39,508	—	39,508
Trading securities	17,086	—	17,086
Trade accounts receivable, net of reserves	7,459	—	7,459
Other receivables	15,265	104	15,369
Inventory	1,929	—	1,929
Prepaid expenses and other current assets	355	—	355
Current assets of discontinued operations	91	—	91
Total current assets	84,109	104	84,213
Property and equipment, net	1,896	—	1,896
Deferred tax asset	5,849	—	5,849
Restricted cash	243	—	243
Total assets	$ 92,097	$ 104	$ 92,201
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable and accrued expenses	$ 4,842	$ —	$ 4,842
Capital lease obligations, current portion	45	—	45
Deferred exclusivity fee revenue, current portion	—	—	—
Deferred tax liability	5,849	—	5,849
Current liabilities of discontinued operations	57	—	57
Total current liabilities	10,793	—	10,793
Other long-term liabilities	355	—	355
Total liabilities	11,148	—	11,148
Commitments and contingencies			
Stockholders' equity			
Common stock, $.001 par value, 90,000 shares authorized, 34,115 shares outstanding	34	—	34
Additional paid-in-capital	282,702	—	282,702
Accumulated other comprehensive loss	(33)	—	(33)
Accumulated deficit	(201,754)	104	(201,650)
Total stockholders' equity	80,949	104	81,053
Total liabilities and stockholders' equity	$ 92,097	$ 104	$ 92,201

The following table presents the effects of the revision of the Company's previously issued Statement of Comprehensive Income (Loss) for the year ended December 31, 2013.

(in thousands, except per share data)	Year ended December 31, 2013 (Previously Reported)	Adjustments	2013 (Revised)
Product revenue	$ 24,308	$ 1,390	$ 25,698
Cost of product revenue	6,656	195	6,851
Gross profit	17,652	1,195	18,847
Operating expenses:			
Research and development	4,330	—	4,330
Sales and marketing	13,367	443	13,810
General and administrative	2,538	—	2,538
Fees paid to related parties	70	(70)	—
Share based payments to related parties	180	—	180
Total operating expenses	20,485	373	20,858
Income (loss) from operations	(2,833)	822	(2,011)
Other income, net	414	—	414
Loss from continuing operations, before income taxes	(2,419)	822	(1,597)
Income tax (expense) benefit	1,326	(332)	994
Loss from continuing operations	(1,093)	490	(603)
Discontinued operations:			
Loss from operations of discontinued operations, net of income taxes of $0	(6,668)	—	(6,668)
Gain from sale of discontinued operations, net of income taxes of $1,374 in 2013	49,399	332	49,731
Income from discontinued operations	42,731	332	43,063
Net income	41,638	822	42,460
Other comprehensive loss			
Unrealized loss on investments available for sale	(13)	—	(13)
Comprehensive income	$ 41,625	$ 822	$ 42,447
Basic and diluted income (loss) per share			
Income (loss) from continuing operations	$ (0.04)	$ 0.02	$ (0.02)
Income (loss) from discontinued operations	1.29	0.00	1.29
Basic and diluted income (loss) per share	$ 1.25	$ 0.02	$ 1.27
Weighted average common shares (basic and diluted)	33,307		33,307

The following table presents the effects of the revision of the Company's previously issued Statement of Cash Flows for the year ended December 31, 2013.

(in thousands)	Year ended December 31, 2013 (Previously Reported)	Adjustments	2013 (Revised)
Cash flows from operating activities:			
Continuing operations			
Loss from continuing operations	$ (1,093)	$ 490	$ (603)
Adjustments to reconcile loss from continuing operations to net cash used in operations of continuing operations:			
Unrealized gain on trading securities	(401)	—	(401)
Depreciation and amortization	587	—	587
Non cash share-based payments	583	—	583
Provision for bad debts	80	—	80
Changes in operating assets and liabilities:			
Accounts receivable	(4,685)	—	(4,685)
Inventory	(651)	195	(456)
Prepaid expenses, and other current assets	158	(70)	88
Tax receivable	(160)	—	(160)
Other assets	—	—	—
Deferred revenue	—	(947)	(947)
Accounts payable, accrued expenses, and other liabilities	2,605	—	2,605
Net cash used in operating activities of continuing operations	(2,977)	(332)	(3,309)
Discontinued operations			
Loss from discontinued operations	(6,668)	—	(6,668)
Adjustments to reconcile loss from discontinued operations to net cash used in operations of discontinued operations:			
Expiration of price protection derivative related to trading securities	(1,705)	—	(1,705)
Depreciation and amortization	156	—	156
Non cash share-based payments	658	—	658
Changes in operating assets and liabilities:		—	
Accounts receivable and other current assets	113	—	113
Accounts payable and accrued expenses	(2,846)	—	(2,846)
Net cash used in operations of discontinued operations	(10,292)	—	(10,292)
Net cash used in operating activities	(13,269)	(332)	(13,601)
Cash flows from investing activities:			
Purchases of property and equipment	(528)	—	(528)
Proceeds from sale of discontinued operations, net	19,419	332	19,751
Proceeds from sale of investments available for sale	55,357	—	55,357
Purchases of investments available for sale	(62,640)	—	(62,640)
Net cash provided by investing activities	11,608	332	11,940
Cash flows from financing activities:			
Principal payments on capital lease obligations	(44)	—	(44)
Restricted cash	74	—	74
Proceeds from the exercise of options to purchase common stock	2,193	—	2,193
Net cash provided by financing activities	2,223	—	2,223
Net increase in cash	562	—	562
Cash at beginning of period	1,854	—	1,854
Cash at end of period	$ 2,416	—	$ 2,416
Supplemental disclosure of cash flows information:			
Cash paid for income taxes	$ 539	—	$ 539
Supplemental disclosure of non cash activities:			
Trading securities from the sales of discontinued operations	15,000	—	15,000
Purchase price guarantee related to trading securities	1,685	—	1,685
Proceeds receivable due from sale of discontinued operations	15,000	—	15,000
Unrealized loss on investments available for sale	13	—	13

The following table presents the effects of the revision of the Company's previously issued Statement of Comprehensive Income (Loss) for the year ended December 31, 2012.

(in thousands, per share data)	Year ended December 31, 2012 (Previously Reported)	Adjustments	2012 (Revised)
Product revenue	$ 7,849	$ (685)	$ 7,164
Cost of product revenue	2,551	(131)	2,420
Gross profit	5,298	(554)	4,744
Operating expenses:			
Research and development	4,059	—	4,059
Sales and marketing	2,836	—	2,836
General and administrative	2,282	—	2,282
Fees paid to related parties	36	(34)	2
Share based payments to related parties	1,918	—	1,918
Total operating expenses	11,131	(34)	11,097
Loss from operations	(5,833)	(520)	(6,353)
Other income, net	49	—	49
Loss from continuing operations, before income taxes	(5,784)	(520)	(6,304)
Income tax benefit	37	—	37
Loss from continuing operations	(5,747)	(520)	(6,267)
Discontinued operations:			
Loss from operations of discontinued operations, net of income taxes of $0	(5,318)	—	(5,318)
Loss from discontinued operations	(5,318)	—	(5,318)
Net loss	(11,065)	(520)	(11,585)
Other comprehensive loss			
Unrealized loss on investments available for sale	(40)	—	(40)
Comprehensive loss	$ (11,105)	$ (520)	$ (11,625)
Basic and diluted loss per share			
Loss from continuing operations	$ (0.17)	$ (0.02)	$ (0.19)
Loss from discontinued operations	(0.16)	—	(0.16)
Basic and diluted loss per share	$ (0.33)	$ (0.02)	$ (0.35)
Weighted average common shares (basic)	32,859		32,859

The following table presents the effects of the revision of the Company's previously issued Statement of Cash Flows for the year ended December 31, 2012.

(in thousands)	Year ended December 31, 2012 (Previously Reported)	Restatement Adjustments	2012 (Revised)
Cash flows from operating activities:			
Continuing operations			
Loss from continuing operations	$ (5,747)	$ (520)	$ (6,267)
Adjustments to reconcile loss from continuing operations to net cash used in operations of continuing operations:			
Depreciation and amortization	552	—	552
Non cash share-based payments	492	—	492
Provision for bad debts	22	—	22
Changes in operating assets and liabilities:			
Accounts receivable	(2,185)	—	(2,185)
Inventory	(511)	(131)	(642)
Prepaid expenses, and other current assets	(259)	(34)	(293)
Tax Receivable	2,188	—	2,188
Other assets		—	—
Deferred revenue	—	685	685
Accounts payable, accrued expenses, and other liabilities	665	—	665
Net cash used in operating activities of continuing operations	(4,783)	—	(4,783)
Discontinued operations			
Loss from discontinued operations	(5,318)	—	(5,318)
Adjustments to reconcile loss from discontinued operations to net cash used in operations of discontinued operations:			
Depreciation and amortization	156	—	156
Non cash share-based payments	598	—	598
Changes in operating assets and liabilities:			
Accounts receivable and other current assets	(172)	—	(172)
Accounts payable and accrued expenses	(419)	—	(419)
Deferred revenue	(3,333)	—	(3,333)
Net cash provided by (used in) operations of discontinued operations	(8,488)	—	(8,488)
Net cash used in operating activities	(13,271)	—	(13,271)
Cash flows from investing activities:			
Purchases of property and equipment	(128)	—	(128)
Proceeds from sale of investments available for sale	217,185	—	217,185
Purchases of investments available for sale	(203,733)	—	(203,733)
Net cash provided by investing activities	13,324	—	13,324
Cash flows from financing activities:			
Principal payments on capital lease obligations	(22)	—	(22)
Restricted cash	75	—	75
Proceeds from the exercise of options to purchase common stock	87	—	87
Net cash provided by financing activities	140	—	140
Net increase in cash	193	—	193
Cash at beginning of period	1,661	—	1,661
Cash at end of period	$ 1,854	—	$ 1,854
Supplemental disclosure of cash flows information:			
Cash paid for income taxes	$ —	—	$ —
Supplemental disclosure of non cash activities:			
Equipment acquired under a capital lease	228	—	228
Unrealized loss on investments available for sale	40	—	40

3. Discontinued Operations

As reported on our Current Report on Form 8-K filed on October 10, 2013, we entered into a Purchase Agreement with Mesoblast, pursuant to the terms of which we sold our 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 are 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.

The Purchase Agreement provides for the $50 million of initial payments and up to $50 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, received in April 2014	15,000
Delivery of all scheduled assets under the Transfer Agreement (paid in stock)	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 received at December 31, 2013, payment of $20 million in cash, and $15 million in Mesoblast Limited ordinary shares, which were delivered to us upon completed delivery of the ceMSC assets. The remaining $15 million of the initial consideration was paid in cash in April 2014. The Mesoblast Limited shares received by us were subject to a one year holding period from the date of receipt, but had limited downside protection for a drop in the Mesoblast Limited share price over the holding period. We evaluated this downside protection, and determined that it met 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 December 31, 2013 at its then fair value of $1.7 million, which was reflected in the calculation of the gain on sale of the Therapeutics business. The price protection ended in December 2014 and Mesoblast Limited agreed to pay us no less than $15 million in cash for the stock prior to the end of the first half of 2015. Accordingly, we no longer have a derivative instrument as of December 31, 2014.

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 Limited, in Mesoblast Limited ordinary shares, based on a then current valuation of such shares. Any such Mesoblast 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 presented. We have no continuing involvement with the 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 2014 or 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 $1.4 million.

The net assets allocable to the Therapeutics business at December 31, 2014 and 2013 were as follows:

(in thousands)	2014	2013
Current assets:		
Accounts receivable	$ —	$ 91
Current liabilities:		
Accounts payable and accrued expenses	$ —	$ 57

Summarized operating results of the Therapeutics segment are as follows:

	Year ended December 31,		
(in thousands)	2014 (Restated)	2013	2012
Revenue from collaborative research agreements and royalties	$ 288	$ 639	$ 3,955
Operating expenses:			
Research and development	$ 299	6,426	8,607
General and administrative	591	881	666
Total operating expenses	$ 890	$ 7,307	$ 9,273
Loss from discontinued operations before income tax expense	(602)	(6,668)	(5,318)
Income tax expense	(516)	—	—
Loss from discontinued operations	$ (1,118)	$ (6,668)	$ (5,318)

Revenue for our Therapeutics segment historically consisted primarily of collaborative research agreements and royalties. Because of the disposition of our Therapeutics business in 2013, we no longer incur R&D expenses related to these discontinued operations. Our Therapeutics segment also earned royalty revenue 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. Revenue from our former Therapeutics business include approximately $288,000 of royalty revenue in 2014, $215,000 of royalty revenue in 2013, and $305,000 of royalty revenue in 2012. Revenue from our former Therapeutics business also include approximately $0, $424,000, and $296,000 in cost reimbursement for Prochymal used in our adult expanded access program during 2014, 2013 and 2012, respectively.

4. Segment Reporting

Prior to the sale of our Therapeutics business in 2013, we 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 2011, and began distribution of Cartiform® during 2013. In the second half of 2014 we began commercial sale of OvationOS® (rebranded by Stryker as BIO ^{4TM} in 2015), a cadaveric bone product used in many of the same clinical applications historically served by our placenta-based Ovation® product. Sales of these products have increased with the expansion of our direct sales force and distribution network and the broadening of our reimbursement coverage. Our rapidly growing direct sales force, started in 2013, focuses exclusively on Grafix® sales. We entered into two new exclusive distribution agreements in the fourth quarter of 2014, with a subsidiary of Stryker for the marketing and distribution of BIO ^{4TM} (formerly branded by the Company as OvationOS®), and with Arthrex for the marketing and distribution of Cartiform®. First sales under these agreements begin in 2015.

Our Therapeutics segment focused on developing and marketing products to treat medical conditions in the inflammatory and cardiovascular disease areas. Its operations focused on clinical trials and discovery efforts. As disclosed in Note 3— *Discontinued Operations* , we entered into a Purchase Agreement with Mesoblast, pursuant to the terms of which we sold our ceMSC business, including Prochymal and other related assets.

Following the sale of our former Therapeutics segment, we now have only one operating segment. 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.

5. Property and Equipment

Property and equipment at December 31, 2014 and 2013 are as follows:

(in thousands)	2014 (Restated)	2013
Laboratory and manufacturing equipment	$ 1,203	$ 663
Computer hardware, furniture and fixtures	1,377	899
Leased assets	228	228
Leasehold improvements	4,365	4,260
	7,173	6,050
Accumulated depreciation and amortization	(5,094)	(4,154)
Property and equipment, net	$ 2,079	$ 1,896

Depreciation expense was $940,000, $587,000, and $552,000 for 2014, 2013 and 2012, respectively.

6. Inventory

We began carrying inventory of our Biosurgery products on our balance sheet following commercial launch of such products. As of December 31, 2014 and 2013, inventory for our Biosurgery business consists of the following:

(in thousands)	2014 (Restated)	2013
Raw materials and supplies	$ 1,025	$ 387
Work-in-process	2,823	371
Finished goods	5,976	1,171
Total Biosurgery inventory, net	$ 9,824	$ 1,929

The finished goods inventory included gross consigned inventory of $2.0 million and $115,000 as of December 31, 2014 and 2013, respectively. These consigned finished goods inventory were reduced by reserves of $136,000 and $0 as of December 31, 2014 and 2013, respectively. In addition, finished goods inventory is stated net of reserves for product known to be unsalable of $288,000 and $0 as of December 31, 2014 and 2013, respectively.

The work-in-process inventory is largely product that is in quarantine pending completion of Company's quality assurance procedures. The amounts presented are net of reserves of $268,000 and $0 as of December 31, 2014 and 2013, respectively.

Prior to the transaction described in Note 3— *Discontinued Operations* , we did not carry any inventory for our Therapeutics products, as we had yet to launch Prochymal for commercial distribution.

7. 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 at the present value of the future minimum lease payments. Future minimum lease payments under the capital lease agreement at December 31, 2014 are as follows:

(in thousands)	Amount
December 31,	
2015	$ 48
2016	48
2017	24
	120
Less: Amount representing interest	(3)
Present value of minimum lease payments	117
Less: Current portion of capital lease obligations	(45)
Long-term portion of capital lease obligations	$ 72

8. 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, 2014, there were approximately 513,906 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 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,		
	2014	2013	2012
Assumptions			
Weighted average risk-free interest rate	1.50%	1.00-1.50%	2.00%
Dividend yield	0.00%	0.00%	0.00%
Expected life of option grants	5.0 Yrs	5.0-6.5 yrs	6.0-6.3 yrs
volatility	60%	52-61%	52-54%

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, 2014, we received cash proceeds of $1.7 million. At December 31, 2014, there was $4.6 million of total unrecognized compensation costs related to non-vested stock options, which is expected to be recognized through 2018.

A summary of stock option activity for the years ended December 31, 2014, 2013 and 2012 is as follows:

	Number of Shares	Weighted Average Exercise Price	Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
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
Granted	988,500	$ 14.59		
Exercised	(204,085)	$ 8.25		$ 1,341
Forfeited or canceled	(409,625)	$ 15.92		
Balance, December 31, 2014	1,608,557	$ 12.01	7.92 years	$ 6,774
Exercisable at December 31, 2014	400,432	$ 9.79	5.04 years	$ 2,759

A summary of stock options outstanding at December 31, 2014, by price range is as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life (in years)	Weighted-Average Exercise Price	Number Outstanding	Weighted-Average Exercise Price
$0.40 - $4.00	8,813	0.9	$ 0.40	8,813	$ 0.40
$4.01 - $5.25	133,790	7.1	5.31	51,790	5.08
$5.26 - $7.25	171,815	5.4	6.89	121,065	6.85
$7.01 - $7.75	210,139	7.3	7.73	86,764	7.74
$7.76 - $8.50	6,625	7.9	8.22	750	7.80
$8.51 - $12.75	151,375	7.9	11.42	42,750	11.23
$12.76 - $14.00	342,000	9.4	13.51	8,250	13.00
$14.01 - $16.00	290,000	9.3	15.01	—	—
$16.01 - $17.50	230,500	8.7	16.48	16,750	17.08
$17.51 - $24.00	63,500	3.6	20.03	63,500	20.03
	1,608,557	8.0	$ 12.01	400,432	$ 9.79

The weighted fair value of options granted during the years ended December 31, 2014, 2013 and 2012 were $7.62, $4.68 and $2.82, respectively.

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 10 below recognized in our statements of comprehensive (loss) income for the years ended December 31, 2014, 2013 and 2012.

	Year Ended December 31,		
(in thousands)	2014 (Restated)	2013	2012
Cost of product revenue	$ 253	$ —	$ —
Sales and marketing	505	—	—
Research and development	505	335	238
General and administrative	1,666	248	254
Discontinued operations	—	658	598
Total	$ 2,929	$ 1,241	$ 1,090

9. Investments Available for Sale

Investments available for sale consisted of the following as of December 31, 2014 and 2013:

The cash equivalents detailed below represent highly liquid investments with maturities of three months or less when purchased that are held in our brokerage investment accounts. They 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.

	December 31, 2014				December 31, 2013			
		Unrealized				Unrealized		
(in thousands)	Cost	Gain	Loss	Fair Value	Cost	Gain	Loss	Fair Value
Cash equivalents								
Money market funds & certificates of deposit	$ 1,043	$ —	$ —	$ 1,043	$ 655	$ —	$ —	$ 655
Corporate debt securities & commercial paper	12,835	21	(24)	12,832	6,355	22	(10)	6,367
	13,878	21	(24)	13,875	7,010	22	(10)	7,022.00
Investments								
Municipal securities	12,400	13	(47)	12,366	12,507	9	(24)	12,492
Agency obligations	5,401	12	(28)	5,385	6,704	5	(35)	6,674
Mutual Funds	—	—	—	—	4,076	—	—	4,076
US & International government agencies	5,680	1	(2)	5,679	9,244	—	—	9,244
	23,481	26	(77)	23,430	32,531	14	(59)	32,486
Investments available for sale	**$ 37,359**	**$ 47**	**$ (101)**	**$ 37,305**	**$ 39,541**	**$ 36**	**$ (69)**	**$ 39,508**

The following tables summarize the securities with unrealized losses, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, as of December 31, 2014 and 2013:

	Less than 12 Months		12 Months or More		Total	
(in thousands)	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
December 31, 2014						
Municipal securities	$ 1,000	$ (1)	$ 1,032	$ (46)	$ 2,032	$ (47)
Agency obligations	3,939	(28)	—	—	3,939	(28)
Corporate debt securities & commercial paper	7,073	(24)	—	—	7,073	(24)
US & International government agencies	2,873	(2)	—	—	2,873	(2)
Total temporarily impaired	**$ 14,885**	**$ (55)**	**$ 1,032**	**$ (46)**	**$ 15,917**	**$ (101)**

	Less than 12 months		More than 12 months		Total	
(in thousands)	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
December 31, 2013						
Corporate debt securities & commercial paper	$ 3,341	$ (10)	$ —	$ —	$ 3,341	$ (10)
Municipal securities	4,530	(24)	—	—	4,530	(24)
Agency obligations	3,804	(35)	—	—	3,804	(35)
Total temporarily impaired	**$ 11,675**	**$ (69)**	**$ —**	**$ —**	**$ 11,675**	**$ (69)**

The following table summarizes maturities of our investments available for sale as of December 31, 2014 and 2013:

	December 31, 2014		December 31, 2013	
(in thousands)	Cost	Fair Value	Cost	Fair Value
Maturities:				
Within 3 months	$ 3,056	$ 3,056	$ 12,663	$ 12,664
Between 3—12 months	12,658	12,660	1,624	1,610
More than 1 year	21,645	21,589	25,254	25,234
Investments available for sale	$ 37,359	$ 37,305	$ 39,541	$ 39,508

Realized gains (losses) and investment income earned on investments available for sale were $(390,000), $(414,000), and $0, respectively, for the years ended December 31, 2014, 2013 and 2012, and have been included as a component of "Other income, net" in the accompanying financial statements.

10. Related Party Transactions and Warrant

Peter Friedli. Peter Friedli, the Chairman of our Board of Directors, or entities with which he is affiliated, has been responsible for procuring since 1993, an aggregate of approximately $270 million in debt and equity financing for us and our predecessor company. As of December 31, 2014, Mr. Friedli is the beneficial owner of approximately 43% of our common stock as of December 31, 2014. Of the shares beneficially owned by Mr. Friedli at December 31, 2014, 85,000 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 85,000 shares received by Mr. Friedli as board compensation since 1996, 10,000 shares, then valued at approximately $149,300, were issued to Mr. Friedli in 2014, 10,000 shares, then valued at approximately $77,000, were issued to Mr. Friedli in 2013, and 10,000 shares, then valued at approximately $51,000, were issued to Mr. Friedli in 2012.

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. 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.

In connection with the Restatement, the Audit Committee evaluated certain issues related to director expense reimbursements. On the basis of that review, the Audit Committee determined that certain requests for reimbursement submitted between 2012 and 2015 by the Company's Chairman of the Board to the Company's former chief financial officer should not have been paid to him. In December 2016 the Chairman returned to the Company $216,000 representing the full amount that the Audit Committee determined should not have been paid to him. The Company has recorded a receivable of $216,000 and $104,000, as of December 31, 2014 and 2013, which represents the amounts that the Audit Committee determined should not have been reimbursed in those years.

Prolexys Pharmaceuticals, Inc. During the third quarter of 2011 we entered into a contract research agreement with Prolexys Pharmaceuticals, Inc. ("Prolexys") 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 on September 14, 2011 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, 2014, the amount of internal resources we have devoted to Prolexys is not material to our operations as a whole.

As of December 31, 2014, 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. As of December 31, 2014,

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. As of December 31, 2014, Lode Debrabandere, our former chief executive officer, served 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.

11. Income Taxes

For income tax reporting purposes, we reported taxable income in 2014 and 2013, compared to a loss in 2012. The income in 2014 and 2013 was primarily attributable to the gain from sale of discontinued operations which are reflected in the statements of comprehensive (loss) income, net of income taxes. Continuing operations below reflect a tax expense in the amount of $97,000 and a benefit in the amount of $1.3 million generated during 2014 and 2013, respectively. Included in the 2013 amount is $79,000 of taxes recoverable from a prior period.

Included as a component of discontinued operations was a tax expense of $516,000 and $1.3 million for 2014 and 2013, respectively. The gain from sale of discontinued operations in 2013 included interest to be accrued in the amount of $70,000 which increased income taxes payable. In the future, the utilization of our tax attributes will be limited to the federal alternative minimum tax threshold.

