OSIRIS THERAPEUTICS, INC.
Form 10-Q
May 11, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2015

Or

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

For the transition period from to

Commission File Number: 001-32966

OSIRIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

443-545-1800

(Registrant s telephone number, including area code)

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

Indicate by check mark 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 x No o

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

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

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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Class	**Outstanding at May 8, 2015**
Common Stock, par value $0.001 per share	34,390,313

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OSIRIS THERAPEUTICS, INC.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements Unaudited

OSIRIS THERAPEUTICS, INC.

CONDENSED BALANCE SHEETS

(amounts in thousands, except per share amounts)

	March 31, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash	$ 3,704	$ 2,208
Investments available for sale	35,367	37,305
Trading securities	8,162	10,591
Trade accounts receivable, net of reserves	32,022	24,307
Other receivables	7,579	9,951
Inventory	11,939	10,924
Prepaids and other current assets	579	650
Total current assets	99,352	95,936
Property and equipment, net	2,165	2,087
Other assets	95	95
Total assets	$ 101,612	$ 98,118
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	9,830	$ 8,854
Capital lease obligations, current portion	45	45
Deferred commissions payable, current portion	1,667	1,667
Total current liabilities	11,542	10,566
Other long-term liabilities	3,586	3,589
Total liabilities	15,128	14,155
Commitments and contingencies		
Stockholders equity		
Common stock, $.001 par value, 90,000 shares authorized, 34,390 shares outstanding - 2015, 34,346 shares outstanding - 2014	35	35
Additional paid-in-capital	288,759	287,525
Accumulated other comprehensive loss	(144)	(54)
Accumulated deficit	(202,166)	(203,543)
Total stockholders equity	86,484	83,963

Total liabilities and stockholders equity	$ 101,612	$ 98,118

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

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OSIRIS THERAPEUTICS, INC.

CONDENSED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

Unaudited
(amounts in thousands, except per share data)

	Three Months Ended March 31,	
	2015	**2014**
Product revenues	$ 21,003	$ 10,054
Cost of product revenues	4,609	2,212
Gross profit	16,394	7,842
Operating expenses:		
Research and development	1,640	670
Selling, general and administrative	12,835	7,235
Fees paid to related parties	76	149
Share based payments to related parties		403
	14,551	8,457
Income (loss) from operations of continuing operations	1,843	(615)
Other income (expense), net	146	(126)
Income (loss) from continuing operations, before income taxes	1,989	(741)
Income tax (expense) benefit	(612)	130
Income (loss) from continuing operations	1,377	(611)
Discontinued operations:		
Loss from operations of discontinued operations, net of income taxes of $165 in 2014		(754)
Loss from discontinued operations		(754)
Net income (loss)	1,377	(1,365)
Other comprehensive income (loss)		
Unrealized (loss) gain on investments available for sale	(90)	88
Comprehensive income (loss)	$ 1,287	$ (1,277)
Basic income (loss) per share		
Income (loss) from continuing operations	$ 0.04	$ (0.02)
Loss from discontinued operations		(0.02)
Basic income (loss) per share	$ 0.04	$ (0.04)
Diluted income (loss) per share		
Income (loss) from continuing operations	$ 0.04	$ (0.02)
Loss from discontinued operations		(0.02)
Diluted income (loss) per share	$ 0.04	$ (0.04)

Weighted average common shares (basic)	34,358	34,148
Weighted average common shares (diluted)	34,821	34,148

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

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OSIRIS THERAPEUTICS, INC.

CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY

For the three months ended March 31, 2015

Unaudited

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount				
Balance at December 31, 2014	**34,345,688**	**$ 35**	**$ 287,525**	**$ (54)**	**$ (203,543)**	**$ 83,963**
Exercise of options to purchase common stock ($.40- $12.91 per share)	44,625		328			328
Share-based compensation - employees			852			852
Net income					1,377	1,377
Unrealized loss on investments available for sale				(90)		(90)
Windfall tax benefit from stock-based compensation			54			54
Balance at March 31, 2015	**34,390,313**	**$ 35**	**$ 288,759**	**$ (144)**	**$ (202,166)**	**$ 86,484**

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

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OSIRIS THERAPEUTICS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

Unaudited
(amount in thousands)

	Three Months ended March 31,	
	2015	**2014**
Cash flows from operating activities:		
Continuing operations		
Income (loss) from continuing operations	$ 1,377	$ (611)
Adjustments to reconcile income (loss) from continuing operations to net cash used in operations of continuing operations:		
Unrealized loss on trading securities		179
Realized loss (gain) on investments available for sale	19	(54)
Depreciation and amortization	267	214
Non cash share-based payments	852	883
Changes in operating assets and liabilities:		
Accounts receivable	(7,715)	(4,204)
Inventory	(1,015)	(408)
Prepaid expenses and other current assets	4,872	72
Lease reserves		(25)
Accounts payable, accrued expenses, and other liabilities	984	(817)
Net cash used in operating activities of continuing operations	(359)	(4,771)
Discontinued operations		
Loss from discontinued operations		(754)
Adjustments to reconcile loss from discontinued operations to net cash used in operations of discontinued operations:		
Changes in operating assets and liabilities:		
Accounts receivable and other current assets		(5)
Accounts payable and accrued expenses		(40)
Net cash used in operations of discontinued operations		(799)
Net cash used in operating activities	(359)	(5,570)
Cash flows from investing activities:		
Purchases of property and equipment	(345)	(127)
Proceeds from sale of investments available for sale	22,221	5,000
Purchases of investments available for sale	(20,392)	
Net cash provided by investing activities	1,484	4,873
Cash flows from financing activities:		
Principal payments on capital lease obligations	(11)	(11)
Proceeds from the exercise of options to purchase common stock	328	634
Windfall tax benefit from stock-based compensation	54	
Net cash provided by financing activities	371	623
Net increase (decrease) in cash	1,496	(74)
Cash at beginning of period	2,208	2,416
Cash at end of period	**$ 3,704**	**$ 2,342**
Supplemental disclosure of cash flows information:		

Cash paid for income taxes	$ 422	$
Supplemental disclosure of non cash activities:		
Guaranteed payment related to trading securities	2,429	
Unrealized loss on investments available for sale	90	
Unrealized gain on investments available for sale		88

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

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

1. Description of Business and Significant Accounting Policies

Description of Business

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

From 2010 to 2013, we operated our business in two segments, Biosurgery and Therapeutics. We now operate only our Biosurgery business, as a result of the sale of our Therapeutics segment assets in the fourth quarter of 2013, as discussed further below. Our Biosurgery business focuses on products for wound care, orthopedics, and sports medicine to harness the ability of cells and novel constructs to promote the body s natural healing. Until it was sold, 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 has continued to grow since its inception, and we have increased our organizational focus on the development and commercialization of products in this segment. Consistent with this organizational focus, as discussed further in Note 2 *Discontinued Operations* below, on October 10, 2013, we entered into a Purchase Agreement to sell our Therapeutics segment, including all of our culture expanded mesenchymal stem cell business, including Prochymal and other related assets. We eliminated the Therapeutics segment from our continuing operations as a result of the disposal transaction, and have presented the assets, liabilities, and results of the segment s operations as a discontinued operation for all periods presented. Our continuing operations now represent the portion of our business previously referred to as our Biosurgery segment.

Unaudited Interim Financial Statements

Except for the Balance Sheet as of December 31, 2014, which was derived from audited financial statements, the accompanying condensed financial statements are unaudited. The accompanying condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete financial statements. In the opinion of management, these statements include all adjustments (consisting of normal recurring adjustments) considered necessary to present a fair statement of our results of operations, financial position and cash flows. Operating results for any interim period are not necessarily indicative of the results that may be expected for the full year. This Quarterly Report on Form 10-Q should be read in conjunction with our financial statements and footnotes included in our Annual Report on Form 10-K for the fiscal year ended

December 31, 2014.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Due to the inherent uncertainty involved in making those assumptions, actual results could differ from those estimates. We believe that the most significant estimates that affect our financial statements are those that relate to deferred tax assets, inventory valuation, share-based compensation and the value of the derivative obtained in connection with the sale of our former Therapeutics business.