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

	2014 (Restated)	2013	2012
U.S. Federal Statutory tax rate	35.0%	35.0%	35.0%
State taxes, net of federal benefits	-0.2%	7.9%	0.4%
Nondeductible expenses	-2.0%	-2.2%	-5.1%
Stock compensation	-16.2%	18.6%	0.00%
Change in valuation allowance	-23.1%	0.0%	-30.3%
Credits	1.4%	5.1%	0.0%
Change in tax rate	4.1%	0.0%	0.0%
Other	-0.1%	0.0%	0.6%
Effective tax rate	-1.1%	64.4%	0.6%

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

(in thousands)	2014 (Restated)	2013
Deferred Tax Assets		
Credits	$ 70,668	$ 75,981
Net Operating loss carry-forward	—	—
Stock options—NQSO	594	1,689
Fixed assets	831	811
Accrued Expenses	327	101
Allowance for doubtful accounts	634	31
Deferred rent	97	—
UNICAP	266	—
Inventory Restatement	2,045	—
Inventory Reserve	150	—
Other	1	—
	75,613	78,613
Valuation allowance	(75,469)	(72,559)
Net deferred tax assets	$ 144	$ 6,054
Deferred Tax Liabilities		
Gain on installment sale	$ —	$ (6,054)
481(a) Adjustment	$ (144)	$ —
	$ (144)	$ (6,054)

We presently have available for federal income tax purposes approximately $71.1 million of general business credit carryforwards, which expire beginning in 2025 through 2032. In addition, we have approximately $1.4 million alternative minimum tax credit carryforwards as of December 31, 2014, which 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 2014, we 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.

Our 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. We have recorded a valuation allowance of $75.5 million and $72.6 million, against the Company's net deferred tax assets as of December 31, 2014 and December 31 2013, respectively, as Management believes it is more likely than not that the assets will not be realized.

Utilization of the credit carryforwards 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 credits attributable to periods before the change and could result in a reduction in the total credits available.

We are subject to income taxes in the United States and several states. 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.

Our policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2014 and December 31, 2013, we had no accruals for interest or penalties related to income tax matters.

12. 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.

13. 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 in connection with a specific clinical trial. We may also utilize CROs for future clinical trials.

We have active contracts with a CRO related to ongoing clinical trials. The total cost of these future obligations is estimated to be approximately $10.7 million which is expected to be paid through 2017.

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 originally expired in July 2016. According to the terms of the lease agreement, we were required to provide a letter of credit which was fully collateralized by restricted cash and as of December 31, 2013, the letter of credit of $243,000 remained outstanding. In September 2014, we entered into an amendment to the operating lease for our Columbia, Maryland facility, extending the term of the lease through July 2023 and increasing the future minimum lease commitment by $9.0 million. The lease amendment includes an allowance for tenant improvements of approximately $1.5 million that we expect to utilize in 2015 to expand our manufacturing facilities and adjust our office space to accommodate our additional employees. Under the amended lease agreement, we also replaced the $243,000 letter of credit with a $95,000 cash deposit and eliminated all restricted cash.

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

(in thousands)		
2015	$	1,194
2016		1,091
2017		1,062
2018		1,088
2019		1,218
Thereafter		4,957
	$	10,610

Our expenses under this lease were $1.3 million, $1.3 million, and $1.3 million, during 2014, 2013 and 2012, 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 7— *Capital Lease* , in July 2012, we leased an additional $228,000 of equipment under a capital lease, which was included in our balance sheets as of December 31, 2014 along with $114,100 of accumulated depreciation.

Legal

The Company is party to outstanding legal proceedings, investigations and claims as described below. The Company cannot predict with any certainty the final outcome of any legal proceedings, investigations (including any settlement discussions with the government seeking to resolve such investigations) or claims made against it as described in the paragraphs below, and there can be no assurance that the ultimate resolution of any such matter will not have a material adverse impact on the Company's consolidated financial position, results of operations, or cash flows.

The Company records accruals for certain outstanding legal proceedings, investigations or claims when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings, investigations and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable. When a loss contingency is not both probable and reasonably estimable, the Company does not accrue the loss. However, if the loss (or an additional loss in excess of the accrual) is at least a reasonable possibility and material, then the Company discloses a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If the Company cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed.

The assessments of whether a loss is probable or a reasonable possibility, and whether the loss or range of loss is reasonably estimable, often involve a series of complex judgments about future events. Among the factors that the Company considers in this assessment are the nature of existing legal proceedings, investigations and claims, the asserted or possible damages or loss contingency (if reasonably estimable), the progress of the matter, existing law and precedent, the opinions or views of legal counsel and other advisers, the involvement of the U.S. Government and its agencies in such proceedings, the Company's experience in similar matters and the experience of other companies, the facts available to the Company at the time of assessment, and how the Company intends to respond, or has responded, to the proceeding, investigation or claim. The Company's assessment of these factors may change over time as individual proceedings, investigations or claims progress. For matters where the Company is not currently able to reasonably estimate the range of reasonably possible loss, the factors that have contributed to this determination include the following: (i) the damages sought are indeterminate, or an investigation has not manifested itself in a filed civil or criminal complaint, (ii) the matters are in the early stages, (iii) the matters involve novel or unsettled legal theories or a large or uncertain number of actual or potential cases or parties, and/or (iv) discussions with the government or other parties in matters that may be expected ultimately to be resolved through negotiation and settlement have not reached the point where the Company believes a reasonable estimate of loss, or range of loss, can be made. In such instances, the Company believes that there is considerable uncertainty regarding the timing or ultimate resolution of such matters, including a possible eventual loss, fine, penalty or business impact, if any.

In addition, the Company does not accrue for estimated legal fees and other directly related costs as they are expensed as incurred.

In addition to the matters described in the paragraphs below, in the normal course of its business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies, none of which we believe to be material.

Based on our analysis and assessment as described above, including 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, except for the matters described below related to the Restatement.

Securities Class Action Complaint

On November 23, 2015, a putative class action lawsuit was filed in the United States District Court for the District of Maryland by a single plaintiff, individually and on behalf of other persons similarly situated, against the Company and three current or former executive officers of the Company. The action, captioned *Kiran Kumar Nallagonda v. Osiris Therapeutics, Inc. et al.* , Case 1:15-cv-03562 (the "Nallagonda Action"), alleges, among other things, that the defendants made materially false or misleading statements and material omissions in the Company's SEC filings in violation of the federal securities laws. The complaint seeks certification as a class action, unspecified damages and reimbursement of

attorneys' fees. On March 21, 2016, the Court entered an order appointing a lead plaintiff and a lead plaintiff's counsel. Subsequently, on August 15, 2016, the Court entered an order providing that the lead plaintiff shall file an amended complaint no later than 15 days after the Company files amended financial statements with the SEC. This matter remains at an early stage and, as of the date of this Form 10-K/A, we cannot reasonably estimate the possible loss, or range of loss, in connection with it.

Shareholder Derivative Complaints

On March 2, 2016, a shareholder derivative complaint was filed in the Circuit Court for Howard County in the State of Maryland (Case No. 13C16106811) by a single plaintiff, derivatively and on behalf of the Company, against individual members of the Company's board of directors and certain executive officers. This action, captioned *Kevin Connelley v. Lode Debrabandere et al* ., alleges that each of the individual directors and officers named as defendants (i) violated their fiduciary duties to the Company's shareholders; (ii) abused their ability to control and influence the Company; (iii) engaged in gross mismanagement of the assets and business of the Company; and (iv) was unjustly enriched at the expense of, and to the detriment of, the Company. The alleged claims generally relate to the matters that are the subject of the Nallagonda Action. The plaintiff seeks, among other things, unspecified monetary damages, reimbursement of attorneys' fees and shareholder votes on amendments to the Company's Articles of Incorporation and Bylaws with respect to various corporate governance policies. On June 2, 2016, the Court entered an order that, subject to certain qualifications, stayed the action until 30 days after the entry of an order either: (1) denying all motions to dismiss in the Nallagonda Action, or (2) finally dismissing the Nallagonda Action with prejudice. This matter remains at an early stage and, as of the date of this Form 10-K/A, we cannot reasonably estimate the possible loss, or range of loss, in connection with it.

On July 26, 2016, an alleged shareholder of the Company filed a complaint in the Circuit Court for Howard County in the State of Maryland (Case 13C16108356) against the Company and certain directors captioned *Brian C. Lee v. Osiris Therapeutics, Inc., et al* . The plaintiff alleged that the Company and its directors failed to schedule or hold an annual meeting within the time period allegedly required by the Company's bylaws and Maryland Law. On March 1, 2017, the parties executed a settlement agreement that will resolve the litigation if the Company provides shareholders with certain additional information on or before March 30, 2017. The Company intends to fulfill its obligations pursuant to the settlement agreement and expects this complaint to be voluntarily dismissed with prejudice.

On February 9, 2017, a shareholder derivative complaint was filed in the United States District Court for the District of Maryland (Case No. 1:17-cv-00381-JKB) by a single plaintiff, derivatively and on behalf of the Company, against individual members of the Company's board of directors. This action, captioned *Recupero v. Friedli et al.,* alleges, among other things, that each of the individual directors named as defendants (i) violated their fiduciary duties to the Company's shareholders, including that such violations constituted constructive fraud; (ii) engaged in gross mismanagement of the assets and business of the Company; and (iii) was unjustly enriched at the expense of, and to the detriment of, the Company. The plaintiff seeks, among other things, unspecified monetary damages, reimbursement of attorneys', accountants' and experts' fees, and that the Company take all necessary actions to improve and comply with corporate governance, internal procedures and existing laws.

Government Investigations

As disclosed in the Company's Current Report on Form 8-K filed on March 15, 2016, the Company has received a subpoena from the SEC relating to a non-public investigation relating to its historic accounting practices, which have been under independent review by the Audit Committee of the Company's Board of Directors, with the assistance of outside professionals. Counsel to the Audit Committee also has voluntarily advised the SEC about the Independent Review. The Company is cooperating fully with the SEC in this matter.

As disclosed in the Company's Current Report on Form 8-K filed on May 27, 2016, the Company was contacted by the United States Attorney's Office for the Southern District of New York (the "U.S. Attorney"), and was notified that a criminal investigation had been opened by that office, which to the Company's knowledge is considering the same issues that are under review by the SEC. The Company is cooperating fully with the U.S. Attorney in this matter.

We cannot predict if, when or how these matters will be resolved or what, if any, actions we may be required to take as part of any resolution of these matters. Any action by the SEC, the U.S. Attorney or other governmental agency could result in civil or criminal sanctions against us and/or certain of our current and former officers, directors and employees. At this stage in the matter, we cannot reasonably estimate the possible loss, or range of loss, in connection with it.

14. Derivative and Securities Received in Business Disposition

The only derivative instrument to which the Company was a party was the price protection related to the shares received from Mesoblast Limited as part of the disposition of our Therapeutics business. As discussed in Note 3— *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 provided that

these shares were subject to a one year holding period, during which time we were afforded limited protection for any drop in the Mesoblast Limited share price. In the event that the shares decreased in value during the holding period, we would 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 have been subject to an additional one year holding period, but would 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 evaluated this downside protection, and determined that it met the criteria of a derivative instrument under ASC 815. As such, the price protection derivative was re-measured at its fair value with change in fair value recorded in net income as a component of "Other income".

In December, the price protection for the Mesoblast Limited ordinary shares expired, but Mesoblast agreed to pay us no less than $15 million in cash for the stock prior to the end of the first half of 2015. Accordingly, we no longer have a derivative instrument as of December 31, 2014. As part of the amended agreement, the holding period of the ordinary shares was extended to May 2015 and the shares remained restricted as of December 31, 2014. The fair value of the price protection derivative was $1.7 million as of December 31, 2013, which was included as a component of "Trading Securities." From the closing of the sale of the Therapeutics business through December 31, 2014 and 2013, respectively, we recorded a loss of $1.7 million and $52,000 on the price protection, which was included as a component of "Other income."

The shares of Mesoblast Limited to which the price protection relates were received by the Company on December 18, 2013 and were 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 elected to remeasure the Mesoblast Limited 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 Limited shares and the statement of comprehensive (loss) income impact of changes in the fair value of the price protection derivative largely offset each other during the mandatory holding.

The fair value of the Mesoblast Limited shares as of December 31, 2014 and 2013, determined by reference to the trading price of identical Mesoblast Limited ordinary shares on the Australian Stock Exchange, was $10.6 million and $15.4 million, respectively. The gain during the period from December 18, 2013 through December 31, 2013 was $401,000. The loss during the year ended December 31, 2014 was $401,000. The difference of $4.4 million between the fair value of the Mesoblast Limited shares, and the guaranteed payment of $15 million is included in "Other Receivables" on our Balance Sheets as of December 31, 2014.

15. 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 Limited 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.

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 Limited 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 Limited shares was 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 Limited shares at a price of $15 million. Significant inputs to the model include the following:

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

The price protection related to Mesoblast Limited shares ended in December 2014. There were 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 Limited stock issued to us in connection with the sale of our former Therapeutics business:

(in thousands)	December 31, 2014	December 31, 2013
Balance at beginning of period	$ 1,685	$ —
Fair value upon receipt of Mesoblast stick	—	1,737
Change in fair value	2,252	(52)
Settlements	(3,937)	—
Balance at end of period	$ —	$ 1,685

Assets and liabilities measured at fair value on a recurring basis are summarized below as of December 31, 2014 and 2013:

(in thousands)	December 31, 2014 Level I	Level II	Level III	Total
Assets				
Investments: Available for Sale Securities				
Cash & Cash Equivalents	$ 1,043	—	—	$ 1,043
US & International government agencies	—	5,679	—	5,679
Mutual Funds	—	—	—	—
Agency Obligations	—	5,385	—	5,385
Corporate Debt Securities & Commercial Paper	—	12,832	—	12,832
Municipal Securities	—	12,366	—	12,366
Total investments available for sale	$ 1,043	$ 36,262	$ —	$ 37,305
Securities received in business disposition				
Restricted shares of Mesoblast common stock	$ 10,591	$ —	$ —	$ 10,591
Total assets	$ 11,634	$ 36,262	$ —	$ 47,896

(in thousands)	December 31, 2013 Level I	Level II	Level III	Total
Assets				
Investments: Available for Sale Securities				
Cash & Cash Equivalents	$ 655	$ —	$ —	$ 655
US & International government agencies		9,244		9,244
Certificates of Deposit		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
Total 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 shares of Mesoblast common stock	—	—	1,685	1,685
Total derivative instruments	15,401	—	1,685	17,086
Total assets	$ 16,056	$ 38,853	$ 1,685	$ 56,594

16. Quarterly Financial Data (Unaudited)

We have restated all quarterly periods of 2014 to reflect the effects of the restatement described herein and revised our previously issued condensed financial information for each quarter in 2013 (Note 2). The following tables summarize the impacts of the results on our previously reported condensed statements of operations and balances sheets included in our Quarterly Reports on Form 10-Q for each respective period.

Condensed Statements of Comprehensive Income (Loss)
(in thousands, except per share data)

	Previously Reported					
	First Quarter	Second Quarter	Year to Date Second Quarter	Third Quarter	Year to Date Third Quarter	Fourth Quarter
2014						
Product revenue	$ 10,054	$ 13,290	$ 23,344	$ 17,204	$ 40,548	$ 19,319
Cost of product revenue	2,212	2,924	5,136	3,785	8,921	4,250
Gross profit	7,842	10,366	18,208	13,419	31,627	15,069
Research and development expenses	670	1,055	1,725	1,207	2,932	3,930
Sales and marketing expenses	6,154	7,748	13,902	9,321	23,223	7,347
General and administrative expenses	1,081	1,590	2,671	1,625	4,296	2,566
Related party expenses	552	39	591	47	638	46
Income (loss) from operations	(615)	(66)	(681)	1,219	538	1,180
Other (expense) income	(126)	(1,232)	(1,358)	(405)	(1,763)	(8)
Net (loss) income from continuing operations, before income taxes	(741)	(1,298)	(2,039)	814	(1,225)	1,172
Income tax (expense) benefit	130	(130)	—	(104)	(104)	(89)
Loss from continuing operations	(611)	(1,428)	(2,039)	710	(1,329)	1,083
Loss from discontinued operations	(754)	(457)	(1,211)	(65)	(1,276)	(267)
Net loss	$ (1,365)	$ (1,885)	$ (3,250)	$ 645	$ (2,605)	$ 816
**Loss from continuing operations per share, basic and diluted	$ (0.02)	$ (0.04)	$ (0.06)	$ 0.02	$ (0.04)	$ 0.03
**Loss from discontinued operations per share, basic and diluted	$ (0.02)	$ (0.01)	$ (0.04)	$ 0.00	$ (0.04)	$ (0.01)
**Net loss per share, basic and diluted	$ (0.04)	$ (0.05)	$ (0.09)	$ 0.02	$ (0.08)	$ 0.02

	Adjustments					
	First Quarter	Second Quarter	Year to Date Second Quarter	Third Quarter	Year to Date Third Quarter	Fourth Quarter
2014						
Product revenue	$ (2,897)	$ (4,084)	$ (6,981)	$ (897)	$ (7,878)	$ (1,154)
Cost of product revenue	(1,157)	(866)	(2,023)	(261)	(2,284)	(1,001)
Gross profit	(1,740)	(3,218)	(4,958)	(636)	(5,594)	(153)
Research and development expenses	(192)	(69)	(261)	(294)	(555)	(2,893)
Sales and marketing expenses	(376)	268	(108)	650	542	5,272
General and administrative expenses	(103)	—	(103)	147	44	657
Related party expenses	(112)	—	(112)	—	(112)	—
Income (loss) from operations	(957)	(3,417)	(4,374)	(1,139)	(5,513)	(3,189)
Other (expense) income	—	—	—	—	—	—
Net (loss) income from continuing operations, before income taxes	(957)	(3,417)	(4,374)	(1,139)	(5,513)	(3,189)
Income tax (expense) benefit	(130)	109	(21)	81	60	36
Loss from continuing operations	(1,087)	(3,308)	(4,395)	(1,058)	(5,453)	(3,153)
(Loss) income from discontinued operations	130	(60)	70	41	111	314
Net loss	$ (957)	$ (3,368)	$ (4,325)	$ (1,017)	$ (5,342)	$ (2,839)
**Loss from continuing operations per share, basic and diluted	$ (0.03)	$ (0.10)	$ (0.13)	$ (0.03)	$ (0.16)	$ (0.09)
**Loss from discontinued operations per share, basic and diluted	$ —	$ (0.01)	$ 0.01	$ —	$ 0.01	$ 0.01
**Net loss per share, basic and diluted	$ (0.03)	$ (0.11)	$ (0.12)	$ (0.03)	$ (0.15)	$ (0.08)

	Restated					
	First Quarter	Second Quarter	Year to Date Second Quarter	Third Quarter	Year to Date Third Quarter	Fourth Quarter
2014						
Product revenue	$ 7,157	$ 9,206	$ 16,363	$ 16,307	$ 32,670	$ 18,165
Cost of product revenue	1,055	2,058	3,113	3,524	6,637	3,249
Gross profit	6,102	7,148	13,250	12,783	26,033	14,916
Research and development expenses	478	986	1,464	913	2,377	1,037
Sales and marketing expenses	5,778	8,016	13,794	9,971	23,765	12,619
General and administrative expenses	978	1,590	2,568	1,772	4,340	3,223
Related party expenses	440	39	479	47	526	46
Income (loss) from operations	(1,572)	(3,483)	(5,055)	80	(4,975)	(2,009)
Other (expense) income	(126)	(1,232)	(1,358)	(405)	(1,763)	(8)
Net (loss) income from continuing operations, before income taxes	(1,698)	(4,715)	(6,413)	(325)	(6,738)	(2,017)
Income tax (expense) benefit	—	(21)	(21)	(23)	(44)	(53)
Loss from continuing operations	(1,698)	(4,736)	(6,434)	(348)	(6,782)	(2,070)
(Loss) income from discontinued operations	(624)	(517)	(1,141)	(24)	(1,165)	47
Net loss	$ (2,322)	$ (5,253)	$ (7,575)	$ (372)	$ (7,947)	$ (2,023)
**Loss from continuing operations per share, basic and diluted	$ (0.05)	$ (0.14)	$ (0.19)	$ (0.01)	$ (0.20)	$ (0.06)
**Loss from discontinued operations per share, basic and diluted	$ (0.02)	$ (0.02)	$ (0.03)	$ —	$ (0.03)	$ —
**Net loss per share, basic and diluted	$ (0.07)	$ (0.16)	$ (0.22)	$ (0.01)	$ (0.23)	$ (0.06)

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

Condensed Balance Sheets
(in thousands, except per share data)

	March 31,		
	2014 (Previously Reported)	Adjustments	2014 (Restated)
Assets			
Cash	$ 2,342	$ —	$ 2,342
Investments available for sale	34,650	—	34,650
Trading securities	16,907	—	16,907
Trade accounts receivable, net of reserves	11,763	(3,136)	8,627
Other receivables	15,130	216	15,346
Inventory	2,337	912	3,249
Prepaid expenses and other current assets	318	162	480
Current assets of discontinued operations	96	—	96
Total current assets	83,543	(1,846)	81,697
Property and equipment, net	1,809		1,809
Deferred tax asset	5,737	59	5,796
Restricted cash	243	—	243
Total assets	$ 91,332	$ (1,787)	$ 89,545
Liabilities and Stockholders' Equity			
Current liabilities			
Accounts payable and accrued expenses	$ 4,025	$ (890)	$ 3,135
Capital lease obligations, current portion	45	—	45
Deferred tax liability	5,737	59	5,796
Current liabilities of discontinued operations	17	—	17
Total current liabilities	9,824	(831)	8,993
Other long-term liabilities	319	—	319
Total liabilities	10,143	(831)	9,312
Commitments and contingencies			
Stockholders' equity			
Common stock, $.001 par value, 90,000 shares authorized, 34,222 shares outstanding	34	—	34
Additional paid-in-capital	284,219	(103)	284,116
Accumulated other comprehensive loss	55	—	55
Accumulated deficit	(203,119)	(853)	(203,972)
Total stockholders' equity	81,189	(956)	80,233
Total liabilities and stockholders' equity	$ 91,332	$ (1,787)	$ 89,545

	June 30,		
	2014 (Previously Reported)	Adjustments	2014 (Restated)
Assets			
Cash	$ 2,658	$ —	$ 2,658
Investments available for sale	45,759	—	45,759
Trading securities	15,584	—	15,584
Trade accounts receivable, net of reserves	16,890	(7,599)	9,291
Other receivables	256	216	472
Inventory	5,540	(187)	5,353
Prepaid expenses and other current assets	404	1,040	1,444
Total current assets	87,091	(6,530)	80,561
Property and equipment, net	1,895		1,895
Deferred tax asset	—	—	—
Restricted cash	223	—	223
Total assets	$ 89,209	$ (6,530)	$ 82,679
Liabilities and Stockholders' Equity			
Current liabilities			
Accounts payable and accrued expenses	$ 8,037	$ (2,167)	$ 5,870
Capital lease obligations, current portion	45	—	45
Total current liabilities	8,082	(2,167)	5,915
Other long-term liabilities	280	—	280
Total liabilities	8,362	(2,167)	6,195
Commitments and contingencies			
Stockholders' equity			
Common stock, $.001 par value, 90,000 shares authorized, 34,310 shares outstanding	34	—	34
Additional paid-in-capital	285,745	(142)	285,603
Accumulated other comprehensive loss	72	—	72
Accumulated deficit	(205,004)	(4,221)	(209,225)
Total stockholders' equity	80,847	(4,363)	76,484
Total liabilities and stockholders' equity	$ 89,209	$ (6,530)	$ 82,679

	September 30,		
	2014 (Previously Reported)	Adjustments	2014 (Restated)
Assets			
Cash	$ 946	$ —	$ 946
Investments available for sale	42,349	—	42,349
Trading securities	15,060	—	15,060
Trade accounts receivable, net of reserves	21,446	(8,934)	12,512
Other receivables	474	149	623
Inventory	8,840	(973)	7,867
Prepaid expenses and other current assets	489	1,745	2,234
Total current assets	89,604	(8,013)	81,591
Property and equipment, net	2,012	(8)	2,004
Other assets	96	—	96
Total assets	$ 91,712	$ (8,021)	$ 83,691
Liabilities and Stockholders' Equity			
Current liabilities			
Accounts payable and accrued expenses	$ 9,276	$ (2,685)	$ 6,591
Capital lease obligations, current portion	45	—	45
Total current liabilities	9,321	(2,685)	6,636
Other long-term liabilities	276	—	276
Total liabilities	9,597	(2,685)	6,912
Commitments and contingencies			
Stockholders' equity			
Common stock, $.001 par value, 90,000 shares authorized, 34,320 shares outstanding	35	—	35
Additional paid-in-capital	286,397	(98)	286,299
Accumulated other comprehensive loss	42	—	42
Accumulated deficit	(204,359)	(5,238)	(209,597)
Total stockholders' equity	82,115	(5,336)	76,779
Total liabilities and stockholders' equity	$ 91,712	$ (8,021)	$ 83,691

The adjustments had an impact on certain captions within the condensed statements of cash flows for the restated interim quarterly periods contained within the years ended December 31, 2014 as discussed in Note 2 to the Company's financial statements included in Part II, Item 8 of this Form 10-K/A.

The following tables summarize our unaudited revised quarterly results for the year ended December 31, 2013:

Condensed Statements of Comprehensive Income (Loss)
(in thousands, except per share data)

	Previously Reported					
	First Quarter	Second Quarter	Year to Date Second Quarter	Third Quarter	Year to Date Third Quarter	Fourth Quarter
2013						
Product revenue	$ 4,055	$ 5,291	$ 9,346	$ 6,882	$ 16,228	$ 8,080
Cost of product revenue	1,135	1,481	2,616	1,858	4,474	2,182
Gross profit	2,920	3,810	6,730	5,024	11,754	5,898
Research and development expenses	1,065	1,206	2,271	968	3,239	1,091
Sales and marketing expenses	1,243	3,517	4,760	3,917	8,677	4,690
General and administrative expenses	1,045	566	1,611	630	2,241	297
Related party expenses	250	—	250	—	250	—
Income (loss) from operations	(683)	(1,479)	(2,162)	(491)	(2,653)	(180)
Other (expense) income	29	25	54	26	80	334
Net (loss) income from continuing operations, before income taxes	(654)	(1,454)	(2,108)	(465)	(2,573)	154
Income tax (expense) benefit	358	(358)	—	—	—	1,326
Loss from continuing operations	(296)	(1,812)	(2,108)	(465)	(2,573)	1,480
Loss from discontinued operations	(2,439)	(1,944)	(4,383)	(1,211)	(5,594)	48,325
Net (loss) income	$ (2,735)	$ (3,756)	$ (6,491)	$ (1,676)	$ (8,167)	$ 49,805
**Loss from continuing operations per share, basic and diluted	$ (0.01)	$ (0.05)	$ (0.06)	$ (0.01)	$ (0.08)	$ 0.04
**Loss from discontinued operations per share, basic and diluted	$ (0.07)	$ (0.06)	$ (0.13)	$ (0.04)	$ (0.17)	$ 1.42
**Net loss per share, basic and diluted	$ (0.08)	$ (0.11)	$ (0.19)	$ (0.05)	$ (0.25)	$ 1.46

	Adjustments					
	First Quarter	Second Quarter	Year to Date Second Quarter	Third Quarter	Year to Date Third Quarter	Fourth Quarter
2013						
Product revenue	$ (92)	$ 468	$ 376	$ 798	$ 1,174	$ 216
Cost of product revenue	(37)	62	25	160	185	10
Gross profit	(55)	406	351	638	989	206
Research and development expenses	—	—	—	—	—	—
Sales and marketing expenses	21	92	113	156	269	174
General and administrative expenses	—	—	—	—	—	—
Related party expenses	(70)	—	(70)	—	(70)	—
Income (loss) from operations	(6)	314	308	482	790	32
Other (expense) income	—	—	—	—	—	—
Net (loss) income from continuing operations, before income taxes	(6)	314	308	482	790	32
Income tax (expense) benefit	—	—	—	—	—	(332)
Loss from continuing operations	(6)	314	308	482	790	(300)
Loss from discontinued operations	—	—	—	—	—	332
Net (loss) income	$ 6	$ (314)	$ (308)	$ (482)	$ (790)	$ 32
**Loss from continuing operations per share, basic and diluted	$ —	$ —	$ 0.01	$ 0.01	$ 0.03	$ (0.01)
**Loss from discontinued operations per share, basic and diluted	$ —	$ —	$ —	$ —	$ —	$ 0.01
**Net loss per share, basic and diluted	$ —	$ —	$ 0.01	$ 0.01	$ 0.03	$ —

	Revised					
	First Quarter	Second Quarter	Year to Date Second Quarter	Third Quarter	Year to Date Third Quarter	Fourth Quarter
2013						
Product revenue	$ 3,963	$ 5,759	$ 9,722	$ 7,680	$ 17,402	$ 8,296
Cost of product revenue	1,098	1,543	2,641	2,018	4,659	2,192
Gross profit	2,865	4,216	7,081	5,662	12,743	6,104
Research and development expenses	1,065	1,206	2,271	968	3,239	1,091
Sales and marketing expenses	1,264	3,609	4,873	4,073	8,946	4,864
General and administrative expenses	1,045	566	1,611	630	2,241	297
Related party expenses	180	—	180	—	180	—
Income (loss) from operations	(689)	(1,165)	(1,854)	(9)	(1,863)	(148)
Other (expense) income	29	25	54	26	80	334
Net (loss) income from continuing operations, before income taxes	(660)	(1,140)	(1,800)	17	(1,783)	186
Income tax (expense) benefit	358	(358)	—	—	—	994
Loss from continuing operations	(302)	(1,498)	(1,800)	17	(1,783)	1,180
Loss from discontinued operations	(2,439)	(1,944)	(4,383)	(1,211)	(5,594)	48,657
Net (loss) income	$ (2,741)	$ (3,442)	$ (6,183)	$ (1,194)	$ (7,377)	$ 49,837
**Loss from continuing operations per share, basic and diluted	$ (0.01)	$ (0.05)	$ (0.05)	$ —	$ (0.05)	$ 0.03
**Loss from discontinued operations per share, basic and diluted	$ (0.07)	$ (0.06)	$ (0.13)	$ (0.04)	$ (0.17)	$ 1.43
**Net loss per share, basic and diluted	$ (0.08)	$ (0.11)	$ (0.18)	$ (0.04)	$ (0.22)	$ 1.46

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

The adjustments had an impact on certain captions within the condensed statements of cash flows for the revised quarterly periods contained within the year ended December 31, 2013 as discussed in Note 2 to the Company's financial statements.

Condensed Balance Sheets
(in thousands, except per share data)

	March 31,		
	2013 (Previously Reported)	Adjustments	2013 (Revised)
Assets			
Cash	$ 1,287	$ —	$ 1,287
Investments available for sale	28,292	—	28,292
Trade accounts receivable, net of reserves	5,346	—	5,346
Other receivables	—	104	104
Inventory	1,611	232	1,843
Prepaid expenses and other current assets	462	—	462
Total current assets	36,998	336	37,334
Property and equipment, net	2,037		2,037
Restricted cash	317	—	317
Total assets	$ 39,352	$ 336	$ 39,688
Liabilities and Stockholders' Equity			
Current liabilities			
Accounts payable and accrued expense	$ 4,985	$ —	$ 4,985
Capital lease obligations, current portion	44	—	44
Deferred revenue, current	—	1,060	1,060
Total current liabilities	5,029	1,060	6,089
Other long-term liabilities	501	—	501
Total liabilities	5,530	1,060	6,590
Commitments and contingencies			
Stockholders' equity			
Common stock, $.001 par value, 90,000 shares authorized, 32,930 shares outstanding	33	—	33
Additional paid-in-capital	279,911	—	279,911
Accumulated other comprehensive loss	5	—	5
Accumulated deficit	(246,127)	(724)	(246,851)
Total stockholders' equity	33,822	(724)	33,098
Total liabilities and stockholders' equity	$ 39,352	$ 336	$ 39,688

	June 30,		
	2013 (Previously Reported)	Adjustments	2013 (Revised)
Assets			
Cash	$ 1,579	$ —	$ 1,579
Investments available for sale	25,626	—	25,626
Trade accounts receivable, net of reserves	6,406	—	6,406
Other receivables	—	104	104
Inventory	1,696	170	1,866
Prepaid expenses and other current assets	356	—	356
Total current assets	35,663	274	35,937
Property and equipment, net	2,040		2,040
Restricted cash	317	—	317
Total assets	$ 38,020	$ 274	$ 38,294
Liabilities and Stockholders' Equity			
Current liabilities			
Accounts payable and accrued expense	$ 6,826	$ —	$ 6,826
Capital lease obligations, current portion	45	—	45
Deferred revenue, current	—	684	684
Total current liabilities	6,871	684	7,555
Other long-term liabilities	469	—	469
Total liabilities	7,340	684	8,024
Commitments and contingencies			
Stockholders' equity			
Common stock, $.001 par value, 90,000 shares authorized, 32,989 shares outstanding	33	—	33
Additional paid-in-capital	280,616	—	280,616
Accumulated other comprehensive loss	(86)	—	(86)
Accumulated deficit	(249,883)	(410)	(250,293)
Total stockholders' equity	30,680	(410)	30,270
Total liabilities and stockholders' equity	$ 38,020	$ 274	$ 38,294

	September 30,		
	2013 (Previously Reported)	Adjustments	2013 (Revised)
Assets			
Cash	$ 1,801	$ —	$ 1,801
Investments available for sale	26,464	—	26,464
Trade accounts receivable, net of reserves	6,773	—	6,773
Other receivables	—	104	104
Inventory	1,672	10	1,682
Prepaid expenses and other current assets	639	—	639
Current assets of discontinued operations	247	—	247
Total current assets	37,596	114	37,710
Property and equipment, net	2,009		2,009
Restricted cash	243	—	243
Total assets	$ 39,848	$ 114	$ 39,962
Liabilities and Stockholders' Equity			
Current liabilities			
Accounts payable and accrued expense	$ 3,652	$ —	$ 3,652
Capital lease obligations, current portion	45	—	45
Deferred revenue, current	—	42	42
Deferred gain on sale	3,500	—	
Current liabilities of discontinued operations	463	—	463
Total current liabilities	7,660	42	7,702
Other long-term liabilities	433	—	433
Total liabilities	8,093	42	8,135
Commitments and contingencies			
Stockholders' equity			
Common stock, $.001 par value, 90,000 shares authorized, 34,115 shares outstanding	34	—	34
Additional paid-in-capital	283,369	—	283,369
Accumulated other comprehensive loss	(89)	—	(89)
Accumulated deficit	(251,559)	72	(251,487)
Total stockholders' equity	31,755	72	31,827
Total liabilities and stockholders' equity	$ 39,848	$ 114	$ 39,962

17. Subsequent Events

We evaluated our December 31, 2014 financial statements for subsequent events through the date the financial statements were issued. Pursuant to the exclusive distribution agreement we entered into with a subsidiary of Stryker in December 2014, we received the initial exclusivity fee of $5 million from Stryker in February 2015. This fee was required to be paid by Stryker within five business days of receipt of documents outlined in the December 2014 agreement.

In May 2015, concurrent with the expiration of the agreed holding period of the Mesoblast Limited shares received as part of the sale of the Company's ceMSC business, described in Note 3, Mesoblast Limited paid the Company $6.2 million representing the decline in the market value of the shares through that date. Later in 2015 the Company sold all of its Mesoblast Limited shares for $6.5 million. A $2.3 million loss was recognized in 2015 in connection with these transactions.

We are not aware of any other subsequent events which would require disclosure in the financial statements.

OSIRIS THERAPEUTICS, INC.
SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS
FOR THE YEARS ENDED DECEMBER 31, 2014, 2013 AND 2012

(in thousands)	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Accounts Receivable Reserve:				
2014 (Restated)	$ 78	$ 1,628	$ —	$ 1,706
2013	25	80	(27)	78
2012	3	22	—	25
Inventory Reserve:				
2014 (Restated)	$ —	$ 692	$ —	$ 692
2013	112	—	(112)	—
2012	274	—	(162)	112
Net Deferred Tax Asset Valuation Allowance:				
2014 (Restated)	$ 72,559	$ 2,910	$ —	$ 75,469
2013	88,243	—	(15,684)	72,559
2012	84,134	4,109	—	88,243

ITEM 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

At the time of the Original Filing, our former chief executive officer and former chief financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2014. In connection with the filing of this Form 10-K/A, under the supervision and with the participation of our management, including our current chief executive officer and current chief financial officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2014. Solely due to the identification of the material weaknesses in internal control over financial reporting that were identified in connection with the preparation of the Restatement and that are described below, our management, including our current chief executive officer and current chief financial officer, re-evaluated the conclusions regarding our disclosure controls and procedures and concluded that our disclosure controls and procedures were not effective as of December 31, 2014.

In the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014, the former chief executive officer and former chief financial officer had concluded that the Company's disclosure controls and procedures were effective for such quarterly periods. In light of the material weaknesses in our internal control over financial reporting that were identified in connection with the preparation of the Restatement and that are described below, the current chief executive officer and current chief financial officer re-evaluated the conclusions regarding the Company's disclosure controls and procedures for the quarterly periods ended March 31, 2014, June 30, 2014 and September 30, 2014 and concluded that the Company's disclosure controls and procedures were also not effective as of March 31, 2014, June 30, 2014 and September 30, 2014 because of the material weaknesses in our internal control over financial reporting described below that existed at that time.

Management's Report on Internal Control over Financial Reporting

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/A have been prepared in accordance with GAAP. Our management believes the financial statements and other financial information included in this Annual Report on Form 10-K/A 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/A. The financial statements included herein have been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report.

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 GAAP, 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.

Prior to our Original Filing, our prior management, including our former chief executive officer and former chief financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, our prior management used the criteria set forth in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its assessment, including the remediation of the material weakness relating to the maintenance of effective controls over income tax accounting described below, our prior management concluded that, as of December 31, 2014, our internal control over financial reporting was effective based on those criteria. The previously identified material weakness relating to the maintenance of effective controls over the application and monitoring of our accounting for income taxes was remediated during the year ended December 31, 2014. We enhanced our processes by engaging a new third-party tax advisor and also enhanced our existing controls over financial reporting by including a formal review of the provision to ensure completeness and accuracy.

Subsequent to our Original Filing, the Company's current management, including our current chief executive officer and our current chief financial officer, re-evaluated the effectiveness of our internal control over financial reporting as of December 31, 2014. The Company identified several material weaknesses in its internal control over financial reporting which are described below.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In connection with our current management's evaluation of our internal control over financial reporting described above, our management has identified the following deficiencies that it believes constituted individually, and in the aggregate, material weaknesses in our internal control over financial reporting as of December 31, 2014:

Control Environment. The Company did not maintain an effective control environment, which is the foundation for the discipline and structure necessary for effective internal control over financial reporting. First, the Company failed to maintain a corporate culture that allowed for an effective tone at the top. Specifically, in 2014 the Company's former chief executive officer and former chief financial officer either participated in, or failed to take action to prevent, the extra-contractual or undocumented terms of arrangements with distributors. Further, for one sales transaction to a distributor in the fourth quarter of 2014, evidence exists indicating that the former chief financial officer of the Company created a document subsequent to filing of the Original Form 10-K in an attempt to support the recognition of revenue in 2014. These actions or inactions led to errors and irregularities in the Company's recognition of revenue. Second, the Company failed to maintain a sufficient complement of personnel with an appropriate level of knowledge, experience, and training to ensure proper selection and application of GAAP in certain circumstances. Specifically, the Company did not have a sufficient number of employees to handle our financial management and reporting requirements during 2014 while the Company was experiencing dramatic growth in its product sales and certain accounting and finance positions were staffed with individuals who did not have the appropriate skills, training, and experience to meet their responsibilities.

Control Activities . The Company's internal control over certain processes, including recognizing revenue for distributor sales arrangements and the areas listed below, were not effective. In some cases, the Company's controls were not effective because the Company did not sufficiently establish or implement adequately designed and effective operating controls over accounting in accordance with GAAP. Further, the Company did not support and monitor effective internal control over financial reporting throughout the Company's management structure. The Company identified the following specific material weaknesses in internal control over financial reporting, some of which have not been previously disclosed:

- *Revenue Recognition under Distribution Sales Arrangements* . We have concluded that we recognized revenue in certain instances in advance of all revenue recognition criteria being met and erred in reporting revenue from certain sales on a net basis excluding certain contracting agent fees, and that our controls were not effective to reasonably ensure accurate recognition of revenue in accordance with GAAP for certain distributor sales arrangements. The Company also lacked procedures around consignment sales and also a type of sales arrangement under which the distributor agrees to be billed in advance of the Company's shipment of ordered products, commonly referred to as "bill and hold" arrangements. The Company lacked controls surrounding the receipt of requisite documentation, such as an invoice or purchase order, needed to ensure that revenue is properly recognized under consignment and "bill and hold" transactions.

- *Valuation of Inventory* . The Company did not design and maintain effective controls related to the Company's computation of costs and quantities for recording inventory.

- *Consignment Arrangements* . The Company did not design and maintain effective processes and controls over the accounting for consignment arrangements, including the validation of third-party reports, which resulted in the failure to monitor the disposition of consignment inventories.

- *Bad Debt Reserve* . The Company did not design and maintain effective processes and controls over assessing the collectability of accounts receivable and determining its bad debt reserve.

- *Costs and Expenses* . The Company did not have effective controls to reasonably ensure accurate classification of costs and expenses in accordance with GAAP.

- *Processing of Directors' Expense Reports* . The Company did not design and maintain effective processes and controls over expense reimbursement for directors.

Attestation Report of Registered Public Accounting Firm

BDO USA, LLP's attestation report on the effectiveness of our internal control over financial reporting is included in Part II, Item 8, "Financial Statements and Supplementary Data", of this Form 10-K/A.

Changes in Internal Control over Financial Reporting

With the exception of the remediation efforts described below, there has been no change in our internal control over financial reporting that occurred in the annual period covered by this report that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. The Audit Committee, the Board of Directors, and current management are committed to maintaining a strong internal control environment. As a result, the Company has initiated the remediation efforts outlined below, but these efforts cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Remediation of Material Weakness Related to Control Environment and Control Activities . Our current management, with assistance from an outside forensic accounting firm, conducted an intensive review of journal entries, invoices and other documents relating to areas in which errors, irregularities or control deficiencies might exist. Management then developed a plan with the oversight of the Audit Committee to remediate the material weaknesses identified above. The Company's remediation efforts, which are either implemented or in process, are intended to both address the identified material weakness and to enhance our overall financial control environment, include:

- Our former chief executive officer and our former chief financial officer have been replaced.

- Our Board has directed the Company's current senior management to ensure that a proper, consistent compliance culture is communicated throughout the organization, which emphasizes the importance of internal control over financial reporting.

- In order to ensure we have a sufficient complement of personnel with an appropriate level of knowledge, experience, and training commensurate with our financial management and reporting requirements, we added personnel in a number of positions including accounting, billing, collections, and financial reporting and, in some cases, created new positions. Key additional positions created include: credit and collections manager, cost accounting manager, staff accountant, collections specialist, cash applications specialist, payroll supervisor, billing manager, and revenue manager. We have also added contract personnel to assist with the Restatement, audit completion and control implementation. The Company's customer service department, which is responsible for order entry and sales activity reporting, was moved from the sales function to report to the finance function. In total, we have added over 24 additional full-time personnel to the accounting and finance departments including the customer service function.

- We have implemented new and enhanced controls for proper revenue recognition of distributor sales transactions in compliance with GAAP. This includes controls related to distributor sales contracts and controls to ensure that adequate written documentation is in place to ensure that revenue is recognized in the proper period

in accordance with GAAP. This also includes new and enhanced controls for (i) recognizing revenue from certain agent sales on a net basis excluding agent fees and (ii) properly accounting for "bill and hold" arrangements.

- We have implemented enhancements to our controls ensure that once a finished good has been determined to be unsalable it is relieved from the computation of inventory on a timely basis. Further, we are implementing additional review of our inventory reserve analysis, including the involvement of both finance and operational executives, and more analysis of days inventory on hand at the product line level, which we expect to provide better controls to assess excess and obsolete inventory based on the current inventory on hand in relation to the demand forecast and related reserve. We have also hired accounting personnel with relevant cost accounting experience whose daily job responsibility is to monitor, analyze and develop processes to properly value the Company's inventory levels.

- We have implemented controls and procedures to monitor and analyze consignment inventories, including periodic field counts held at customer sites.

- We have implemented controls and procedures to assess the collectability of trade accounts receivable and determine its bad debt reserve, which will be overseen by the newly hired credit and collections manager.

- We have developed new controls and procedures regarding the classification of costs and expenses and we have adopted a formal director expense reimbursement policy.

Management is implementing and monitoring the effectiveness of these and other processes, procedures and controls and will make any further changes deemed appropriate. Management believes the foregoing remedial efforts will effectively remediate the material weaknesses. As the Company continues to evaluate and work to improve its internal control over financial reporting, management may determine to take additional measures to address control deficiencies or determine to modify the remediation plan described above.

If not remediated, these control deficiencies could result in further material misstatements to the Company's financial statements.

Remediation of Previously Reported Material Weakness Related to Controls Over Income Tax Accounting. During the year ended December 31, 2014, we developed and implemented new control procedures to address a previously identified material weakness in our internal control over financial reporting. As of December 31, 2013, our management 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 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. We have taken steps to remediate the material weakness, including adherence to existing control procedures and implementation of enhanced controls related to review and oversight of complex transactions and infrequent events. Additionally, we engaged a new third-party tax advisor to oversee and prepare the Company's tax provision and other related documents. We believe that these remediation efforts have improved our internal control over tax accounting, as well as our disclosure controls and procedures, and that the material weakness related to controls over income tax accounting has been remediated at December 31, 2014.

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 Part II, Item 8 of this Form 10-K/A:

FINANCIAL STATEMENT SCHEDULES

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).
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).
10.2.3	Second Amendment to Amended & Restated 2006 Omnibus Plan, effective as of May 6, 2014 (Incorporated herein by reference to Exhibit 4.5 to the Registration Statement on Form S-8 filed by the Registrant with the SEC on October 3, 2014).
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	Third Amendment to Agreement of Lease by and between the Registrant and Columbia Gateway S-28, L.L.C., dated September 30, 2014 (filed herewith).
10.8	Asset Purchase Agreement by and between the Registrant and Mesoblast International SARL, dated as of October 10, 2013 (Incorporated herein by reference to Exhibit 10.7 to the Annual Report on Form 10-K filed by the Registrant with the SEC on March 31, 2014).
10.9*	Exclusive Service Agreement by and between the Registrant and Howmedica Osteonics Corp., also referred to as Stryker Orthopaedics, dated as of December 19, 2014 (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	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) (filed herewith).
31.2.1	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) (filed herewith).
32.1.1	Section 1350 Certification of Chief Executive Officer and 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.

* Confidential portions omitted and filed separately with the United States Securities and Exchange Commission pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

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 27, 2017

By: /s/ DAVID A. DRESNER
David A. Dresner
Interim Chief Executive Officer

By: /s/ GREGORY I. LAW
Gregory I. Law
Chief Financial Officer

Exhibit 10.7

THIRD AMENDMENT TO AGREEMENT OF LEASE

THIS THIRD AMENDMENT TO AGREEMENT OF LEASE (this "Amendment") is made this 25th day of September 2014, by **COLUMBIA GATEWAY S-28, L.L.C.,** a Maryland limited liability company ("Landlord") and **OSIRIS THERAPEUTICS, INC.,** a Maryland corporation ("Tenant").

W I T N E S S E T H:

WHEREAS, Landlord and Tenant entered into that Agreement of Lease dated June 6, 2006, as amended by that certain Letter Agreement dated June 14, 2006, that certain First Amendment to Agreement of Lease dated June 19, 2010, and that certain Second Amendment to Agreement of Lease dated July 9, 2010 (collectively, the "Lease"), by the terms of which Tenant leases from Landlord and Landlord leases to Tenant that certain premises containing an agreed upon equivalent of 61,203 square feet of rentable area (the "Premises"), comprised of the entire office building located at 7015 Albert Einstein Drive, Columbia, Maryland 21044 (the "Building"), all as more particularly described in the Lease for a term which expires on July 31, 2016;

WHEREAS, Landlord and Tenant mutually desire to extend the term of the Lease and to amend the same with respect to the Base Rent and certain other matters of the Lease, all as more particularly set forth below; and

WHEREAS, all capitalized terms used in this Amendment which are not defined herein shall have the meanings given to them in the Lease, unless the context otherwise requires.