Reclassifications

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

Cash and Cash Equivalents

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

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

1. Description of Business and Significant Accounting Policies - continued

Investments Available for Sale

Investments available for sale consist primarily of marketable securities with maturities less than one year. Investments available for sale are valued at their fair value, with unrealized gains and losses reported as a separate component of stockholders equity in accumulated other comprehensive income (loss). 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.

Trading Securities - Derivative and Securities Received in Business Disposition

As discussed in Note 2 *Discontinued Operations*, we disposed of our Therapeutics segment in October 2013. A portion of the consideration for the sale of that business was stock of Mesoblast Limited (Mesoblast), the parent of the purchaser. We were required to hold that stock for one year from the date of receipt. Mesoblast is a public company and its stock is traded on the Australian stock exchange.

The Mesoblast 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 stock. Any additional Mesoblast stock would also have to be held for one year during which period there was no further price protection. 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*. In December 2014, the price protection on these shares expired, although Mesoblast agreed to pay us $15 million in cash for the stock in the first half of fiscal 2015. Accordingly, as of March 31, 2015 and December 31, 2014, we reflect the stock as a current asset in Trading Securities. As of March 31, 2015, this $15 million is shown as $8.2 million in Trading Securities and $6.8 million in Other Receivables on our Balance Sheets. As of December 31, 2014, this $15 million is shown as $10.6 million in Trading Securities and $4.4 million in Other Receivables on our Balance Sheets.

Trade Accounts Receivable

Trade accounts receivable are reported at their net realizable value. We charge off uncollectible receivables when the likelihood of collection is remote. We set credit terms with individual customers, and consider receivables outstanding longer than the time specified in the respective customer s contract, typically 45-days, to be past due. As of March 31, 2015 and December 31, 2014, accounts receivable in the accompanying balance sheets are each reported net of $1.3 million allowance for doubtful accounts. Trade accounts receivable balances are not collateralized. We did not have bad debt expense in the first quarters of fiscal 2015 or 2014.

Other Receivables

Other receivables at March 31, 2015 include the $6.8 million difference between the market value of the Mesoblast ordinary shares held by us and the $15 million agreed to be paid to us by Mesoblast. Other receivables at December 31, 2014 included the $5.0 million fee payable from Stryker, as further described below, and the $4.4 million difference between the market value of the Mesoblast ordinary shares held by us and the $15 million to be paid to us by Mesoblast for such shares.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

1. Description of Business and Significant Accounting Policies - continued

Inventory

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

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 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 the first quarter of fiscal 2015 or during fiscal year 2014.

Biosurgery Revenue Recognition

We recognize revenue from product distribution when title passes to the customer. Title usually passes when the product is shipped to the customer and leaves our loading dock. In some situations, we store consigned inventory on site in freezers at hospital or clinic facilities. No revenue is recognized upon the placement of inventory into consignment as we retain title and maintain the inventory on our balance sheets. For these products, revenue is recognized when we receive appropriate notification that the product has been used in a surgical procedure. We verify the condition and status of all consigned inventory on at least a quarterly basis. Due to the nature of our products and the need to ensure they are maintained at the proper frozen temperature, we generally do not allow product returns.

In December 2014, we entered into an exclusive distribution agreement with a subsidiary of Stryker Corporation for the marketing and distribution of BIO(4), 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 are responsible for supply, manufacturing, inventory management, shipments to customers, continued research and product improvement activities. We recognize as revenue the amounts charged to customers for the allografts. Commissions and administrative fees paid to Stryker are accounted for as selling expenses, as Stryker is acting as outside sales and marketing agent for Osiris. We received an initial exclusivity fee of $5.0 million in the first quarter of fiscal 2015 and are 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. The exclusivity fee and any extension fees subsequently received are considered to be adjustments of the selling expenses. As such, we recognize the exclusively fee as a liability, which will be amortized over the related exclusivity period in proportion to the expected fees to be paid to Stryker, as an offset to selling expenses. During the first quarter of fiscal 2015, we amortized $59,000. At December 31, 2014, we recorded a $5.0 million receivable with the offset to short-term deferred commissions of $1.7 million and long-term deferred commissions of $3.3 million. At March 31, 2015, the short-term and long-term deferred commissions were $1.7 million and $3.2 million, respectively.