NOW, THEREFORE, in consideration of the above Recitals and the mutual covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Landlord and Tenant agree as follows:

1. Extension of Term . Landlord and Tenant agree that the Term of the Lease shall be extended for one (1) additional period of seven (7) years and three (3) months, commencing on August 1, 2016, and expiring October 31, 2023 (the "First Renewal Term"). Tenant's rental of the Premises during the First Renewal Term shall be on the same terms, covenants and conditions set forth in the Lease, provided, however, that Tenant shall pay as Base Rent during the First Renewal Term the amounts set forth below:

Period of First Renewal Term			$PSF	Annual Base Rent	Monthly Installment of Annual Base Rent
8/1/16*	-	7/31/17	$ 18.75	$ 1,147,556.28	$ 95,629.69
8/1/17*	-	7/31/18	$ 19.22	$ 1,176,321.72	$ 98,026.81
8/1/18*	-	7/31/19	$ 19.70	$ 1,205,699.16	$ 100,474.93
8/1/19	-	7/31/20	$ 20.19	$ 1,235,688.60	$ 102,974.05
8/1/20	-	7/31/21	$ 20.69	$ 1,266,290.04	$ 105,524.17
8/1/21	-	7/31/22	$ 21.21	$ 1,298,115.60	$ 108,176.30
8/1/22	-	7/31/23	$ 21.74	$ 1,330,553.28	$ 110,879.44
8/1/23	-	10/31/23	$ 22.28	$ 1,363,602.84*	$ 113,633.57

*The entire Base Rent, Building CAM Expenses and Taxes shall be abated for the entire calendar months of August 2016, 2017, 2018 during the First Renewal Term.

**Annualized based on a full year.

2. Tenant Improvement Allowance . Tenant acknowledges that except as otherwise described herein, the Premises are leased to Tenant for the First Renewal Term in its "as-is" condition as of the date of this Amendment and that Landlord is not obligated to make any improvements to the Premises. At anytime during the period of January 1, 2015 – December 31, 2016, Tenant, at Tenant's request, shall have the right to make such improvements to the Premises as are approved by Landlord, such approval not to be unreasonably withheld, conditioned or delayed. Landlord hereby grants Tenant an allowance not to exceed One Million Five Hundred Thirty Thousand Seventy Five and 00/100 Dollars ($1,530,075.00) (the "Allowance") towards the costs of such improvements. Such improvements shall be subject to the provisions of Section 10 of the Lease. Tenant shall be responsible for preparing all construction documents ("Tenant's Construction Documents"), subject to Landlord's prior consent, which consent shall not be unreasonably withheld, conditioned or delayed. Tenant shall submit to Landlord completed construction documents for Landlord's review and approval. Within ten (10) business days following Landlord's receipt of the Tenant Construction Documents, Landlord shall review, and in Landlord's reasonable discretion, either approve the same or notify Tenant of Landlord's objections thereto and, if applicable, Landlord's proposed modifications. If Landlord has any objections to the Tenant Construction Documents, Landlord shall identify such objections in a written notice to Tenant. Within five (5) business days of receiving Landlord's objections, Tenant shall address the objections and deliver revised Tenant Construction Documents to Landlord for approval in the same manner. The Tenant Construction Documents shall conform to all Legal Requirements applicable to the Tenant Work, and to Landlord's rules and regulations concerning Building safety, fire and protection of persons from injury. Notwithstanding the foregoing, Landlord's approval of the Tenant Construction Documents shall not constitute a representation or warranty by Landlord that the Tenant Construction Documents are in compliance with building codes or other applicable laws. Tenant's improvements shall be referred to as the "Tenant's Work." Tenant shall apply for and obtain all required permits and deliver copies thereof to Landlord prior to commencing Tenant's Work. In such event, Landlord shall disburse the Allowance in accordance with the following provisions:

2.1 The Allowance shall be disbursed to Tenant on a progress payment basis. Proper draw requests submitted by the 20th day of any calendar month shall be paid by the 15th day of the following calendar month. Each of Landlord's progress payments shall be limited to an amount equal to the aggregate amounts theretofore paid by Tenant (as certified by Tenant's architect) to Tenant's contractors, subcontractors, material suppliers, and vendors, and which have not been subject to previous disbursements from the Allowance. Tenant shall withhold from its general contractor, and shall require its general contractor to withhold from each subcontractor, a retainage equal to ten percent (10%) of each progress payment made until the Tenant's Work is fifty percent (50%) complete, and thereafter no further incremental retainage shall be required if the work is being satisfactorily prosecuted. Tenant shall, upon Landlord's request, provide adequate evidence of such retainage, and in the event that Tenant fails to provide such evidence, then Landlord may withhold an amount equal to the retainage described above. All requests for disbursement of the Allowance, if any, shall be accompanied by certificate signed by Tenant or Tenant's architect (a) that the sum then requested was paid by Tenant to contractors, subcontractors, materialmen, engineers and other persons who have rendered services or furnished materials in connection with work on the Tenant Work, (b) a complete description of such services and materials and the amounts paid or to be paid to each of such persons in respect thereof, and (c) that the work described in the certificate has been completed substantially in accordance with the approved plans and specifications and (ii) paid receipts or such other proof of payment as Landlord shall reasonably require for all such work completed.

2.2 If any of the Allowance is not paid pursuant to subsection 2.1 above, it shall be paid by Landlord to Tenant upon completion of the Tenant's Work, to reimburse Tenant for amounts actually paid by Tenant in connection therewith to Tenant's vendors, suppliers or contractors, provided that Landlord shall have received (i) a certificate in accordance with the requirements of subsection 2.1 above, accompanied by lien waivers satisfactory to Landlord executed by any contractors or subcontractors for whose labor or material Tenant has previously been reimbursed pursuant to subsection 2.1 above, (ii) paid receipts or such other proof of payment as Landlord shall reasonably require evidencing that final payment has been made for all materials and labor furnished in connection with the Tenant Work, and (iii) a copy of a final unconditional certificate of occupancy evidencing that Tenant may commence occupancy of the Premises for all purposes set forth in the Lease if one is required for Tenant's occupancy.

2.3 Tenant shall be permitted to apply the Allowance and Amortized Amount to costs associated with Tenant's Work, including without limitation, the Tenant's Work, space planning and design, mechanical, electrical and plumbing engineering costs, construction fees, tenant improvement cabling, voice/data, phone data costs, built-in furniture and any professional or consulting fees specifically related to Tenant's Work. Any unused Allowing remaining as of January 1, 2016 shall be deemed forfeited by Tenant and shall not be reserved for future improvements or credited to rent due under the Lease. Notwithstanding the foregoing, in the event Tenant is involved in litigation, arbitration or other similar claim dispute with a vendor, supplier or contractor that completed work as part of Tenant's Work and as the result of such dispute Tenant is unable to provide the necessary lien waiver documentation to Landlord as part of its request for final Allowance disbursement, upon receipt of written notice from Tenant, Landlord agrees to extend the deadline of January 1, 2016 for an amount not to exceed ten percent (10%) of the Allowance, until July 1, 2016.

3. Landlord's HVAC Work . On or before March 31, 2015, subject to reasonable delays caused by weather events, Landlord, at its sole cost and expense and not paid from the Allowance or included as a Building Expense, shall replace and resize all existing base Building HVAC units, including those which service the Premises, but excluding those specific units which have been previously installed by Tenant which are dedicated to Tenant's clean room (i.e, Units #10, 13, 17, 19, 24 and 27) ("Landlord's HVAC Work"). Landlord's HVAC Work shall be fully designed and engineered by a professional engineer registered in the state of Maryland, permitted and inspected by the authority having jurisdiction, and meet the performance criteria (i.e. thermal comfort, dehumidification, and energy consumption) for similar Class A flex buildings in Columbia, MD and ASHRAE and humidity standards for office use and upon completion of Landlord's HVAC Work, Landlord shall ensure the new units have been properly balanced by an NEBB Certified balancing contractor and all operation and controls fully tested and commissioned by the installation contractor, building controls vendor and HVAC equipment manufacturer, with such commissioning observed by Tenant or Tenant's representatives. Landlord and Tenant hereby agree to reasonably cooperate with each other during the completion of Landlord's HVAC Work in order to minimize any disruption to Tenant's business. Following the completion of Landlord's HVAC Work, Tenant shall be responsible for the repair and maintenance of the new HVAC units at its sole cost and expense in accordance with Section 11 of the Lease. Landlord shall purchase a one (1) year warranty from the installation contractor on all parts and labor and shall administer this warranty on behalf of Tenant during this one (1) year period. Landlord shall also reasonably assist Tenant in administering any manufacturer warranties on behalf of Tenant. Landlord and Landlord's installation contractor shall provide training on all new HVAC equipment and shall provide detailed O&M manuals to Tenant.

4. Landlord's Roof Work . On or before March 31, 2015, subject to reasonable delays caused by weather events, Landlord, at its sole cost and expense and not paid from the Allowance or included as a Building Expense, shall replace the roof of the Building ("Landlord's Roof Work"). Landlord and Tenant hereby agree to use commercially reasonable efforts to cooperate with each other during the completion of Landlord's Roof Work in order to minimize any disruption to Tenant's business.

5. Laboratory Restoration . As part of Tenant's Work, Tenant hereby agrees to perform certain improvements to the laboratory portion of the Premises approved by Landlord, such approval not to be unreasonably withheld, conditioned or delayed.

6. Repairs and Maintenance . Effective as of January 1, 2015, Sections 11.1 and 11.2 of the Lease are hereby deleted in their entirety and the following is hereby inserted in lieu thereof:

11.1 Tenant's Care of the Premises and Building . During the Term Tenant shall:

(i) keep the Premises and the fixtures, appurtenances, improvements and equipment therein in good order and condition;

(ii) make any and all repairs and replacements to the Premises required because of Tenant's misuse or primary negligence, except to the extent that the repairs or replacements are covered by Landlord's insurance as required hereunder;

(iii) repair and replace special equipment or decorative treatments installed by or at Tenant's request and that serve the Premises only, except to the extent the repairs or

replacements are needed because of Landlord's misuse or primary negligence, and are not covered by Tenant's insurance as required hereunder;

(iv) pay for all damage to the Building, its fixtures and appurtenances, as well as all damages sustained by Tenant or occupants of the Building due to any waste, misuse or neglect of the Premises, its fixtures and appurtenances by Tenant, except to the extent that the repair of such damage is covered by Landlord's insurance as required hereunder to the extent that Landlord actually receives proceeds there from;

(v) provide regular janitorial service to the Premises and remove all trash to receptacles designated by Landlord; and

(vi) not commit waste.

In addition Tenant shall not place a load upon any floor of the Premises exceeding the floor load per square foot area which such floor was designed to carry and which may be allowed under Applicable Laws. Landlord reserves the right to prescribe the weight and position of all heavy equipment brought onto the Premises and prescribe any reinforcing required under the circumstances, all such reinforcing to be at Tenant's expense.

11.2 Landlord's Repairs . Except for the repairs and replacements that Tenant is required to make pursuant to Section 11.1 above, Landlord shall maintain, repair and replace, as necessary, the exterior Common Areas and Building (including Building fixtures and equipment) as shall be reasonably deemed necessary to maintain the Building in a condition comparable to other first class suburban office buildings in the Baltimore-Washington corridor area. This maintenance shall include the roof, designated parking areas, foundation, exterior walls, interior structural walls, all structural components, and all systems such as mechanical, electrical, HVAC, and plumbing. The costs associated with such repairs shall be deemed a part of Building Expenses; provided, however, that costs of all of such repairs which would be considered capital in nature under generally accepted accounting principles ("GAAP") shall be included in Building Expenses, amortized in accordance with GAAP. There shall be no allowance to Tenant for a diminution of rental value, no abatement of rent, and no liability on the part of Landlord by reason of inconvenience, annoyance or injury to business arising from Landlord, Tenant or others making any repairs or performing maintenance as provided for herein. Notwithstanding, Landlord will use commercially reasonable efforts to not interfere with Tenant's business operations.

7. Building Expenses . Effective as of January 1, 2015, Section 6.2.2 of the Lease is hereby deleted in its entirety and the following is hereby inserted in lieu thereof:

6.2.2 "Building Expenses" shall be all those expenses, charges and fees paid or incurred by Landlord in connection with the owning, maintaining, operating, servicing, insuring and repairing of the Property or any part thereof, in a manner deemed reasonable and appropriate by Landlord and shall include, without limitation, the following:

6.2.2.1 All costs and expenses of operating, repairing, lighting, cleaning, and insuring (including liability for personal injury, death and property damage and workers' compensation insurance covering personnel) the Property or any part thereof, as well as all costs incurred in removing snow, ice and debris therefrom and of policing and regulating traffic with respect thereto, and depreciation of all machinery and equipment used therein or thereon, replacing or repairing of pavement, parking areas, curbs, walkways, drainage, lighting facilities, landscaping (including replanting and replacing flowers and other planting);

6.2.2.2 Except to the extent directly paid by Tenant pursuant to Section 24 of the Lease, electricity, steam and fuel used in lighting, heating, ventilating and air conditioning and all costs, charges, and expenses incurred by Landlord in connection with any change of any company

providing electricity service, including, without limitation, maintenance, repair, installation and service costs associated therewith, as well as all expenses associated with the installation of any energy or cost savings devices;

6.2.2.3 Maintenance and repair of mechanical and electrical equipment including heating, ventilating and air conditioning equipment;

6.2.2.4 Window cleaning;

6.2.2.5 Maintenance of any exterior Common Areas;

6.2.2.6 Repair and maintenance of the parking areas, including without limitation, the resurfacing and striping of said areas;

6.2.2.7 Sales or use taxes on supplies or services;

6.2.2.9 Management fees equal to 3% of gross rental received by Landlord at the Property (allocated to their time spent working with respect to the Property) and the provision of amenities to all tenants in the Property (including Landlord's share of all payroll taxes and the cost of an on-site or near-site office and segregated storage area for Landlord's parts, tools and supplies);

6.2.2.8 Costs and expenses that may result from compliance with any governmental laws or regulations that were not applicable to the Property at the time same were originally constructed; and

6.2.2.9 All other expenses which under generally accepted accounting principles would be considered as an expense of the Property. Notwithstanding the foregoing, all expenses (whether or not such expenses are enumerated on items 1 through 11 of this Section 6.2.2) which would be considered capital in nature under generally accepted accounting principles shall be excluded from "Building Expenses" unless same are amortized in accordance with generally accepted accounting principles over the useful life of the improvement.

8. Services and Utilities . Effective as of January 1, 2015, Section 23 of the Lease is hereby deleted in its entirety and the following is hereby inserted in lieu thereof:

23. Services and Utilities . Landlord shall provide the following listed services and utilities, namely:

(a) electric energy in accordance with Section 24 following;

(b) hot and cold water sufficient for drinking, lavatory toilet and ordinary cleaning purposes from fixtures either within the Premises (if provided pursuant to this Lease) or on the floor on which the Premises are located, all in accordance with Section 24 following; and

(c) maintenance of exterior Common Areas in a manner comparable to other first class suburban office buildings in the Baltimore-Washington corridor.

Landlord reserves the right to stop service of the plumbing and electric systems, when necessary, by reason of accident, or emergency, or for repairs, alterations, replacements, or improvements, which in the judgment of Landlord are desirable or necessary to be made, until the repairs, alterations, replacements, or improvements shall have been completed. Landlord shall have no responsibility or liability for failure to supply plumbing and electric service, during the period when prevented from so doing by laws, orders, or regulations of any Federal, State, County or Municipal authority or by strikes, accidents or by any other cause whatsoever beyond Landlord's control.

9. Tenant's Proportionate Share . As of the date of this Amendment, the term "Tenant's Proportionate Share" means that percentage which is computed by a fraction, the numerator of which is the Rentable Area of the Premises and the denominator of which is the Rentable Area of the Building. As of the date of this Amendment, Tenant's Proportionate Share is 100%.

10. Option to Extend Lease Term . Landlord and Tenant hereby agree that all remaining options to extend the Term of the Lease pursuant to Section 3.3 of the Lease are hereby deleted and Tenant shall have the right and option to extend the Term of the Lease in accordance with the provisions set forth below.

Tenant shall have the option to extend the Term of the Lease for two (2) additional periods of five (5) years each (the "Second Renewal Term" and "Third Renewal Term") to commence immediately upon the expiration of the First Renewal Term or the Second Renewal Term, as applicable, provided Tenant is not in default of any term, covenant or condition of the Lease after the expiration of all applicable cure periods (i) on the date Tenant notifies Landlord of its intent to exercise for the applicable Renewal Term and (ii) on the date the applicable Renewal Term is otherwise scheduled to commence.

Tenant's rental of the Premises during the Second Renewal Term and Third Renewal Term shall be upon the same terms, covenants and conditions contained in the Lease, except that Tenant shall pay to Landlord as Base Rent the "Prevailing Market Rate" for the Premises for the Second Renewal Term or the Third Renewal Term, as applicable, as hereinafter defined (including annual adjustments). The term "Prevailing Market Rate" shall mean the then prevailing market rate being charged for comparable space in comparable office buildings within a ten (10) mile radius of the Premises, with consideration given for construction allowances, commissions, free rent, and other concessions or premiums. In order to exercise its option granted herein, Tenant shall notify Landlord in writing of its intent to renew not less than twelve (12) months prior to the expiration of the First Renewal Term or the Second Renewal Term, as applicable. Within thirty (30) days following the exercise by Tenant of its option to extend the Lease for the Second Renewal Term or the Third Renewal Term, as applicable, Landlord shall notify Tenant in writing of its determination of the Prevailing Market Rate for the Second Renewal Term or the Third Renewal Term, as applicable, as reasonably determined by Landlord ("Landlord's Notice"). Within ten (10) days after receipt of Landlord's Notice, Tenant shall notify Landlord in writing of Tenant's acceptance or rejection of such rate. If Tenant shall accept such Prevailing Market Rate, Landlord and Tenant shall enter into an amendment to the Lease acknowledging such renewal and setting forth any terms at variance with the terms of the Lease. If within the ten (10) day period, Tenant shall reject such Prevailing Market Rate as determined by Landlord for the Second Renewal Term or the Third Renewal Term, as applicable, then within twenty (20) days thereafter, Landlord and Tenant shall meet at a mutually acceptable time and place and shall use their reasonable efforts to agree upon the Prevailing Market Rate. If Landlord and Tenant shall fail to agree upon such Prevailing Market Rate within the twenty (20) day period, Landlord and Tenant shall each appoint an independent experience Howard County commercial leasing broker licensed in the Maryland area with at least ten (10) years experience working with tenants having a title equivalent to Vice President or above within the next ten (10) days (the "Brokers"). Such Brokers shall deliver their respective estimates of the Prevailing Market Rate within ten (10) days after being appointed. If the estimates of the Prevailing Market Rate as quoted by the Brokers are within seven percent (7%) of each other, the Prevailing Market Rate shall be deemed to be the average of the estimates presented by the Brokers. If the estimates of the Prevailing Market Rate as quoted by the Brokers differ by more than seven percent (7%), then Landlord and Tenant shall jointly appoint a third independent commercial leasing broker licensed in the Maryland area using the same broker criteria set forth above within ten (10) days after the receipt of the initial brokers' estimates (the "Third Broker") who shall deliver its estimate of the Prevailing Market Rate within ten (10) days after being appointed and such estimate shall be deemed to be the Prevailing Market Rate. Tenant shall notify Landlord within ten (10) days after receipt of the estimate of the Prevailing Market Rate (whether as resulting from the average of the Brokers or from the Third Broker, as applicable), whether Tenant shall accept such Prevailing Market Rate, whereupon Landlord and Tenant shall enter into an amendment to the Lease acknowledging such renewal and setting forth any terms at variance with the terms of the Lease. If (i) Tenant shall fail to deliver the requisite notice exercising its option to extend by the date prescribed above, (ii) Tenant does not respond within ten (10) days following receipt of Landlord's Notice or (iii) Tenant does not accept the Prevailing Market Rate within ten (10) days following Landlord's notification of the Prevailing Market Rate, as determined either by the average of the Brokers or from the Third Broker, as applicable, then Tenant's option to extend the Lease for the Second Renewal Term or the Third

Renewal Term, as the case may be, shall be void and inoperable. Landlord and Tenant shall each pay the fee of the broker designated by them originally and shall split the fees of the Third Broker.

Notwithstanding anything to the contrary contained herein, Landlord hereby agrees that Tenant may elect to exercise either Renewal Term for only a portion of the Premises which is not less than fifty percent (50%) of the Rentable Area of the Premises as of the date of this Amendment; provided, however, the surrendered portion of the Premises shall be of size, dimension and location which is reasonably approved by Landlord so that Landlord can market such space to a third-party. In such event, Landlord shall pay all costs to re-demise the Premises.

11. Options to Terminate .

11.1 First Termination Right . Tenant shall have the right to terminate the Lease during the First Renewal Term effective on July 31, 2019, provided that (i) Tenant gives Landlord at least nine (9) months prior written notice of its intent to terminate the Lease, (ii) prior to the effective date of termination, there has been a "change in control" event whereby (A) more than fifty percent (50%) of the voting stock of Tenant has been acquired by any individual or entity (other than employees or shareholders of Tenant) or (B) a sale of substantially all of Tenant's assets has occurred, (iii) there is no outstanding Event of Default beyond all applicable cure periods at the time that Tenant notifies Landlord of its intent to terminate the Lease or as of the date of termination, and (iv) on or before the effective date of termination, Tenant pays to Landlord a termination fee in the amount equal to the sum of (w) the unamortized amount of the Allowance paid by Landlord, at Landlord's expense, in accordance with the provisions of Section 2 of this Amendment applying an interest rate of eight and one-half percent (8.5%) per annum, (x) unamortized amount of the brokerage commissions payable in accordance with Section 15 of this Amendment, applying an interest rate of eight and one-half percent (8.5%) per annum, (y) unamortized amount (using a 15 year amortization period) of the costs of Landlord's HVAC Work and Landlord's Roof Work (as such terms are defined in Sections 3 and 4 of this Amendment, respectively), applying an interest rate of eight and one-half percent (8.5%) per annum, and (z) an amount equal to nine (9) Monthly Installments of Annual Base Rent in effect as of the date of termination. If Tenant fails to exercise its termination rights strictly in accordance with the foregoing provision, the Lease shall remain in full force and effect and Tenant shall have no further right to terminate the Lease except as set forth in Section 11.2 below.

11.2 Second Termination Right . Provided Tenant has exercised its right to terminate the Lease in accordance with Section 11.1 above, Tenant shall have the right to terminate the Lease during the First Renewal Term effective on July 31, 2021, provided that (i) Tenant gives Landlord at least twelve (12) months prior written notice of its intent to terminate the Lease, (ii) prior to the effective date of termination, there has been a "change in control" event whereby (A) more than fifty percent (50%) of the voting stock of Tenant has been acquired by any individual or entity (other than employees or shareholders of Tenant) or (B) a sale of substantially all of Tenant's assets has occurred, (iii) there is no outstanding Event of Default beyond all applicable cure periods at the time that Tenant notifies Landlord of its intent to terminate the Lease or as of the date of termination, and (iv) on or before the effective date of termination, Tenant pays to Landlord a termination fee in the amount equal to the sum of (x) the unamortized amount of the Allowance paid by Landlord, at Landlord's expense, in accordance with the provisions of Section 2 of this Amendment applying an interest rate of eight and one-half percent (8.5%) per annum, (y) unamortized amount of the brokerage commissions payable in accordance with Section 15 of this Amendment, applying an interest rate of eight and one-half percent (8.5%) per annum and (z) an amount equal to six (6) Monthly Installments of Annual Base Rent in effect as of the date of termination. If Tenant fails to exercise its termination rights strictly in accordance with the foregoing provision, the Lease shall remain in full force and effect and Tenant shall have no further right to terminate the Lease.

12. Reserved Parking . Within thirty (30) days following the date of this Amendment, Landlord shall designate twenty (20) parking spaces directly in front of the Building as "OSIRIS or Visitor Reserved" at no cost to Tenant, and any reasonable and actual costs incurred by Landlord to properly designate such spaces shall be paid from the Allowance or reimbursed by Tenant within thirty (30) days following receipt of written request. The designation of such twenty (20) parking spaces shall continue so long as Tenant is the sole occupant of the Building.

13. Security Deposit . Within ten (10) days following the date of this Amendment, Landlord hereby agrees to release the Letter of Credit issued by Wells Fargo Bank, N.A. to satisfy Tenant's obligations under Section 4 of the Lease, and in lieu thereof, Landlord agrees to accept from Tenant a cash or Letter of Credit Security Deposit in an

amount equal to Ninety Five Thousand Six Hundred Twenty Nine and 69/100 Dollars ($95,629.69) (the "Security Deposit'). The Security Deposit shall be paid by Tenant simultaneously with the execution of this Amendment. Landlord shall deliver the released Letter of Credit to Tenant within ten (10) days following receipt of the Security Deposit. The Security Deposit shall be held by Landlord for the remainder of the Tern in accordance with Section 4 of the Lease as modified below.

Accordingly, as of the date of this Amendment, Section 4 of the Lease is hereby deleted in its entirety and the following is inserted in its place:

4. Security Deposit .

4. Security Deposit . Tenant has this day paid to Landlord the Security Deposit to be held by Landlord as security for the payment and performance by Tenant of all obligations imposed on Tenant hereunder, in an account the proceeds of which may be commingled by Landlord with any other account or proceeds. If Tenant shall perform all such obligations, the Security Deposit shall be refunded to Tenant, without interest, following the end of the Term. If Tenant shall default in any such obligation and such default shall continue beyond all applicable cure periods, Landlord shall be entitled to apply all or any portion of the Security Deposit, pro tanto, to cure any such default, and Tenant shall replenish the Security Deposit to the full amount within thirty (30) days after receipt of a written notice from Landlord which sets forth the amount to be replenished. If the Security Deposit is not fully restored, it shall constitute an immediate Event of Default (as defined in Section 21) under the terms of the Lease (without need of notice or the expiration of any cure period), and Landlord shall have the benefit of all remedies permitted pursuant to the terms of the Lease and the laws of the State of Maryland. The Security Deposit shall not be considered an advance payment of rent or a measure of Landlord's damages in case of default by Tenant. In the event of the sale or transfer of Landlord's interest in the Building, Landlord shall have the right to transfer the Security Deposit to the purchaser or transferee and upon such transfer Tenant shall look only to the new landlord for the return of the Security Deposit and Landlord shall thereupon be released from all liability to Tenant for the return of or accounting for the Security Deposit."

Notwithstanding anything contained herein to the contrary, there shall be no reduction in the amount of the Security Deposit held by Landlord prior to the expiration of the of the Lease.

14. SNDA . Within sixty (60) days following the date of this Amendment, Landlord, at its sole cost and expense, hereby agrees to use commercially reasonable efforts to procure a Subordination, Nondisturbance and Attornment Agreement ("SNDA") signed by any current mortgagee in the form attached hereto as Exhibit "A" . In addition, Landlord shall use commercially reasonable efforts to obtain an SNDA from any future mortgagee.

15. Broker . Tenant represents that Tenant has not dealt directly or indirectly with any broker in connection with this Amendment other than Jones Lang LaSalle Brokerage, Inc. ("Broker"), and Tenant warrants that no other broker negotiated this Amendment or is entitled to any commissions in connection with this Amendment. Tenant shall indemnify and hold Landlord harmless for any breach of the foregoing representations. Landlord shall pay Broker its commission due for the First Renewal Term.

16. Ratification of Lease . All other terms, covenants and conditions of the Lease shall remain the same and continue in full force and effect, and shall be deemed unchanged, except as such terms, covenants and conditions of the Lease have been amended or modified by this Amendment and this Amendment shall, by this reference, constitute a part of the Lease.

[SIGNATURES ON FOLLOWING PAGE]

IN WITNESS WHEREOF, Landlord and Tenant have respectively affixed their hands and seals to this Amendment as of the day and year first above written.

WITNESS:

LANDLORD:

COLUMBIA GATEWAY S-28, L.L.C.

/s/ LEE W. MURRAY

By: /s/ STEPHEN E. BUDORICK (SEAL)

Stephen E. Budorick

Executive Vice President

WITNESS:

TENANT:

OSIRIS THERAPEUTICS, INC.

/s/ MEENU MARIE SURI

By: /s/ PHILIP R. JACOBY, JR. (SEAL)

Name: Philip R. Jacoby, Jr.

Title: Chief Financial Officer

STATE OF MARYLAND, COUNTY OF HOWARD, TO WIT:

I HEREBY CERTIFY, that on this 30th day of September, 2014, before me, the undersigned Notary Public of said State, personally appeared STEPHEN E. BUDORICK, who acknowledged himself to be Executive Vice President of COLUMBIA GATEWAY S-28, L.L.C., a Maryland limited liability company, known to me (or satisfactorily proven) to be the person whose name is subscribed to the within instrument, and acknowledged that he executed the same for the purposes therein contained as the duly authorized Executive Vice President by signing the name of the company by himself as Executive Vice President.

WITNESS my hand and Notarial Seal.

/s/ MONIQUE Y. JONES

Notary Public

My Commission Expires: November 21, 2016

STATE OF MARYLAND, COUNTY OF HOWARD, TO WIT:

I HEREBY CERTIFY, that on this 25 th day of September, 2014, before me, the undersigned Notary Public of said State, personally appeared Philip R. Jacoby, Jr., known to me (or satisfactorily proven) to be the person whose name is subscribed to the within instrument, and acknowledged himself/herself to be the Chief Financial Officer of OSIRIS THERAPEUTICS, INC., a Maryland corporation, that he/she, as such Chief Financial Officer, being authorized so to do, executed the foregoing instrument on behalf of said Corporation by himself/herself as such Chief Financial Officer.

WITNESS my hand and Notarial Seal.

/s/ DIANE KATHLEEN SAVOIE

Notary Public

My Commission Expires: May 16, 2015

EXCLUSIVE SERVICE AGREEMENT

THIS EXCLUSIVE SERVICE AGREEMENT , including all appendices hereto and as may be amended from time to time (this " **Agreement** "), is made and entered into effective as of the 19th day of December, 2014 (the " **Effective Date** "), by and between Howmedica Osteonics Corp., also referred to as Stryker Orthopaedics (" **Stryker** "), a New Jersey corporation, having a place of business at 325 Corporate Drive, Mahwah, New Jersey 07430 and Osiris Therapeutics, Inc. (" **Osiris** "), a Maryland corporation, having a place of business at 7015 Albert Einstein Drive, Columbia, Maryland 21046. Stryker and Osiris are sometimes referred to herein, individually, as a " **Party** " and, collectively, as the " **Parties** ."

WHEREAS, Osiris develops, processes and distributes human tissue allografts for medical use, including its proprietary OvationOS® viable bone matrix allograft;

WHEREAS, Stryker, together with its Affiliates (as defined below), develops, manufactures, distributes and sells a wide range of medical technology products and services, including products and services for use in orthopaedic surgery; and

WHEREAS, Osiris wishes to appoint Stryker as its exclusive (to the extent provided below), worldwide marketer and promoter of the Allograft Services (as defined below), and Stryker wishes to accept such appointment, all subject to and in accordance with the terms and conditions of this Agreement.

NOW THEREFORE , for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows.

ARTICLE I
CERTAIN DEFINITIONS

1.1 " **Act** " means the United States Federal Food, Drug and Cosmetic Act, as amended to date and as may be further amended from time to time during the Term, and the regulations promulgated with respect thereto.

1.2 " **Affiliate** " means, with respect to any particular Person, any other Person controlling, controlled by or under common control with such Person. For purposes of this definition, " **control** " (including the terms " **controlling** ," " **controlled by** " and " **under common control with** ") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise, and such "control" will be presumed if any Person owns 50% or more of the voting capital stock or other ownership interests, directly or indirectly, of any other Person.

1.3 " **Allograft** " means: (i) Osiris's OvationOS® viable bone matrix allografts and (ii) any extensions, improvements and next generation versions of and other modifications to any such allograft for use in the Field of Use **,** whether or not provided under the OvationOS® name, and whether or not acquired, processed, preserved, controlled, stored, transported, or distributed in the same manner as OvationOS®.

1.4 " **Allograft Services** " means the acquisition, processing, preservation, quality control, storage, transportation, and distribution of the Allografts.

1.5 " **Bio [4] Mark** " means any Mark that incorporates the term "Bio [4] " or any other term that is confusingly similar to or derived from the term "Bio [4] ."

1.6 " **Change of Control** " means, with respect to a Party, the consummation of any transaction or series of related transactions that result in: (i) the direct or indirect acquisition of more than fifty percent (50%) of any class of equity securities of a Party (or of any Affiliate that directly or indirectly controls such Party), (ii) the direct or indirect acquisition of all or substantially all assets of a Party (or of any Affiliate that directly or indirectly

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*** Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

controls such Party), (iii) the direct or indirect acquisition of all or substantially all assets of any line of business (which is materially related to this Agreement) of such Party (or of any of its Affiliates) or (iv) merger, consolidation, share exchange, business combination, recapitalization, liquidation, dissolution or similar transaction involving such Party (or any Affiliate that directly or indirectly controls such Party) that if consummated would result in a Person or "group" (as defined in Section 13(d) of the Securities Exchange Act of 1934, as amended) beneficially owning more than fifty percent (50%) of any class of equity securities of such Party (or of any Affiliate that directly or indirectly controls such Party).

1.7 **"Confidential Information"** means any and all proprietary and/or confidential information of a Party or any of its Affiliates (the " **Disclosing Party** ") including trade secrets, technical information, intellectual property, business information, sales information, inventions, developments, discoveries, know-how, methods, techniques, data, processes, and other information) that the other Party (the " **Receiving Party** ") has access to or receives in connection with this Agreement, whether furnished in any form, including written, verbal, visual, electronic or in any other media or manner. Notwithstanding the foregoing, " **Confidential Information** " does not include any information that is: (i) rightfully known to the Receiving Party prior to receipt from the Disclosing Party, and not subject to any obligation of confidentiality; (ii) rightfully obtained from a third party authorized to make such a disclosure, and not subject to any obligation of confidentiality; (iii) independently developed by the Receiving Party; (iv) available to the public without restrictions or (v) approved for disclosure with the prior, written approval of the Disclosing Party. The Receiving Party shall not be relieved of its obligations as to any Confidential Information which is specific, merely because such specific Confidential Information is contained in general information falling within one or more of the above categories.

1.8 " **Copyrights** " shall mean any and all rights in and to works of authorship and rights associated with works of authorship subject to protection under copyright law, whether or not registered, throughout the world, including without limitation: (i) copyrights, rights in and to copyright applications, and copyright registrations issued or filed throughout the world; and (ii) Moral Rights.

1.9 " **Customer** " means any purchaser of the Allograft Services.

1.10 " **Exclusivity Period** " means the Initial Exclusivity Period and any Extended Exclusivity Period.

1.11 " **Extended Exclusivity Period** " means, to the extent Stryker elects to extend the exclusive rights granted to it under this Agreement in accordance with Section 2.3(b) below, the period that begins upon expiration of the Initial Exclusivity Period and ends four (4) years thereafter (or, if earlier, on the effective date of any earlier termination of this Agreement).

1.12 " **FDA** " means the United States Food and Drug Administration, or any successor agency having the same or similar authority.

1.13 " **Field of Use** " means all surgical applications, including spine surgery, trauma surgery, extremity surgery, cranial surgery and foot and ankle surgery, and all of their respective osteogenic applications.

1.14 " **First Commercial Sale Date** " means the date of the first Service Order for Allograft Services.

1.15 " **Initial Exclusivity Period** " means the period that begins on the First Commercial Sale Date and ends four (4) years thereafter (or, if earlier, on the effective date of any earlier termination of this Agreement).

1.16 " **Initial Payment Trigger Date** " means the date on which Osiris provides Stryker with a copy of a fully-executed agreement between Osiris and NuVasive, Inc. (" **NuVasive** "), in a form reasonably acceptable to Stryker (and Stryker agrees not to unreasonably withhold, condition, or delay acceptance of the same), which agreement (the " **NuVasive — Osiris Agreement** ") contains terms and conditions that are consistent in all material respects with the proposed terms and conditions set forth in that certain "Term Sheet — Covenant Not to Sue" between NuVasive and Osiris dated December 18, 2014.

*** Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

1.17 " **Intellectual Property Rights** " shall mean and include any and all procedures, processes, designs, discoveries, Know-how, Patents, Marks, Copyrights, trade secrets, computer programs (in source code and object code form), flow charts, algorithms, formulae, enhancements, updates, modifications, translations, adaptations, Confidential Information, Specifications, process technology, manufacturing requirements, quality control standards, designs and design rights, customer relationships, distributor networks, covenants not to compete and supply chain information systems, whether registered or unregistered.

1.18 " **Know-how** " shall mean and include technical knowledge, expertise, practice, proprietary rights, patented or unpatented inventions, trade secrets, surgical and other techniques and procedures, analytical and clinical methodologies, clinical data and/or other experience in tangible or intangible form.

1.19 " **Law** " means any law, common law, statute, code, ordinance, regulation or rule of any governmental authority.

1.20 " **Marks** " shall mean and include those trademarks, brand names, trade names, trade dress, logos, slogans, service marks, domain names, copyrights, pictorial depictions or symbols intended to indicate the origin of goods or services, other branding and similar designations, anywhere in the world, whether registered or unregistered, and all applications and registrations related thereto.

1.21 **"Moral Rights"** shall mean any and all rights to claim authorship to, to be named as the author of or to publish a copyright protected work, to revoke or to object to any distortion, mutilation, or other derogatory action or modification in relation to such work, whether or not the copyright under such work is registered, whether or not such would be prejudicial to the author's reputation, and any similar right existing under common or statutory law of any country in the world or under any treaty, regardless of whether or not such right is denominated or generally referred to as a "moral right."

1.22 " **Minimum Average Service Fee** " or " **Minimum ASF** " means [***] for Allograft Services (including any related shipping costs) provided per cubic centimeter of Allograft, or such other amount as is determined by the JSC pursuant to Section 3.2(a) .

1.23 " **NOTA** " means the National Organ Transplant Act of 1984 (Pub. L. No. 98-507, 98 Stat. 2339, codified at 42 U.S.C. §§273 to 274e).

1.24 " **Osiris Domain Names** " means OvationOS.com and any other domain name registrations used prior to the Effective Date in connection with any Allograft or Allograft Services. For the avoidance of doubt, Osiris Domain Names does not include Osiris.com or Osiris.net.

1.25 " **Osiris Marks** " means OvationOS® and any other Mark used prior to the Effective Date in connection with any Allograft or Allograft Services. For the avoidance of doubt, the Osiris Marks shall not include any of the Bio [4] Marks.

1.26 " **Person** " means any individual, sole proprietorship, partnership, joint venture, trust, unincorporated association, corporation, limited liability company, entity or governmental entity (whether foreign, federal, state, county, city or otherwise and including any instrumentality, division, agency or department thereof).

1.27 " **Revenue** " means, with respect to a given period, the total amount of Customer Fees invoiced by Stryker during such period.

1.28 " **Stryker Services** " means the commercialization, billing and collections services provided by Stryker under this Agreement with respect to the Allograft Services.

*** Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

1.29 " **Territory** " means the entire world.

1.30 **Additional Definitions.** Each of the following terms is defined in the Section set forth opposite such term:

Term	Section
AATB	9.2
Actual Revenue	5.6(i)
Administration Fees	6.4(b)
Aggregate Fees Charged	5.4(a)
Aggregate Quantity	5.4(a)
Agreement	Preamble
Average Service Fee	5.4(a)
Bio [4] Domain Names	2.4(a)
Claims	14.1
Commissions	6.4(a)
Consignment Terms	5.2
Customer Fees	5.8
Customer Return	5.9(c)
Effective Date	Preamble
Exclusivity Fee Refund	8.4(b)
Extended Exclusivity Fee	6.2
Extension Term	8.1(c)
Initial Exclusivity Fee	6.1
JSC	3.1
Losses	14.1
Lost Revenue	5.6
Non-Exclusive Extension Fee	6.3
Transaction Notice	7.1
Osiris	Preamble
Osiris Change of Control	8.4
Osiris Indemnitee	14.1
Osiris Promotional Materials	4.1(b)
Parties	Preamble
Party	Preamble
Payment Date	5.9(a)
Post-Termination Payment	8.4(c)
Quality Agreement	9.6
RA#	5.10
Review Period	7.1
Rolling Forecast	5.1
Scientific Strategy	3.2(b)
Scientific Strategy Costs	4.3
Sell-Off Period	8.8(c)
Service Order	5.3
Study Results	4.3(a)
Stryker	Preamble
Stryker Change of Control	8.5
Stryker Indemnitee	14.1
Subcontractor	2.2
Supply Failure	5.6
Supply Failure Payments	6.5
Supply Failure Trigger	5.6
Term	8.1(c)

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Term	Section
Third Party Claims	14.1
Transferring Party	15.2

ARTICLE II
APPOINTMENT OF STRYKER; EXCLUSIVITY

2.1 Appointment of Stryker. Osiris hereby appoints Stryker as the exclusive (to the extent provided in Section 2.3 below) marketer and promoter of the Allograft Services for the Field of Use in the Territory during the Term (and, thereafter, on a non-exclusive basis during any Sell-Off Period).

2.2 Subcontractors; Affiliates. Stryker may appoint any third party agents, distributors, co-promotion partners or other third parties to assist Stryker in the marketing and promotion of the Allograft Services and/or the provision of the Stryker Services (each, a "**Subcontractor**"). Any Affiliate of Stryker may exercise any of Stryker's rights under this Agreement. Stryker will be responsible for the performance of any of its Subcontractors and Affiliates under this Agreement, and will ensure that the rights granted to each Subcontractor or Affiliate (i) do not conflict with the provisions of this Agreement and (ii) are in compliance with applicable Law.

2.3 Exclusivity; Extended Exclusivity Period; Non-Exclusivity Period.

(a) Exclusivity. During the Exclusivity Period, neither Osiris nor any of its Affiliates will (nor will any of them appoint or permit any other Person to) directly or indirectly promote, market, sell or distribute (other than through Stryker in accordance with this Agreement) any Allograft or Allograft Services to any Person in the Territory for use in the Field of Use. Osiris retains the right to present and inform (but not sell or distribute) regarding the Allografts in the Field of Use, through Osiris corporate reports and scientific presentations. With respect to scientific presentations, Osiris agrees to submit the proposed manuscript to Stryker for review and comment reasonably in advance of the proposed presentation and agrees to take into account any reasonable comments provided by Stryker with respect to the presentation.

(b) Extended Exclusivity Period. At the end of the Initial Exclusivity Period, Stryker, at its sole option, may elect to continue the exclusive rights granted to Stryker under this Agreement for the Extended Exclusivity Period, by paying Osiris the Extended Exclusivity Fee (as determined pursuant to Section 6.2), if any, on or before the last day of the Initial Exclusivity Period.

(c) Non-Exclusive Extension. At the end of the Initial Exclusivity Period, if Stryker does not elect to extend the exclusive rights granted to Stryker under this Agreement in accordance with Section 2.3(b), then Stryker may, at its sole option, extend the Term on a non-exclusive basis for a period of two (2) years from the end of the Initial Exclusivity Period, by paying Osiris the Non-Exclusive Extension Fee (as determined pursuant to Section 6.3), if any, on or before the last day of the Initial Exclusivity Period. In the event Stryker elects to extend the Term on a non-exclusive basis, Sections 2.1, 2.4, and 4.1 will become non-exclusive and the following terms in this Agreement will no longer apply: Section 2.3, Section 2.4(c), Section 5.6, Section 7.1 and Section 8.4.

(d) Termination of Agreement. If at the end of the Initial Exclusivity Period, Stryker neither elects to extend the Exclusivity Period pursuant to Section 2.3(b) nor elects to extend the Term on a non-exclusive basis pursuant to Section 2.3(c), then this Agreement shall automatically terminate, with such termination effective as of the end of the Initial Exclusivity Period; provided, however, that if the Revenue for the Initial Exclusivity Period is less than [***], then, without limiting Stryker's right to receive any applicable Supply Failure Payment under Section 6.5, Stryker will pay Osiris a

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termination fee equal to One Million Five Hundred Thousand U.S. Dollars ($1,500,000) for every [***] by which the Revenue for the Initial Exclusivity Period is below [***].

(e) **Notice to Osiris** . Stryker will notify Osiris in writing at least ninety (90) days before the end of the Initial Exclusivity Period as to whether Stryker will elect to proceed under Section 2.3(b) , Section 2.3(c) or Section 2.3(d) .

2.4 Bio 4 Marks and Bio 4 Domain Names; Osiris Marks and Osiris Domain Names .

(a) **Bio 4 Marks and Bio 4 Domain Names .** Osiris acknowledges that Stryker intends to use the Bio 4 Marks in connection with the Allografts and Allograft Services in lieu of any of the Osiris Marks. Stryker will, in its sole discretion, file and prosecute a trademark application with the United States Patent and Trademark Office for the Bio 4 Mark. In addition, Stryker may register, and operate websites located at, domain names that incorporate any of the Bio 4 Marks for the purposes of promoting the Allograft Services (the " **Bio 4 Domain Names** "). Stryker will own all rights to the Bio 4 Marks and any registrations for the Bio 4 Domain Names and all goodwill established thereunder shall inure solely to the benefit of Stryker; provided , however , that following any expiration or termination of this Agreement and the Sell-Off Period, (i) Stryker will promptly discontinue use of the Bio 4 Marks and the Bio 4 Domain Names and (ii) thereafter, neither Party (or any of their respective Affiliates) shall use or permit any Third Party to use any of the Bio 4 Marks or Bio 4 Domain Names.

(b) **License to Osiris Marks** . Osiris hereby grants Stryker a royalty-free, fully paid-up, transferable (to the extent provided in Section 15.2), license during the Term and any Sell-Off Period in the Territory for the use in the Field of Use, with the right to grant sublicenses to Subcontractors and Affiliates pursuant to Section 2.2 , to use the Osiris Marks in Stryker's promotional materials, on Stryker's and its Affiliates' websites, and otherwise in connection with the marketing and promotion of the Allograft Services and Stryker's and its Subcontractors' and Affiliates' other activities under this Agreement with respect to the Allograft Services, all on the terms and conditions as approved in advance in writing by the JSC or otherwise approved by Osiris (such approval not to be unreasonably withheld); provided , however , that: (i) any proposed usage of the Osiris Marks that is submitted by Stryker to Osiris for approval will be deemed to be approved unless Osiris provides Stryker with written notice of its disapproval of such proposed usage within ten (10) business days after the date on which such proposed usage was submitted to Osiris for approval and (ii) no approval shall be required for a proposed usage of the Osiris Marks that is substantially similar to a proposed usage of the Osiris Marks that was previously approved (or deemed approved) by Osiris. Stryker is under no obligation to use the Osiris Marks. To the extent Stryker does use any of the Osiris Marks, Stryker will use the Osiris Marks solely to promote, market, sell and distribute Allograft Services during the Term and any Sell-Off Period in the Field of Use, and will not use the Osiris Marks for any other purposes. The foregoing license: (i) during the Exclusivity Period, shall be exclusive for use in the Field of Use (even as to Osiris), except with regard to (A) the Osiris name and trade dress and (B) Osiris's use of the Osiris Marks to perform its obligations under this Agreement, and (ii) shall be non-exclusive in all other respects. Any use of the Osiris Marks by Stryker will be in accordance with trademark usage guidelines reasonably specified by Osiris. Any goodwill arising from the use of the Osiris Marks shall inure to the benefit of Osiris.

(c) **Osiris Domain Names .** During the Term, Stryker and its Affiliates shall have the right to register, and operate websites located at, the Osiris Domain Names for the purposes of promoting the Allograft Services. To enable Stryker to exercise the foregoing rights, during the Term, Osiris will provide Stryker and its Affiliates with full administrative control of the OvationOS.com domain name and any other Osiris Domain Names that are registered in the name of Osiris or any of its Affiliates.

*** Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

ARTICLE III
JOINT STEERING COMMITTEE

3.1 **Composition and Meetings of the JSC .** Promptly after the Effective Date, the Parties will establish a joint steering committee (the " **JSC** ") to serve as a forum for consultation and decision-making with regard to certain strategic decisions regarding the marketing and commercialization of the Allograft Services, as set forth in Section 3.2 below.

(a) The JSC shall be comprised of three (3) representatives designated by Stryker and three (3) representatives designated by Osiris. Each Party shall be free to replace any of its representatives to the JSC with a new representative, upon prior, written notice to the other Party (which notice may be provided by email).

(b) The JSC shall meet in-person or by teleconference, on a calendar quarter basis (or on such other frequency as is agreed to by the Parties), on such dates and at such times as the Parties shall agree. In the event the JSC meets in person, the venue of such meetings shall alternate between each Party's facilities in the United States. The JSC will be co-chaired by one (1) representative from each Party. The co-chairs shall be responsible for calling and leading meetings of the JSC, and the secretary of the JSC, shall be responsible for generating and circulating minutes of the meetings of the JSC within two (2) weeks following each such meeting. Such minutes shall be approved or otherwise finalized by the JSC promptly thereafter or at the following JSC meeting. Each Party shall be solely responsible for all travel and related costs for its representatives to attend meetings of, and otherwise participate in, meetings of the JSC.

(c) A quorum for a meeting of the JSC shall require the presence of at least two (2) Stryker representatives and at least two (2) Osiris representatives. All JSC decisions will be made by unanimous consent, with each Party having one (1) vote. If the JSC is unable to decide or resolve any matter properly presented to it for action, then each Party will refer the issue to a designated member of its senior management for further review in an attempt to resolve the issue.

(d) The Parties acknowledge and agree that the JSC shall not have the power to amend any of the terms or conditions of this Agreement other than by mutual written agreement of authorized representatives of each Party.

3.2 **Responsibilities of the JSC .** The JSC shall have the following powers and duties:

(a) to review the Minimum ASF on an annual basis and make any changes to the Minimum ASF as are agreed to by both Parties in writing;

(b) subject to Section 4.3, to discuss, agree upon and oversee the execution of a pre-clinical and/or clinical strategy for the Allografts, with the goal of generating evidence to support market differentiation for the Allografts (the " **Scientific Strategy** "), and agree upon the budget for executing the Scientific Strategy; and

(c) to discuss and review such other matters related to this Agreement as may be referred to the JSC by the Parties from time to time.

ARTICLE IV
MARKETING

4.1 **Generally .** Except as expressly provided in the next sentence with respect to regulatory compliance matters, Stryker shall have sole primary decision-making authority with respect to all operational and other decisions related to the marketing and promotion of the Allograft Services, including decisions regarding the amount and allocation of sales force resources, market segment focus, and promotional activities. Stryker agrees to provide Osiris with reasonable advance notice of marketing and promotional materials (both written and for presentations) which relate to the Allograft Services, to permit Osiris an opportunity to review for accuracy and

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completeness and have the final decision regarding all regulatory compliance matters with respect to such marketing and promotional materials; provided , however , that: (i) Osiris will not unreasonably withhold any approval of such marketing and promotional materials; (ii) any such marketing and promotional materials that are submitted by Stryker to Osiris for approval will be deemed to be approved unless Osiris provides Stryker with written notice of its disapproval of such proposed usage within ten (10) business days after the date on which such proposed materials were submitted to Osiris for approval and (iii) no approval shall be required for marketing and promotional materials that are substantially similar to marketing and promotional materials that were previously approved (or deemed approved) by Osiris. Stryker also agrees to use commercially reasonable efforts to continue to support Osiris's existing customer base for the OvationOS product, by providing Allograft Services and Allografts on Stryker's standard commercial terms to such customers for a period not to exceed sixty (60) days from the Effective Date. Notwithstanding anything to the contrary, Stryker shall have no obligation to use any minimum degree of efforts with respect to the marketing and promotion of the Allograft Services or to generate a minimum quantity of sales of Allograft Services. During a period not to exceed sixty (60) days from the Effective Date, Stryker agrees that Osiris may wind down the operations of its existing sales force for the OvationOS product.

4.2 Osiris Sales Support.

(a) Sales Training Support . Osiris will provide Stryker with commercially reasonable support in connection with the training of Stryker's sales force with respect to the Allografts and the Allograft Services. Such support shall include: (i) the provision of appropriate sales training materials to Stryker and (ii) the attendance and participation by a qualified Osiris representative as is agreed upon by the Parties (x) at training meetings for Stryker medical and marketing personnel and sales representatives for launch of the Allograft Services, (y) at Stryker's national sales meetings and large regional sales training and marketing meetings at Stryker's reasonable request and (z) for specific engagements with Customers at Stryker's reasonable request.

(b) Promotional Materials . Osiris will provide Stryker with copies of all promotional materials, clinical study results, pre-clinical study, results, journal reprints and other information and materials reasonably related to the Allograft that are in the possession or control of Osiris and which may be useful for the marketing and promotion of the Allograft Services in the Territory (" **Osiris Promotional Materials** "). Osiris Promotional Materials do not include, for example, materials primarily designed to convey information regarding the methods, testing, or processes utilized in the manufacture of the Allografts. For avoidance of doubt, Stryker may use, copy and distribute any Osiris Promotional Materials in the form in which they are provided by Osiris and may modify Osiris Promotional Materials for Stryker's use and/or may create and produce its own promotional materials independent of Osiris Promotional Materials for the marketing and promotion of the Allograft Services, subject to Osiris's right of review and approval, as provided in Section 4.1 above.

(c) Samples . Osiris will provide Stryker with Allograft samples that are not intended for clinical use, for use by Stryker's sales force in their promotional activities related to the Allograft Services. Osiris will provide Stryker with an initial quantity of [***] units of Allograft samples prior to launch of the Allograft Services, and will provide Stryker with such additional quantities of samples as may be reasonably requested by Stryker from time to time. At Stryker's option, such samples will either be: (i) where available to Osiris, samples that have been rejected by Osiris (of any volume size) but have passed serology and has donor consent for research or (ii) samples that have not been rejected by Osiris (in 2.5cc sample volume size only). Osiris will provide any such rejected Allograft samples to Stryker at no charge. For any samples that have not been rejected by Osiris, Stryker will pay Osiris for Allograft Services related to such samples at the rate of [***] per cubic centimeter of such samples, such payments to be made on a quarterly basis.

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(d) **Additional Information .** Osiris will provide Stryker with such information and assistance related to the Allografts and Allograft Services as is reasonably requested by Stryker from time to time to respond to technical and other questions from Stryker and/or Customers regarding the Allografts and Allograft Services.

4.3 **Scientific Strategy .** The Parties will execute the Scientific Strategy as agreed upon by the JSC, with each Party being responsible for carrying out the Scientific Strategy activities assigned to such Party by the JSC. Subject to Section 8.8(b), Stryker and Osiris each will bear fifty percent (50%) of the out-of-pocket costs of executing the Scientific Strategy, to the extent that such costs are included with the budget approved by the JSC for the Scientific Strategy (the " **Scientific Strategy Costs** "). To the extent that either Party anticipates that the costs of executing the Scientific Strategy will exceed the budget approved by the JSC for the Scientific Strategy, such Party will refer such matter to the JSC for review and determination as to how such costs will be handled. The Scientific Strategy Costs incurred by each Party will be submitted to the JSC for review and confirmation on a quarterly basis, and within thirty (30) days after such review and confirmation by the JSC, the Parties will make any reconciling payments necessary to achieve equal sharing of such Scientific Strategy Costs. Osiris will have primary responsibility for the management of the Scientific Strategy activities. Osiris will keep Stryker reasonably informed of such Scientific Strategy activities and will seek Stryker's input with respect to the management of such activities. All invoices and payments included in the Scientific Strategy Costs will be documented and each Party will provide the other Party with copies of such documentation upon request. The Parties agree that the Scientific Strategy activities will be primarily undertaken by third party pre-clinical or clinical research organizations (or other entities) identified by the JSC, the costs, fees, and related expenses for which will be considered "out of pocket costs."

(a) The Parties agree that the results of any Scientific Strategy activities (the " **Study Results** ") will be Osiris proprietary and Confidential Information, subject to Osiris's agreement to permit Stryker to use the same for marketing and promotional purposes pursuant to Sections 4.1, 4.2(b), and 4.4. Osiris hereby grants Stryker and its Affiliates a perpetual, irrevocable right to reference the Study Results in any regulatory applications and filings related to any products or services of Stryker or any of its Affiliates.

(b) If Osiris wishes to publish any results of Scientific Strategy activities, Osiris will submit the proposed manuscript to Stryker for review and comment reasonably in advance of the proposed publication date, and will take into account any reasonable comments provided by Stryker with respect to manuscript.

(c) Subject to such other restrictions as are provided by this Agreement, including obligations of non-disclosure and non-use and the retention of background Intellectual Property Rights, nothing herein limits either Party's ability to independently perform clinical studies, analyses or further research regarding the Allografts or Allograft Services, within or without the Field of Use independent of this Agreement or JSC approval. The Parties agree to inform one another at the JSC of their respective research, studies, and analyses and discuss any additional intellectual property protections they may elect to pursue, related to the Allografts or Allograft Services.

4.4 **Training and Education Programs .** The Parties will collaborate from time to time in creating and improving training and educational programs relating to the safe and effective use of the Allografts, which programs may be used by Stryker's personnel as a way to help promote and market the Allograft Services. Stryker will have the right to make all final decisions regarding any such programs and their implementation; provided, however, that Osiris will make final decisions related to communication of information involving pending and future regulatory approvals and clearances, regulatory correspondence, and compliance with regulatory approvals and clearances, as applicable.

4.5 **First Commercial Sale Date**. Stryker will inform Osiris in writing of the First Commercial Sale Date.

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ARTICLE V
SUPPLY OF ALLOGRAFTS

5.1 Rolling Forecasts. At least thirty (30) days before the beginning of each calendar month during the Term, Stryker will provide Osiris with a non-binding forecast of the quantities of each Allograft (broken down by Allograft code and by month) that Stryker estimates will be required for shipment to Customers during such calendar month and the next five (5) succeeding calendar months (each, a " **Rolling Forecast** "). Within ten (10) business days after receiving a Rolling Forecast, Osiris will provide Stryker with written acknowledgement of its receipt of the Rolling Forecast. Such acknowledgement will describe any constraints (such as donor supply shortages, anticipated processing capacity issues or other reasons) that Osiris anticipates may prevent it from shipping quantities of Allografts in accordance with the Rolling Forecast.

5.2 Consignment Terms. Promptly after the Effective Date, the Parties will agree on the terms for a standard addendum to Stryker's standard hospital consignment agreement that sets forth terms governing the consignment of Allografts to Customers and the purchase and sale of Allograft Services by such Customers (the " **Consignment Terms** "). The form of the Consignment Terms will be agreed upon by both Parties. The Consignment Terms will include provisions to make clear that Osiris (and not Stryker) is the supplier of the Allografts and Allograft Services and that Stryker will have no obligation or liability to the Customer with respect to the Allografts or Allograft Services. Stryker will require each Customer to agree to the Consignment Terms as a condition to receiving any Allografts. The Consignment Terms will constitute a contract between the Customer and Osiris. Stryker will have no responsibility to either Customer or Osiris under the Consignment Terms. Osiris hereby authorizes Stryker to agree to the Consignment Terms (including any non-material changes thereto) on Osiris's behalf. To the extent a Customer wishes to make any material changes to the Consignment Terms, Stryker will obtain Osiris's approval prior to agreeing to such changes. The JSC will periodically review the Consignment Terms and changes requested by (or anticipated to be requested by) Customers and determine changes and fallbacks to the Consignment Terms that Stryker is authorized to agree to with Customers.

5.3 Service Orders. If a prospective Customer wishes to purchase the Allograft Services (whether such purchase of Allograft Services is in connection with a withdrawal of Allografts from the Customer's consignment inventory or in connection with a shipment of Allografts to the Customer), Stryker will obtain from the Customer (or will issue on behalf of the Customer) a written order that sets forth: (i) the quantity of Allografts subject to the Allograft Services ordered, (ii) if applicable, the requested delivery date, (iii) if applicable, the shipping destination and any special shipping instructions and (iv) the fee to be paid by the Customer for the Allograft Services (a " **Service Order** "). Stryker will submit to Osiris by fax, email or direct entry into Osiris's order processing system, requests for shipment of Allografts to replenish Customer consignment inventory and/or requests for provision of Allograft Services consistent with the Service Orders. Each such request will contain ship to information, reference number, freight directions, quantities and product codes. Osiris will provide the Allograft Services, and the quantity of Allografts subject to such Allograft Services, indicated on such Service Order to the applicable Customer at the Customer address set forth on the Service Order. Notwithstanding anything to the contrary, Stryker will not be a party to any Service Order, and will not be responsible for any failure by Osiris to supply Allograft Services or Allografts in accordance with the Service Order, or for any failure by the Customer to make any payment for the Allograft Services provided in connection with a Service Order. Osiris agrees to exercise commercially reasonable efforts to satisfy Service Orders that do not materially comply with the standard Consignment Terms. Stryker will use commercially reasonable efforts to minimize any Service Orders that do not materially comply with the standard Consignment Terms. The Parties agree to exercise best efforts to minimize shipments of single units of Allografts in connection with the purchase of Allograft Services and to develop supply chain efficiencies and related practices to permit shipments of multiple units.

5.4 Pricing.

(a) Following the end of each calendar quarter, Stryker will calculate the amount (the " **Average Service Fee** ") equal to (i) the aggregate Customer Fees invoiced to Customers during such calendar quarter for Allograft Services (the " **Aggregate Fees Charged** ") divided by (ii) the aggregate quantity (in cubic centimeters) of Allograft to which such Allograft Services relate (the " **Aggregate Quantity** ").

*** Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

(b) If the Average Service Fee with respect to a calendar quarter is less than the then-current Minimum ASF, then, within sixty (60) days after the end of such calendar quarter, Stryker will pay Osiris an amount equal to: (i) the Aggregate Quantity multiplied by the then-current Minimum ASF minus (ii) the Aggregate Fees Charged.

5.5 Shipment and Delivery . Subject to Section 5.3 , Osiris will ship all Allografts directly to the Customer destination specified by Stryker, by the delivery dates and using the carrier, method and route of shipment specified by Stryker. Unless otherwise agreed by the Parties with respect to a particular shipment, the cost of shipping (including any expedited shipping, where required) shall be borne by Osiris. In no event will Stryker be responsible for any shipping charges with respect to any shipment or for any damage or loss of Allograft in transit. Osiris shall provide proof of delivery and lot code information to Stryker for each shipment. Osiris will honor all requests for next business day-morning delivery of Allografts that are submitted at or before 3:00pm Eastern Time of the business day preceding the requested delivery date. Stryker will use commercially reasonable efforts to limit such requests for next business day-morning delivery of Allografts. The Parties agree to equally share (50% / 50%) any shipping fees for next business day-morning delivery, such costs to be settled within ten business days of the end of each calendar quarter based on statements provided by Osiris.

5.6 Supply Failures . After the end of each calendar quarter during the Initial Exclusivity Period, Stryker will send Osiris a report of (i) all cases during such calendar quarter where Osiris fails to ship Allograft to a Customer that conforms to the requirements of this Agreement by the delivery date requested by Stryker (excluding any such cases where Stryker was able to fulfill a Customer request from Allograft inventory held in consignment at such Customer) (each, a " **Supply Failure** ") and (ii) for each Supply Failure, the amount that the Customer would have paid for the Allograft Services for said order (the " **Lost Revenue** "). Osiris's inability to fulfill a Customer request will not constitute a "Supply Failure" (x) to the extent due to (a) Customer or Stryker error (e.g., incorrect shipping information), (b) Force Majeure Events or (c) transportation or shipping errors due to the failure by one or more common carriers or (y) to the extent orders for the pertinent calendar quarter exceed the average of Stryker's rolling forecasts for the pertinent calendar quarter by 25% or more. For the purposes of Section 6.2(b)(ii) and Section 6.5 , a " **Supply Failure Trigger** " shall be deemed to have occurred if both of the following conditions are met with respect to the Initial Exclusivity Period:

(i) the actual cumulative Revenue for the Initial Exclusivity Period (the " **Actual Revenue** ") is less than [***]; and

(ii) the sum of the Actual Revenue and the aggregate Lost Revenue for the Initial Exclusivity Period is greater than [***].

5.7 Consignment Inventory; Risk of Loss . Title to all Allografts delivered to a Customer will remain with Osiris, and such Allografts shall be consigned to the Customer pursuant to the Consignment Terms, until the Customer withdraws the Allograft from consignment inventory for use (at which point title to, and risk of loss for, the Allograft will pass to the Customer). For the avoidance of doubt, although Stryker will not be required to obtain any approval from Osiris with respect to the quantity of Allograft inventory held in consignment by each Customer, consignment practices and procedures will be subject to review by the JSC. Stryker will work with each Customer to: (i) manage the replenishment, tracking and returns of consignment inventory of Allografts and (ii) reconcile such consignment inventory at least every four (4) months. Stryker will provide Osiris with quarterly reporting on all consignment inventory of Allografts by lot number, location and expiry date. Osiris will bear all risk of expired, obsolete, or damaged (if damaged prior to Customer's receipt) Allografts and other risk of loss with respect to the Allografts not attributable to Customer inaction or failure of care (whether or not located at the Customer) at all times prior to a Customer's withdrawal of such Allograft from consignment inventory; provided , however , that notwithstanding the foregoing, Stryker (or the applicable Customer) shall be responsible for any Allografts that are consigned to a Customer but cannot be located in the Customer's consignment inventory.

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5.8 **Billing and Collection of Customer Fees .** Stryker will invoice each Customer at the applicable fee for the Allograft Services (minus any associated discounts and rebates, the " **Customer Fees** "). Stryker will use at least commercially reasonable efforts to collect the Customer Fees from the Customers.

5.9 **Remittance of Customer Fees to Osiris; Uncollectable Amounts; Customer Returns**

(a) For each Service Order, Stryker will remit the Customer Fee to Osiris (whether or not such Customer Fee has been collected from the applicable Customer) on or before the date (the " **Payment Date** ") that is forty-five (45) days after the end of the month in which Stryker invoices the Customer with respect to such Service Order. Such remittance of Customer Fees to Osiris shall be subject to netting of the applicable Commissions and Administration Fees that are payable to Stryker as provided in Section 6.4(c) .

(b) If Stryker reasonably determines that any Customer Fee is uncollectable, Stryker will invoice Osiris for an amount equal to (i) the uncollectable Customer Fee minus (ii) the sum of (A) any Commission paid by Osiris to Stryker with respect to such Customer Fee and (B) fifty percent (50%) of any Administration Fee paid by Osiris to Stryker with respect to such Customer Fee. Osiris will pay such invoice within forty-five (45) days of the end of the month in which Osiris receives the invoice.

(c) Any refunds or credits associated with returns of Allografts by Customers will be handled in accordance with Section 5.11 .

5.10 **Returns .** If Osiris or Stryker is notified that Allograft consigned to a Customer was not utilized and needs to be returned, Stryker or the Customer will contact Osiris at a toll-free number to be established by Osiris and provide the Osiris representative with minimal information regarding the Allograft (part number, lot number, unit number and reason for return). Osiris will promptly notify Stryker, within no more than five (5) business days from receipt of the foregoing information, whether Osiris agrees to accept the return. Osiris may elect to decline or condition acceptance of any returns, in its sole discretion, if Osiris is unable to confirm the continuing viability of the Products (e.g., if the Allograft packaging has been compromised); provided , however , that notwithstanding the foregoing, Osiris will accept all returns of expired Allografts or for which Osiris otherwise bears risk of loss pursuant to Section 5.7 . Osiris will provide Stryker or the Customer with a Return Authorization Number (" **RA#** "). The RA# will be utilized to track the status of the return. Allograft intended for return must be returned in the original sealed shipper, which was packed and sealed by Osiris personnel, and the shipper must be received at Osiris within the validated shipper expiry. The shipping fees for returns will be equally shared by Osiris and Stryker, settled each calendar quarter.

(a) Returns are to be shipped indicating reference to the RA# on the airbill or on the shipper for return to an address specified by Osiris.

(b) Upon receipt, Osiris shall notify Stryker of receipt and inspect according to established procedure to ensure packaging and sterility has not been compromised.

5.11 **Refunds and Credits of Customer Fees .** Each Party will bear fifty percent (50%) of any refunds or credits of Customer Fees issued to a Customer under this Agreement, together with fifty percent (50%) of the Administration Fees, whether on account of returns of Allografts associated with the Allograft Services ordered or for other reasons.

ARTICLE VI
FINANCIAL TERMS

6.1 **Initial Exclusivity Fee .** In consideration for the exclusive rights granted to Stryker under this Agreement during the Initial Exclusivity Period, Stryker will pay Osiris Five Million U.S. Dollars ($5,000,000) (the " **Initial Exclusivity Fee** ") within five (5) business days after the Initial Payment Trigger Date.

*** Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

6.2 **Extended Exclusivity Fee .** If Stryker, at its sole option, extends the Exclusivity Period in accordance with Section 2.3(b) so that it also includes the Extended Exclusivity Period, then Stryker will pay Osiris a fee determined in accordance with this Section 6.2 (the " **Extended Exclusivity Fee** ").

(a) If the Revenue for the Initial Exclusivity Period is less than [***], then the Extended Exclusivity Fee will be an amount that is equal to:

(i) Seven Million Five Hundred Thousand U.S. Dollars ($7,500,000), plus

(ii) an additional One Million Five Hundred Thousand U.S. Dollars ($1,500,000) for every [***] by which the Revenue for the Initial Exclusivity Period is below [***].

For the avoidance of doubt, any increases in the Extended Exclusivity Fee under Section 6.2(a)(ii) will be applied in full increments of $1,500,000 for each [***] shortfall in Revenue, and there will be no pro rating for cases where the shortfall is not evenly divisible by [***]. For example: (A) if the Revenue for the Initial Exclusivity Period is [***], then the Extended Exclusivity Fee will be [***] but (B) if Revenue for the Initial Exclusivity Period is [***], then the Extended Exclusivity Fee will be [***].

(b) If the Revenue for the Initial Exclusivity Period is greater than [***], but less than [***], then the Extended Exclusivity Fee will depend on whether or not a Supply Failure Trigger has occurred, as follows:

(i) If a Supply Failure Trigger has not occurred, then the Extended Exclusivity Fee will be an amount that is equal to:

(A) Seven Million Five Hundred Thousand U.S. Dollars ($7,500,000), minus

(B) an amount equal to (1) 0.15 multiplied by (2) the amount by which Revenue for the Initial Exclusivity Period exceeds [***].

(ii) If a Supply Failure Trigger has occurred, then the Extended Exclusivity Fee will be an amount that is equal to:

(A) Five Million U.S. Dollars ($5,000,000), minus

(B) an amount equal to (1) 0.10 multiplied by (2) the amount by which Revenue for the Initial Exclusivity Period exceeds [***].

(c) If the Revenue for the Initial Exclusivity Period is greater than or equal to [***], then the Extended Exclusivity Fee will be zero U.S. Dollars.

6.3 **Non-Exclusive Extension Fee .** If Stryker, at its sole option, extends the Term on a non-exclusive basis for a period of two (2) years from the end of the Initial Exclusivity Period in accordance with Section 2.3(c) , then Stryker will pay Osiris a fee determined in accordance with this Section 6.3 (the " **Non-Exclusive Extension Fee** ").

*** Confidential information has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to this omitted information.

(a) If the Revenue for the Initial Exclusivity Period is less than [***], then the Non-Exclusive Extension Fee will be an amount that is equal to One Million Five Hundred Thousand U.S. Dollars ($1,500,000) for every [***] by which the Revenue for the Initial Exclusivity Period is below [***].

(b) If either: (i) a Supply Failure Trigger has occurred or (ii) the Revenue for the Initial Exclusivity Period is greater than or equal to [***], then the Non-Exclusive Extension Fee will be zero U.S. Dollars.

6.4 Commissions and Administration Fees .

(a) **Commissions .** For each Service Order, Osiris will pay Stryker a commission equal to [***] of the Customer Fees that apply with respect to such Service Order (the " **Commissions** ") on or before the Payment Date that applies to such Customer Fees. For the avoidance of doubt, Osiris will pay the Commission to Stryker whether or not the associated Customer Fees have been collected from the applicable Customer (subject, however, to Section 5.9(b) regarding return of Commissions if Stryker determines that the associated Customer Fee is uncollectable and to Section 5.9(c) regarding Customer Returns).

(b) **Administration Fees .** In addition to the Commissions, in consideration for Stryker's provision of billing and accounts receivable administration services under this Agreement, Osiris will pay Stryker an administration fee equal to [***] of the gross amount invoiced to the Customer for each Service Order (the " **Administration Fees** "). The Administration Fee for a particular Service Order will be payable to Stryker at the same time that the Commission for such Service Order is payable to Stryker. For the avoidance of doubt, Osiris will pay the Administration Fee to Stryker whether or not the associated Customer Fees have been collected from the applicable Customer (subject, however, to Section 5.9(b) regarding return of fifty percent (50%) of an Administration Fee if Stryker determines that the associated Customer Fee is uncollectable and to Section 5.9(c) regarding Customer Returns).

(c) **Netting of Payments .** The Parties will reasonably cooperate to minimize the administrative burden of the payment provisions in Section 5.9 and this Section 6.4 , including by netting of amounts payable to and by each Party under such provisions.

6.5 Supply Failure Payments to Stryker . If a Supply Failure Trigger has occurred, then:

(a) if Revenue for the Initial Exclusivity Period is greater than or equal to [***], but is less than or equal to Ninety Million U.S. Dollars ($90,000,000), then Osiris will pay Stryker One Million U.S. Dollars ($1,000,000) for every [***] by which the Revenue for the Initial Exclusivity Period is below [***]; and

(b) if Revenue for the Initial Exclusivity Period is less than [***], then Osiris will pay Stryker One Million Five Hundred Thousand U.S. Dollars ($1,500,000) for every [***] by which the Revenue for the Initial Exclusivity Period is below [***].

The payments described in the preceding clauses (a) and (b) are referred to herein as " **Supply Failure Payments** ." Osiris will pay any applicable Supply Failure Payment to Stryker within sixty (60) days after the end of the Initial Exclusivity Period. For the avoidance of doubt, Osiris will pay any applicable Supply Failure Payment to Stryker whether this Agreement terminates or whether Stryker elects to extend the Term on an exclusive basis in accordance

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with Section 2.3(b) or on a non-exclusive basis in accordance with Section 2.3(c). For the avoidance of doubt, any increases in any Supply Failure Payment to Stryker under Section 6.5(a) or Section 6.5(b) will be applied in full increments of $1,000,000 or $1,500,000 (as applicable) for each [***] shortfall in Revenue, and there will be no pro rating for cases where the shortfall is not evenly divisible by [***].

6.6 Termination Payments to Stryker. Osiris will make certain termination-related payments to Stryker as provided in Section 8.4 and Section 8.6, subject to and in accordance with the provisions set forth in those Sections.

6.7 Mode of Payment. All Customer Fees will be remitted to Osiris in the currency in which they were collected (or to be collected, as applicable). All Commissions and Administration Fees will be paid to Stryker in the currency in which the Customer Fees associated with such Commissions and Administration Fees were collected (or to be collected, as applicable).

6.8 Taxes. Osiris will be responsible for all sales, use, value-added and other taxes, customs duties and other governmental charges with respect to the provision of the Allograft Services and the associated Allografts to Customers. The Commissions, Administration Fees and other amounts payable by Osiris to Stryker pursuant to this Agreement will not be reduced on account of any taxes unless required by applicable law. Any taxes, duties, or other levies which Osiris is required by applicable law to withhold on remittance of any payment(s) due to Stryker under this Agreement will be deducted from such payment(s) to Stryker and timely paid to the appropriate taxing authority. Osiris will secure and send to Stryker proof of any such taxes, duties or other levies withheld and paid by Osiris for the benefit of Stryker, and cooperate, at Stryker's expense, with any reasonable request to help ensure that amounts withheld and/or paid are reduced and/or recovered to the extent permitted by the relevant jurisdiction.

ARTICLE VII
OTHER OPPORTUNITIES

7.1 Right of First Refusal. During the Term, Stryker shall have a right of first refusal with respect to any proposed transaction pursuant to which Osiris or any of its Affiliates would transfer, license or otherwise provide a third party with any rights with respect to any Allograft or any other product or service of Osiris or any of its Affiliates for orthopaedic or spinal bone growth application (a " **Covered Transaction** "). Prior to Osiris or any of its Affiliates entering into any Covered Transaction, Osiris will provide Stryker with written notice of the Covered Transaction, including the identity of the other party to the Covered Transaction and the terms and conditions on which Osiris or its Affiliate is willing to enter into the Covered Transaction (a " **Transaction Notice** "). Stryker will notify Osiris, within ten (10) business days after receiving the Transaction Notice (the " **Review Period** "), as to whether or not Stryker wishes to enter into a an agreement with Osiris or its Affiliate on the terms set forth in the Transaction Notice. If Stryker notifies Osiris that it wishes to enter into such agreement, then Osiris and Stryker will work in good faith to complete and execute definitive documentation for such agreement within thirty (30) business days after the date of such notice from Stryker (the " **Documentation Period** "). If either (i) Stryker notifies Osiris that it does not wish to enter into such agreement, (ii) Stryker fails to notify Osiris by the end of the applicable Review Period that it wishes to enter into such agreement or (iii) the parties do not complete and execute definitive documentation for such agreement within thirty (30) business days after the date of Stryker's notice that it wishes to enter into such agreement; then, in each of the foregoing cases, Osiris or its Affiliate (as applicable) shall be free to enter into a Covered Transaction with a third party on terms that are no more favorable to the third party than those set forth in the Transaction Notice. In no event will Osiris or any of its Affiliates enter into any agreement with a third party with respect to any matter for which Osiris is required to provide a Transaction Notice on terms that are more favorable to the third party than the terms set forth in a Transaction Notice, unless Osiris provides Stryker with another Transaction Notice that sets forth such more favorable terms, which other Transaction Notice will be subject to the provisions of this Section 7.1. Neither Osiris nor any of its Affiliates will enter into any agreement with a third party with respect to the subject matter of a Transaction Notice prior to the expiration of the applicable Review Period (or, if applicable, any applicable Documentation Period).

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ARTICLE VIII
TERM AND TERMINATION

8.1 **Term; Post-Term Right of First Refusal .** The initial term of this Agreement shall commence on the Effective Date and shall continue until the end of the Initial Exclusivity Period, unless terminated as provided herein (the " **Initial Term** ").

(a) Upon expiration of the Initial Term, Stryker, at its sole option and upon ninety (90) days prior written notice to Osiris, may either: (i) extend the term of this Agreement on an exclusive basis for the Extended Exclusivity Period, as provided in Section 2.3(b) or (ii) extend the term of this Agreement on a non-exclusive basis for an additional two (2) years, as provided in Section 2.3(c) .

(b) If Stryker has elected to extend the term of this Agreement on an exclusive basis for the Extended Exclusivity Period, as provided in Section 2.3(b) , then at the end of the Extended Exclusivity Period, Stryker, at its sole option and upon ninety (90) days prior written notice to Osiris, may extend the term of this Agreement on an exclusive basis for an additional two (2) years.

(c) Any extensions of the term of this Agreement pursuant to Section 8.1(a) or Section 8.1(b) are referred to herein as an " **Extension Term.** " The Initial Term, collectively with any Extension Terms, is referred to herein as the " **Term** ."

(d) Following any expiration or termination of the Term, before granting any third party exclusive rights to market and promote the Allografts or Allograft Services, Osiris will offer the exclusive rights to Stryker on the same terms and conditions as Osiris has offered or will offer to third parties. Stryker will have 30 days during which to accept or reject the offer. If Stryker does not accept the offer within the time period, Osiris may enter into such an agreement with a third party on the terms and conditions that were offered to Stryker (or on terms and conditions that are more onerous to the third party). If Osiris offers the third party more favorable terms, Osiris agrees to first present those terms to Stryker, as provided herein. Osiris's obligation to present this right of first refusal expires 90 days after any expiration or termination of the Term.

8.2 **Termination for Material Breach.** This Agreement may be terminated upon ninety (90) days prior written notice by either Party if the other Party materially breaches any of the terms, conditions or provisions of this Agreement and fails to remedy the breach within such ninety (90) day period; provided , however , that if such breach cannot be cured within such ninety (90) day period but (i) the breach is capable of cure, (ii) the breaching Party commences to effect a cure within such ninety (90) day period and (iii) the breaching Party diligently pursues such cure, then such Party will have so much time as is reasonably necessary to cure such default (but in no event more than six (6) months from the date of the notice of original notice of such breach).

8.3 **Insolvency/Bankruptcy .** Either Party may terminate this Agreement immediately upon written notice to the other: (i) if the other Party ceases to do business, or otherwise terminates its business operations or (ii) if the other Party becomes insolvent or seeks protection under any bankruptcy, receivership, trust deed, creditors arrangement, composition or comparable proceeding, or if any such proceeding is instituted against the other Party and not dismissed within ninety (90) days.

8.4 **Termination Due to Osiris Change of Control .** In the event of a Change of Control with respect to Osiris or of any of its Affiliates that directly or indirectly control Osiris (an " **Osiris Change of Control** "), either Party may terminate this Agreement by providing the other Party with written notice of such termination; provided , however , that: (i) in no event will either Party provide such notice of termination more than thirty (30) days after the closing date of the Osiris Change of Control transaction and (ii) in no event will either Party provide such notice of termination at any time prior to January 1, 2016. If a Party terminates this Agreement under this Section 8.4 , then the following provisions will apply:

(a) The effective date of the termination under this Section 8.4 will be the date that is twelve (12) months after the closing date of the Osiris Change of Control transaction.

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(b) If either Party provides such notice of termination during the Exclusivity Period, Osiris will pay Stryker, within thirty (30) days after providing Stryker notice of termination under this Section 8.4 , an amount determined as follows (the " **Exclusivity Fee Refund** "):

(i) if the notice of termination was provided during the Initial Exclusivity Period, the Exclusivity Fee Refund that Osiris will pay to Stryker will be an amount equal to (A) Five Million U.S. Dollars ($5,000,000) multiplied by (B) a fraction: (1) the numerator of which is equal to the number of days between the effective date of termination of this Agreement and the date that would have been the last day of the Initial Exclusivity Period if this Agreement had not been terminated early and (2) the denominator of which is 1460; and

(ii) if the notice of termination was provided during the Extended Exclusivity Period, the Exclusivity Fee Refund that Osiris will pay to Stryker will be an amount equal to (A) the Extended Exclusivity Fee multiplied by (B) a fraction: (1) the numerator of which is equal to the number of days between the effective date of termination of this Agreement and the date that would have been the last day of the Extended Exclusivity Period if this Agreement had not been terminated early and (2) the denominator of which is 1460.

(c) In addition, only if Osiris provides such notice of termination during the Exclusivity Period, then Osiris will make a one-time payment to Stryker (the " **Post-Termination Payment** ") equal to the greater of:

(i) thirty percent (30%) of the Revenue for the twelve (12) month period preceding the date on which Osiris provided Stryker with notice of termination under this Section 8.4 ; and

(ii) [***].

Osiris will pay the Post-Termination Payment to Stryker on or before the effective date of termination under this Section 8.4 .

8.5 **Stryker Change in Control** . In the event of a Change of Control with respect to the Stryker division that is performing or directing the Stryker Services, such that such division is no longer directly or indirectly controlled by Stryker's ultimate parent company (a " **Stryker Change of Control** "), Osiris may terminate this Agreement by providing Stryker with prior, written notice of such termination; provided , however , that:

(i) in no event will Osiris provide such notice of termination more than thirty (30) days after the closing date of the Stryker Change of Control transaction (or Osiris being informed of the transaction, whichever is later);

(ii) if such notice of termination is provided during the first three (3) years of the Initial Term, such termination will not become effective until the end of the Initial Term;

(iii) if such notice of termination is provided during the last year of the Initial Term, such termination will not become effective until the date that is one (1) year after the end of the Initial Term (and the Term will be automatically extended past the Initial Term for such one (1) year period without any obligation of Stryker to pay any Non-Exclusive Extension Fee or other amount, provided that the exclusive rights granted to Stryker under this Agreement will convert to non-exclusive rights effective as of the end of the Initial Term);

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(iv) if such notice of termination is provided during the first three (3) years of the Extended Exclusivity Period, such termination will not become effective until the end of the Extended Exclusivity Period;

(v) if such notice of termination is provided during the last year of the Extended Exclusivity Period, such termination will not become effective until the date that is one (1) year after the end of the Extended Exclusivity Period (and the Term will be automatically extended past the Extended Exclusivity Period for such one (1) year period without any obligation of Stryker to pay any Non-Exclusive Extension Fee or other amount, provided that the exclusive rights granted to Stryker under this Agreement will convert to non-exclusive rights effective as of the end of the Extended Exclusivity Period); and

(vi) if such notice of termination is provided during any Extension Term that Stryker has elected pursuant to Section 2.3(c) or Section 8.1(b) , such termination will not become effective until the end of such Extension Term.

8.6 Termination by Stryker Due to Third Party Action. In the event that Stryker's marketing, promotion or sales of the Allograft Services is materially, adversely affected by any change in applicable Laws (excluding, however, any changes in applicable Law governing human allograft viable bone matrix products and related services generally) or any action of a third party imposing an injunction against the sales and marketing activities contemplated by this Agreement (i.e., any action by the FDA or any other governmental organization and/or any injunction resulting from a third party claim), unless such third party action is attributable to Stryker's marketing or promotion in violation of this Agreement or other wrongful conduct by Stryker or its Affiliates or Subcontractors that is in violation of this Agreement, then Stryker shall have the right to terminate this Agreement upon ninety (90) days prior, written notice to Osiris, unless the third party action or other basis for such termination is resolved during the aforementioned ninety (90) day period. If Stryker terminates this Agreement under this Section 8.6 , then Osiris will pay Stryker, within thirty (30) days after the effective date of such termination, an amount determined as follows:

(a) if the notice of termination was provided during the Initial Exclusivity Period, the Exclusivity Fee Refund that Osiris will pay to Stryker will be an amount equal to (A) Five Million U.S. Dollars ($5,000,000) multiplied by (B) a fraction: (1) the numerator of which is equal to the number of days between the date on which such notice of termination was provided to Stryker and the date that would have been the last day of the Initial Exclusivity Period if this Agreement had not been terminated early and (2) the denominator of which is 1460; or

(b) if the notice of termination was provided during the Extended Exclusivity Period, the Exclusivity Fee Refund that Osiris will pay to Stryker will be an amount equal to (A) the Extended Exclusivity Fee multiplied by (B) a fraction: (1) the numerator of which is equal to the number of days between the date on which such notice of termination was provided to Stryker and the date that would have been the last day of the Extended Exclusivity Period if this Agreement had not been terminated early and (2) the denominator of which is 1460.

8.7 Termination for Non-Occurrence of Commencement Date . If the Initial Payment Trigger Date has not occurred by February 28, 2015, then Stryker may terminate this Agreement by providing written notice to Osiris at any time after February 28, 2015, but prior to the date (if any) on which the Initial Payment Trigger Date actually occurs.

8.8 Effect of Expiration or Termination; Survival .

(a) In the event of any expiration or termination of this Agreement, and without prejudice to any other rights and remedies available to the parties hereunder: (a) Osiris will provide Allograft Services and associated Allografts in accordance with Service Orders placed prior to the effective date of such expiration or termination and (b) all provisions in this Agreement related to such Service Orders (including provisions regarding payment of Customer Fees, Commissions and Administrative Fees) will remain in effect with respect to such Service Orders.

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(b) Notwithstanding Section 4.3 , in the event of any expiration or termination of this Agreement during the Initial Exclusivity Period, or in the event of any termination of this Agreement at the end of the Initial Exclusivity Period pursuant to Section 2.3(d) , Osiris will pay Stryker, within thirty (30) days after the effective date of such termination, an amount equal to fifty percent (50%) of the Scientific Strategy Costs that have been incurred by Stryker.

(c) Notwithstanding anything to the contrary, in the event of any expiration or termination of this Agreement (other than by OTI pursuant to Section 8.2), Stryker shall have the right to continue to sell Allograft Services with respect to any Allografts remaining in inventory at a customer until such inventory is exhausted (or, if shorter, until the date that is six (6) months after the effective date of such expiration or termination (or such later date as may be agreed upon by the Parties)) (the " **Sell-Off Period** "). The provisions set forth in Section 5.7 , Section 5.8 , Section 5.9 , Section 5.10 , Section 5.11 , Section 6.4 and all other provisions in this Agreement that are applicable to the sale of Allograft Services will continue to apply with respect to any such sales during the Sell-Off Period, and each Party will continue to perform its obligations under this Agreement with respect to any such sales during the Sell-Off Period. Upon expiration of the Sell-Off Period, Osiris will be responsible for the disposition of any remaining inventory of Allografts; provided, however, that in no event will Osiris be permitted to sell or otherwise provide any Allograft Services with respect to any Allografts that are in packaging that bears any Bio ^{4} Mark or any other Marks of Stryker or its Affiliates.

(d) Termination or expiration of this Agreement will not relieve either party of its obligations or liabilities for breaches of this Agreement incurred prior to or in connection with such termination or expiration.

(e) Article I ("Certain Definitions"), Section 2.4(a) ("Bio ^{4} Marks and Bio ^{4} Domain Names"), Section 4.3(a) , Section 5.10 ("Returns"), Section 5.11 ("Refunds and Credits of Customer Fees"), Section 6.5 ("Supply Failure Payments to Stryker"), Section 8.1(d) , Section 8.4 ("Termination by Osiris Due to Osiris Change of Control"), Section 8.6 ("Termination by Stryker Due to Third Party Action"), this Section 8.8 ("Effect of Termination or Expiration; Survival"), Article IX ("Regulatory Requirements and Responsibilities"), Article VIII ("Liability"), Article X ("Intellectual Property"), Article XI ("Confidentiality"), Article XII ("Representations and Warranties; Disclaimer"), Article XIII ("Liability"), Article XIV ("Indemnification and Insurance") and Article XV ("Miscellaneous") will survive any termination or expiration of this Agreement.

ARTICLE IX
REGULATORY REQUIREMENTS AND RESPONSIBILITIES

9.1 **NOTA .** The Parties acknowledge that NOTA prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for "valuable consideration." The Parties acknowledge that NOTA permits reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human bone tissue and that Osiris provides services in some of these areas with respect to the Allografts. The Parties believe that NOTA permits payments in connection with the Stryker Services as reasonable payments associated with the processing, transportation, and implantation of the Allografts. The Parties acknowledge and agree that: (i) the Customer Fees to be paid by Customers to Osiris are in recognition of and are reasonable payment for the Allograft Service provided by Osiris and (ii) the fees to be paid by Osiris to Stryker are in recognition of and are reasonable payment for the Stryker Services.

9.2 **Compliance with Law .** Osiris shall comply with, and shall ensure that all Allograft supplied under this Agreement is developed, processed, stored, labeled, packaged, and distributed in accordance with, applicable Law, including 21 C.F.R. Part 1271 and all applicable state and Canadian tissue bank registration requirements (including laws of California, Florida, New York, and Maryland), all other applicable federal, state, Canadian and professional standards and regulations including those of the American Association of Tissue Banks (the " **AATB** "), and current good tissue practices.

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9.3 Osiris Responsibilities .

(a) Osiris shall recover or cause recovery of donor tissues in accordance with all applicable Laws.

(b) Osiris will maintain donor eligibility records and production records and will make such records available to Stryker (i) during routine audits by Stryker and (ii) in a timely manner at such other times as reasonably requested by Stryker.

(c) Osiris shall obtain and maintain all regulatory and governmental approvals, certifications and clearances necessary or advisable to enable Stryker and its Affiliates to market the Allograft Services in accordance with this Agreement, including all appropriate state licenses, FDA registrations and AATB accreditations.

(d) Osiris shall obtain a fully informed authorization for donation for all donors conforming with guidelines set forth from time to time by the AATB, and as otherwise required by applicable Law. Osiris shall use tissues for the Allografts only from those donors in which the consent allows the donated tissue to be provided to a for-profit organization for distribution within the United States and Canada. Osiris also agrees to reasonably work with Stryker to investigate means for increasing the volume of tissues available from donors in which the consent allows the donated tissue to be provided to a for-profit corporation for distribution outside of the United States.

(e) Outside of the United States, upon agreement and budgeting by the JSC, Osiris shall apply for, and satisfy any requirements needed for obtaining, any regulatory and government approvals, certifications and clearances related to the activities contemplated under this Agreement, in each case as requested by Stryker and its Affiliates. Stryker will provide Osiris with reasonable assistance with respect to such efforts. The JSC will select the countries, if any, outside of the United States, for which to apply for and obtain such approvals, certifications or clearances.

(f) Osiris shall notify Stryker of any recalls relating to any Allograft supplied to Customers hereunder within five (5) business days of receipt of initial information. Osiris shall be responsible for all Allograft recalls and for coordinating the recall with Stryker; provided , however , that Stryker shall be responsible for all communications with Customers concerning recalls, using messaging for such communications that is agreed upon by Stryker and Osiris. Osiris shall be responsible for the disposition of retrieved Allograft. Osiris shall be responsible for all costs associated with Allograft recalls and complaints, and will promptly reimburse Stryker and its Affiliates for any costs incurred in connection therewith.

(g) Osiris shall accept, record, and investigate all complaints and adverse events regarding any Allograft supplied to Customers hereunder and shall notify Stryker of such complaints or adverse events and of the resolution in accordance with the Quality Agreement.

(h) Osiris shall provide Stryker with copies of all notices of non-compliance with applicable regulatory requirements (including any FDA Form 483's, notices from Health Canada and any state-issued non-compliance notices) received from any applicable regulatory authority related to Allograft supplied to Customers hereunder within five (5) business days of receipt.

(i) Osiris shall be responsible for maintaining accurate return cards of Allograft distributed under this Agreement.

(j) Osiris shall comply with all applicable reporting and vigilance requirements and file all applicable adverse events in accordance with applicable FDA regulations.

(k) Osiris shall notify Stryker of the response to all FDA, AATB and state investigations related to the Allograft supplied to Customers under this Agreement before said response is sent.

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9.4 Stryker Responsibilities .

(a) Stryker will comply with all applicable Laws in connection with its activities under this Agreement.

(b) Stryker shall cooperate with Osiris in all recalls of Allografts or other field actions required for the Allografts supplied to Customers under this Agreement.

(c) Stryker shall notify Osiris of any complaints or adverse events related to the Allograft supplied to Customers hereunder as determined in the Quality Agreement.

(d) Stryker agrees to notify Osiris of all notices of non-compliance with applicable regulatory requirements (including any FDA Form 483's, notices from Health Canada and any state-issued non-compliance notices) received from any applicable regulatory authority related to Allograft supplied to Customers hereunder within five (5) business days of receipt.

(e) Stryker shall pay to Osiris a royalty of [***] on Net Sales (as defined in the NuVasive-Osiris Agreement) of Allograft Services that qualify as Osiris Products (as defined in the NuVasive-Osiris Agreement) during the Royalty Term (as defined in the NuVasive-Osiris Agreement). The Parties will consult and agree with respect to matters related to the NuVasive-Osiris Agreement, including with respect to the payment of royalties to NuVasive and termination of the NuVasive-Osiris Agreement. Stryker agrees to pay the aforereferenced royalties to Osiris no later than ten (10) days before Osiris is obligated to pay NuVasive under the NuVasive-Osiris Agreement.

9.5 Stryker Inspections . Osiris shall permit Stryker to inspect the records and facilities of Osiris solely to the extent required to confirm Osiris's compliance with Osiris's undertakings set forth in this Agreement. Any such inspections shall be scheduled prior to the actual inspection by Stryker (with at least sixty (60) days' advance notice) to occur during normal business hours on a date that is mutually-acceptable to the Parties, and shall occur with such frequency as is reasonably determined by Stryker but no more than twice per year, plus any additional inspections in accordance with the criteria set forth in the Quality Agreement.

9.6 Quality Agreement . Within sixty (60) days after the Effective Date, the Parties shall negotiate in good faith the terms of, and enter into, a reasonable and customary quality agreement (the " **Quality Agreement** "). The Quality Agreement shall include provisions with respect to, among other things, release testing, change control procedures with respect to the specifications and the processing methods for the Allografts and record retention requirements. In the event of any conflict between the terms of the Quality Agreement and the terms of this Agreement, the terms of the Quality Agreement shall control with respect to Allograft quality-related matters, and the terms of this Agreement shall control with respect to all other matters.

ARTICLE X
INTELLECTUAL PROPERTY

10.1 Ownership of Intellectual Property. Nothing in this Agreement constitutes a transfer of ownership by either Party with respect to any of its Intellectual Property Rights, whether previously developed or developed hereunder. Without limiting the foregoing or any licenses granted under this Agreement: (i) Osiris shall retain ownership of its Intellectual Property Rights related to the Allografts and Allograft Services (including the Osiris Marks and any clinical or other data it generates related to the Allografts and/or the Allograft Services), (ii) Stryker shall retain ownership of any and all of its Intellectual Property Rights, including those related to Stryker's products and services and (iii) Stryker shall solely own any and all Intellectual Property Rights arising from Stryker's creation of its own promotional materials, independent of Osiris Promotional Materials, and Stryker will own any independent contributions it makes to new or modified promotional materials (separate from the Osiris promotional materials, to which Osiris reserves all rights). Following expiration or termination of this Agreement,

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Osiris will not use (or permit any of its Affiliates or any Third Party to use) any contributions that Stryker makes to the Osiris Promotional Materials.

10.2 Enforcement of Intellectual Property. In the event that Stryker and/or Osiris becomes aware that any of Osiris' Intellectual Property Rights related to the Allografts and Allograft Services are being infringed, either directly or indirectly by any third party, the Party possessing such knowledge or belief shall promptly notify the other and shall include in its notice all facts in its possession on which such knowledge or belief is based. Prior to bringing suit or notifying a third party of infringement of any of Osiris' Intellectual Property Rights related to the Allografts and Allograft Services, Osiris agrees to consult with Stryker.

ARTICLE XI
CONFIDENTIALITY

11.1 Confidential Information.

(a) The Receiving Party will not use any Confidential Information of the Disclosing Party other than in connection with the performance of its obligations and exercise of its rights under this Agreement, and will not disclose any such Confidential Information to any third party, other than the Receiving Party's Affiliates, and its and their respective employees, consultants, advisors and contractors, in each case who are bound by obligations of confidentiality at least as protective of the Disclosing Party's Confidential Information as those set forth herein. The Receiving Party agrees to be contractually responsible for and defend the Disclosing Party against any losses arising from or relating to use or disclosure (to the extent such use or disclosure is in violation of this Section 11.1) of the Disclosing Party's information by an Affiliate or other person to which the Receiving Party disclosed or otherwise made available the Disclosing Party's information.

(b) The Receiving Party will maintain the confidentiality of the Disclosing Party's Confidential Information, using no less than a reasonable degree of care.

(c) If the Receiving Party is requested to disclose any of the Disclosing Party's Confidential Information pursuant to any subpoena or requirement under applicable Law, the Receiving Party will give the Disclosing Party written notice of the request and sufficient opportunity to contest the order and/or seek an appropriate protective order, or other remedies or protections, for the purpose of resisting or restricting the disclosure and protecting the confidentiality of the Confidential Information, including protecting this Agreement and anything related to it as available on an "attorneys eyes" only basis in litigation. Without limiting the foregoing, each Party may disclose the other Party's Confidential Information to the extent necessary to comply with any securities Laws applicable to such Party or the rules or regulations of any securities exchange on which such Party's stock is listed.

ARTICLE XII
REPRESENTATIONS AND WARRANTIES; DISCLAIMER

12.1 Stryker Representations and Warranties. Stryker represents and warrants (and, where applicable, covenants) to Osiris as follows:

(a) Organization and Power. Stryker is a corporation duly incorporated, validly existing and in good standing under the laws of the State of New Jersey. Stryker has all requisite corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Enforceability. This Agreement has been duly executed and delivered by Stryker and constitutes a valid and binding obligation of Stryker, enforceable in accordance with its terms (in each case

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except as limited by the application of bankruptcy, moratorium and other laws affecting creditors' rights generally and as limited by the availability of specific performance and the application of equitable principles).

(c) **No Violation .** Stryker is not subject to or obligated under its articles of incorporation, bylaws, or any applicable Law, or any agreement, instrument, license or permit, or subject to any order, writ, injunction or decree, which would be breached or violated by its execution, delivery or performance of this Agreement.

(d) **Litigation** . There are no actions, suits, proceedings, orders or investigations pending or, to the best of Stryker's knowledge, threatened against or affecting Stryker at law or in equity, or before or by any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, which would adversely affect Stryker's performance under this Agreement.

(e) **Compliance .** Stryker will comply in all material respects with all Laws applicable to its performance under this Agreement.

(f) **No Debarment .** Stryker is not debarred under subsections 306(a) or (b) of the Act and has not and will not use in any capacity the services of any person or entity debarred under such law with respect to its performance of this Agreement. Stryker will immediately notify Osiris in writing in the event that it or any such person or entity is debarred during the Term.

(g) **Allografts and Allograft Services.** Stryker will perform all services under this Agreement in a professional manner and in accordance with applicable Laws.

(h) **Non-Infringement .** To Stryker's actual knowledge, and except to the extent provided by Osiris, any marketing material content created by Stryker will not infringe any Copyright or Mark of any third party.

12.2 **Osiris Representations and Warranties .** Osiris represents and warrants (and, where applicable, covenants) to Stryker as follows:

(a) **Organization and Power .** Osiris is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Maryland. Osiris has all requisite corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

(b) **Enforceability .** This Agreement has been duly executed and delivered by Osiris and constitutes a valid and binding obligation of Osiris, enforceable in accordance with its terms (in each case except as limited by the application of bankruptcy, moratorium and other laws affecting creditors' rights generally and as limited by the availability of specific performance and the application of equitable principles).

(c) **No Violation .** Osiris is not subject to or obligated under its articles of incorporation, bylaws, or any applicable Law, or any contract, agreement, instrument, license or permit, or subject to any order, writ, injunction or decree, which would be breached or violated by its execution, delivery or performance of this Agreement. Osiris is not (and covenants that it at no time during the Term will become) subject to any agreement with or obligation to any third party or any other legally binding commitment of any kind or nature whatsoever that may conflict with, diminish or limit in any manner the full right and authority of Osiris to grant the exclusive rights granted to Stryker under this Agreement and to otherwise perform under this Agreement. Osiris further covenants that it will not divest itself of any right now or hereafter possessed where the effect of so doing may be to diminish or impair Stryker's rights under this Agreement.

(d) **Litigation .** There are no actions, suits, proceedings, orders or investigations pending or, to the best of Osiris's knowledge, threatened against or affecting Osiris at law or in equity, or before or

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by any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, which would adversely affect Osiris's performance under this Agreement.

(e) **Non-Infringement.** To the best of Osiris's knowledge, the marketing and provision of the Allografts and Allograft Services to Customers in accordance with this Agreement, and the use of the Allografts and Allograft Services by Customers for their intended purposes will not infringe any Intellectual Property Rights of any third party. Osiris has obtained, and will at all times during the Term maintain, all licenses and rights necessary for Osiris and Stryker to perform under this Agreement with respect to the Allografts and Allograft Services. Osiris represents and warrants that any prior transactions with third parties have not resulted in the loss of any Intellectual Property Rights necessary for both Osiris and Stryker to perform under this agreement, including any prior agreements with NuVasive, Inc. and Mesoblast International Sarl.

(f) **Compliance.** Osiris will comply in all material respects with all Laws applicable to its performance under this Agreement.

(g) **No Debarment.** Osiris is not debarred under subsections 306(a) or (b) of the Act and has not and will not use in any capacity the services of any person or entity debarred under such law with respect to its performance of this Agreement. Osiris will immediately notify Stryker in writing in the event that it or any such person or entity is debarred during the Term.

(h) **Allografts and Allograft Services.** Osiris will perform all Allograft Services in a professional manner and in accordance with applicable Laws. Each Allograft, at the time received by the applicable Customer: (i) will conform to all applicable specifications and not be adulterated or misbranded, within the meaning of the Act and (ii) will be free and clear from all liens, encumbrances, and defects of title.

12.3 **Disclaimer.** EXCEPT AS EXPRESSLY PROVIDED IN THIS SECTION 12, NEITHER PARTY MAKES, ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED WITH RESPECT TO THE ALLOGRAFTS, THE ALLOGRAFT SERVICES, THE STRYKER SERVICES OR OTHERWISE ARISING FROM OR RELATING TO THIS AGREEMENT, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER REPRESENTATIONS AND WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT, AND ANY REPRESENTATIONS OR WARRANTIES ARISING FROM COURSE OF DEALING, COURSE OF PERFORMANCE OR USAGE OF TRADE.

ARTICLE XIII
LIABILITY

13.1 **Liability Exclusions.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING DAMAGES FOR LOSS OF BUSINESS, LOSS OF PROFITS OR THE LIKE) ARISING OUT OF OR RELATING TO THE ALLOGRAFTS, THE ALLOGRAFT SERVICES, THE STRYKER SERVICES OR OTHERWISE ARISING OUT OF OR RELATED TO THIS AGREEMENT OR SUCH PARTY'S PERFORMANCE HEREUNDER, EVEN IF A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY OR OTHERWISE).

13.2 **Exceptions.** Notwithstanding anything to the contrary, the liability exclusions set forth in Section 13.1 will not apply: (i) to the extent that acts or omissions of a Party constitute gross negligence, fraud or willful misconduct or (ii) to the Parties' respective indemnity obligations under Article XIV with respect to Third Party Claims.

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ARTICLE XIV

INDEMNIFICATION AND INSURANCE

14.1 **Indemnity by Osiris .** Osiris shall defend, at its cost, indemnify and hold harmless Stryker and its Affiliates, and their respective directors, employees, officers and agents (collectively, the " **Stryker Indemnitees** ") from and against any and all liability, demands, damages, fines, costs and expenses (including, without limitation reasonable legal fees and expenses) and losses (including, without limitation, with respect to death, personal injury, illness or property damage) (collectively, " **Losses** "), in connection with any Third Party claim, complaint, demand, suit, action, investigation or proceeding (collectively, " **Third Party Claims** ") to the extent arising from, or alleged to arise from: (i) death or injury to any Person resulting from any Allograft or Allograft Services provided by Osiris, (ii) any breach of any representation, warranty or covenant or agreement of Osiris under this Agreement, (iii) the gross negligence or intentional misconduct, whether by action or inaction, of Osiris or any of its Affiliates or any of their respective personnel or subcontractors or (iv) any claim that the marketing, promotion, processing, manufacturing, offer for sale, sale, use or distribution of Allograft supplied or other Allograft Services provided hereunder infringes, misappropriates or violates any Intellectual Property Rights or any other proprietary or contractual right of any third party or Person (except for any claim that marketing material content created by Stryker or its Affiliates or agents infringes any third party copyrights or trademarks).

14.2 **Indemnity by Stryker .** Stryker shall defend, at its cost, indemnify and hold harmless Osiris and its Affiliates, and their respective directors, employees, officers and agents (collectively, the " **Osiris Indemnitees** ") from and against any and all Losses in connection with any Third Party Claim to the extent arising from, or alleged to arise from: (i) the gross negligence or intentional misconduct, whether by action or inaction, of Stryker or any of its Affiliates or any of their respective personnel or subcontractors in the performance of the Stryker Services or (ii) any breach of any representation, warranty or covenant or agreement of Stryker under this Agreement.

14.3 **Indemnity Procedures .** A Party seeking indemnification for a Third Party Claim under Section 14.1 or Section 14.2 will give the Indemnitor written notice of the Third Party Claim promptly (and in any event within fifteen (15) calendar days after the service of the citation or summons); provided , however , that the failure to give timely notice hereunder will not affect rights to indemnification hereunder, except to the extent that Indemnitor demonstrates actual damage caused by such failure. Indemnitor may elect to direct the defense or settlement of any such Third Party Claim by giving written notice to the Party seeking indemnity, which election will be effective immediately upon receipt by the Party seeking indemnity of such written notice of election. The Indemnitor will employ counsel selected by the Party seeking indemnity to defend any such Third Party Claim and/or to compromise, settle or otherwise dispose of the same, all at the expense of the Indemnitor; provided , however , that the Indemnitor will not settle, or consent to any entry of judgment in, any such Third Party Claim without obtaining either: (i) an unconditional release of the Party seeking indemnity (and all of its other Indemnified Parties) from all liability with respect to all claims underlying such Third Party Claim or (ii) the prior, written consent of the Party seeking indemnity, and in both cases without any additional obligations on the part of Stryker. The Parties will fully cooperate with each other in any such Third Party Claim and will make available to each other any books or records useful for the defense of any such Third Party Claim.

14.4 **Insurance .** Osiris shall maintain general liability insurance, including products liability coverage, and professional/ errors & omissions liability insurance each in a minimum amount of [***] per occurrence or claims and [***] in the annual aggregate annually, with deductibles not exceeding [***] per occurrence or claim that provides coverage for the Allografts, the Allograft Services and the transactions contemplated by this Agreement.

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At a minimum, Osiris shall maintain such insurance coverage required hereunder for the entire Term and for a period of not less than five (5) years following expiration or termination of the Agreement, if any such policy shall provide coverage on a claims made basis, Osiris shall be required to maintain a claims made policy providing such coverage for an additional period of not less than five (5) years following the expiration or termination of this Agreement. Each policy required hereunder shall name Stryker and its Affiliates as additional insureds with respect to this Agreement. Osiris shall deliver to Stryker a certificate from the insurance carrier or broker evidencing such coverage and the fact that Stryker and its Affiliates are named as additional insureds for the general/ product liability insurance and noting any exclusions and agreeing to provide no less than thirty (30) days' prior written notice to Stryker in the event of a material change in coverage or policy cancellation.

ARTICLE XV
MISCELLANEOUS

15.1 Relationship of the Parties . Nothing contained in this Agreement shall be construed to place the Parties in a relationship of partners, joint ventures, or principal and agent. Neither Party is authorized to assume or undertake any obligation of any kind, expressed or implied, on behalf of the other Party.

15.2 Assignment; Change of Control . This Agreement and the rights and duties appertaining hereto may not be assigned or otherwise transferred by either Party without first obtaining the written consent of the other Party, which consent shall not be unreasonably withheld. Any such purported assignment or transfer without the written consent of the other Party shall be null and of no effect. Notwithstanding anything to the contrary, either Party (the " **Transferring Party** ") may, without the consent of the other Party, assign or otherwise transfer this Agreement: (i) to an Affiliate of the Transferring Party or (ii) in connection with a Change of Control involving the Transferring Party (or involving the line of business of the Transferring Party to which this Agreement relates), subject, however, to Section 7.1 and Section 8.4 in the case of an Osiris Change of Control and Section 8.5 in the event of a Stryker Change of Control).

15.3 Notices . All notices, demands and other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given (i) when personally delivered or sent by telecopy (with hard copy to follow), (ii) one (1) business day following the day when deposited with a reputable and established overnight express courier (charges prepaid), or (iii) three (3) days following mailing by certified or registered mail, postage prepaid and return receipt requested. Unless another address is specified in writing, notices, demands and communications to Stryker and Osiris shall be sent to the addresses indicated below:

Notices to Stryker :

Howmedica Osteonics Corp.
2 Pearl Ct.
Allendale, New Jersey 07401
Attn: Vice President of Business Development

With copy to (which shall not constitute notice): Legal Counsel

Notices to Osiris :

Osiris Therapeutics, Inc.
7015 Albert Einstein Avenue
Columbia, Maryland 21046
Attn: Chief Executive Officer

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With copy to (which shall not constitute notice): Chief Legal Counsel

and

With copy to (which shall not constitute notice):

McKenna Long & Aldridge LLP
303 Peachtree Street, Suite 5300
Atlanta, Georgia 30308
Attn: Michael Cochran

15.4 Public Announcements . No Party hereto shall issue any press release or make any public announcement of any type whatsoever relating to the subject matter of this Agreement, including the terms, conditions, and status of the transactions contemplated herein, without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed by such other Party. Notwithstanding the foregoing, either Party may make any public disclosure that it believes in good faith is required by applicable Law or the rules or regulations of any securities exchange on which such Party's stock is listed, in which case the Party making such disclosure shall use its reasonable efforts to advise the other Party prior to making such disclosure. All requests for written consent of Stryker under this Section 15.4 shall be directed to the Corporate Vice-President - Government Affairs, Public Affairs, Corporate Communication of Stryker, Inc.

15.5 Unforeseen Occurrences . In the event that either Party is unable to perform any of its obligations under this Agreement, or to enjoy any of its benefits because of any of the following events, but only to the extent such event is beyond the reasonable control of the Party affected by such event and such event occurs without the fault or negligence of such Party or any of its subcontractors or suppliers: an act of God, disruption in transportation system, fire, flood, earthquake, storm, war, riot, revolt, act of a public enemy, embargo, explosion, civil commotion, loss or shortage of power or any law, rule, regulation, order or other action by any public authority (a " **Force Majeure Event** "), the Party who has been so affected shall immediately give written notice to the other Party and shall use commercially reasonable efforts to resume performance in accordance with this Agreement as promptly as possible. Upon receipt of such notice, all obligations under the Agreement shall be immediately suspended for the duration of the Force Majeure Event. If the period of nonperformance exceeds ninety (90) days from the receipt of notice of the Force Majeure Event, the Party whose ability to perform has not been so affected may by giving written notice terminate the Agreement without penalty or payment required by either party except as provided in Section 8.6 . Delays in delivery due to a Force Majeure Event shall automatically extend the delivery date for a period equal to the duration of such Force Majeure Event. Any acceptance or warranty period affected by a Force Majeure Event shall likewise be extended for a period equal to the duration of such Force Majeure Event. Notwithstanding anything to the contrary, Force Majeure Event shall not include (and a Party shall not be entitled to benefit from this Section 15.5 on account of): (i) any governmental action of an enforcement nature that arises from or relates to such Party's failure to comply with any Law applicable to such Party's performance hereunder (including, in the case of Osiris, Osiris's performance of the Allograft Services) or (ii) any other event that arises from such Party's negligence or willful misconduct, or that could have been avoided if such Party had not failed to take reasonable precautions to do so. For the avoidance of doubt, materials shortages, strikes, slowdowns or other labor related delays are not Force Majeure Events.

15.6 Governing Law . THE LAWS OF THE STATE OF NEW YORK AND THE FEDERAL LAWS OF THE UNITED STATES OF AMERICA SHALL GOVERN ALL QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, INTERPRETATION AND ENFORCEABILITY OF THIS AGREEMENT AND THE APPENDICES ATTACHED HERETO, AND THE PERFORMANCE OF THE OBLIGATIONS IMPOSED BY THIS AGREEMENT, WITHOUT GIVING EFFECT TO ANY CHOICE OF LAW OR CONFLICT OF LAW RULES OR PROVISIONS (WHETHER OF THE STATE OF NEW YORK OR ANY OTHER JURISDICTION) THAT WOULD CAUSE THE APPLICATION OF THE LAWS OF ANY JURISDICTION OTHER THAN THE STATE OF NEW YORK OR THE FEDERAL LAWS OF THE UNITED STATES OF AMERICA.

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15.7 Dispute Resolution .

(a) Subject to Section 15.7(f) , in the event of any dispute or disagreement between or among the parties following the Effective Date that directly or indirectly arises from or relates to this Agreement or the performance of any Party hereunder (a " **Dispute** "), such Dispute shall, upon the written request of either Party, first be referred to the JSC, which shall promptly meet in a good faith effort to resolve the Dispute. If the JSC does not agree upon a decision within ten (10) calendar days after reference of the matter to the JSC, then the Dispute shall then be referred to a senior representative (for Osiris, the Chief Executive Officer or Chief Financial Officer; for Stryker, the President or any Vice President) with decision-making authority to meet and confer regarding the Dispute. Such senior representatives shall promptly meet in a good faith effort to resolve the Dispute. If the Representatives do not agree upon a decision within thirty (30) calendar days after reference of the matter to them, each Party shall be free to exercise the remedies available to it under Section 15.7(b) below.

(b) The Parties agree that any claims arising under this Agreement shall be exclusively venued in the state and federal courts located in New York County, New York. Each Party hereby irrevocably submits to the exclusive jurisdiction of such courts for any such claims, and waives any objections to the laying of venue in such courts. Each party further agrees that service or any process, summons, notice or document in the manner provided for in Section 15.3 shall be effective service of process for any action, suit or proceeding in any such court with respect to any matters to which it has submitted to jurisdiction in this Section.

(c) Notwithstanding any of the foregoing, each Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party.

(d) During the pendency of any Dispute, each Party will continue to perform its obligations under this Agreement, unless and until such time as this Agreement expires or is terminated in accordance with its terms.

15.8 Severability . Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement or the application of any such provision to any Person or circumstance shall be held to be prohibited by or invalid, illegal or unenforceable under applicable law in any respect by a court of competent jurisdiction, such provision shall be ineffective only to the extent of such prohibition or invalidity, illegality or unenforceability, without invalidating the remainder of such provision or the remaining provisions of this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible.

15.9 Interpretation . The headings and captions used in this Agreement are for convenience of reference only and do not constitute a part of this Agreement and shall not be deemed to limit, characterize or in any way affect any provision of this Agreement, and all provisions of this Agreement shall be enforced and construed as if no caption or heading had been used herein or therein. Each defined term used in this Agreement shall have a comparable meaning when used in its plural or singular form. The use of the word "including" (or variations thereof) herein shall mean "including without limitation" and, unless the context otherwise requires, "neither," "nor," "any," "either" and "or" shall not be exclusive. The Parties intend that each representation, warranty and covenant contained herein shall have independent significance. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

15.10 Amendment and Waiver . This Agreement may be amended, modified or altered only by an instrument in writing duly executed by both Parties. No course of dealing between or among any Persons having any interest in this Agreement shall be deemed effective to modify, amend or discharge any part of this Agreement or any rights or obligations of any Person under or by reason of this Agreement. No waiver of any of the provisions

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of this Agreement shall be deemed or shall constitute a waiver of any other provisions, whether or not similar, nor shall any waiver constitute a continuing waiver.

15.11 Entire Agreement. This Agreement (together with the Quality Agreement) contains the entire agreement of the Parties with respect to the subject matter hereof and shall be deemed to supersede all prior agreements, whether written or oral.

15.12 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

15.13 Delivery by Facsimile. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, to the extent signed and delivered by means of a facsimile machine or by other electronic transmission of a manual signature (by portable data format (PDF) or other method that enables the recipient to reproduce a copy of the manual signature) shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any Party, the other Party shall re-execute original forms thereof and deliver them to the requesting Party.

(signature page follows)

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IN WITNESS WHEREOF , the Parties have executed this Agreement effective as of the Effective Date.

HOWMEDICA OSTEONICS CORP.	**OSIRIS THERAPEUTICS, INC.**
By: /s/ Spencer S. Stiles	By: /s/ Lode Debrabandere
Print Name: Spencer S. Stiles	Print Name: Lode Debrabandere
Title: President	Title: President & CEO

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Exhibit 23.1.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Osiris Therapeutics, Inc.
Columbia, Maryland

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-148750) and Forms S-8 (No. 333-137952, 333-137953, 333-167652, 333-184838 and 333-199132) of Osiris Therapeutics, Inc. of our reports dated March 27, 2017, relating to the financial statements and financial statement schedule (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the restatement discussed in Note 2), and the effectiveness of Osiris Therapeutics, Inc.'s internal control over financial reporting, which appear in this Form 10-K/A. Our report on the effectiveness of internal control over financial reporting expressed an adverse opinion on the effectiveness on the Company's internal control over financial reporting as of December 31, 2014.

/s/ BDO USA, LLP

McLean, Virginia
March 27 , 2017

Exhibit 31.1.1

Certification of Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, David A. Dresner, certify that:

1. I have reviewed this Annual Report on Form 10-K/A of Osiris Therapeutics, Inc., the Registrant;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2017

/s/ DAVID A. DRESNER
David A. Dresner, *Interim Chief Executive Officer*

Exhibit 31.2.1

Certification of Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Gregory I. Law., certify that:

1. I have reviewed this Annual Report on Form 10-K/A of Osiris Therapeutics, Inc., the Registrant;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2017

/s/ Gregory I. Law
Gregory I. Law, *Chief Financial Officer*

Exhibit 32.1.1

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Osiris Therapeutics, Inc., (the "Company"), does hereby certify, to the best of each officer's knowledge that:

The Annual Report on Form 10-K/A for the year ended December 31, 2014 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2017

/s/ DAVID A. DRESNER
David A. Dresner
Interim Chief Executive Officer

Date: March 27, 2017

/s/ GREGORY I. LAW
Gregory I. Law
Chief Financial Officer