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

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

1. Description of Business and Significant Accounting Policies - continued

Therapeutics Revenue Recognition

In our former Therapeutics business, we evaluated revenues from agreements that had 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 required us to exercise judgment. We account for the activities of our former Therapeutics business as discontinued operations.

Revenues from research licenses associated with our former Therapeutics business were recognized as earned upon either the incurring of reimbursable expenses directly related to the particular research plan or the completion of certain development milestones as defined within the terms of the agreement. Payments received in advance of research performance were designated as deferred revenue. Non-refundable upfront license fees and certain other related fees associated with our former Therapeutics business were recognized on a straight-line basis over the development periods of the contract deliverables. Fees associated with substantive at risk performance based milestones are 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.

Research and Development Costs

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

Income Taxes

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

period and the change during the period in deferred tax assets and liabilities.

We recognize in our financial statements the impact of a tax position, if that position is more likely than not to be sustained upon an examination, based on the technical merits of the position. Interest and penalties related to income tax matters are recorded as income tax expense. At March 31, 2015 and December 31, 2014 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 income per common share for the three months ended March 31, 2015 includes the dilutive impact of options equivalent to 462,903 shares.

Diluted loss per common share for the three months ended March 31, 2014 excluded all 1,481,708 of our outstanding options as of March 31, 2014, as their impact on our net loss is anti-dilutive. As a result, basic and diluted weighted average common shares outstanding are identical for this period.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

1. Description of Business and Significant Accounting Policies - continued

Share-Based Compensation

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

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

Comprehensive Income

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

Concentration of Risk

We maintain cash and short-term investment balances in accounts that exceed federally insured limits, although we have not experienced any losses on such accounts. We also invest excess cash in investment grade securities, generally with maturities of one year or less. We have historically provided credit in the normal course of business to contract counterparties and to the distributors of our product. Trade accounts receivable in the accompanying balance sheets consist primarily of amounts due from distributors of our Biosurgery products within the United States. During the first fiscal quarters of fiscal 2015 and 2014, revenues from one of the distributors of our Biosurgery products, Stability Biologics, comprised approximately 13% and 15%, respectively, of our total Biosurgery product revenues. As of March 31, 2015 and December 31, 2014, receivables from this distributor comprised 14% and 13%, respectively, of our trade receivables. We are experiencing some collection issues due to the termination of distributorships related to our new strategic partnerships with Arthrex and Stryker, and accordingly we have recorded an allowance. As discussed under *Trade Accounts Receivable*, we have not incurred any bad debt expense for the three months ended March 31, 2015 or 2014.

Recent Accounting Guidance at March 31, 2015

We evaluated the accounting standards updates (ASUs) issued by the Financial Accounting Standards Board (FASB) and determined they are either (i) not applicable or (ii) have an immaterial impact on our financial statements.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

2. Discontinued Operations

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

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

Milestone		Amount ($000)
Initial consideration		
Letter of intent payments	$	3,500
Initial closing payment		16,500
Additional closing payment, received in April 2014		15,000
Delivery of all scheduled assets under the Transfer Agreement		15,000
Total initial consideration		50,000
Contingent Consideration		
First marketing authorization received in the U.S.		20,000
First marketing authorization received from France, Germany, or European Union.		10,000
Completion of the enrollment of the Phase 3 Crohn s Trial or Mesoblast s election to discontinue the trial		10,000
Receipt of final data for the Crohn s trial or first marketing approval for Crohn s		10,000
Total conditional consideration		50,000
Total possible purchase price	$	100,000

Of the $50 million in total initial consideration, we received payment of $35 million in cash, and $15 million in Mesoblast ordinary shares, which were delivered to us upon completed delivery of the ceMSC assets. Our ability to receive the second $50 million is subject to satisfaction of the milestones indicated above all of which are largely dependent upon the clinical and regulatory success of Mesoblast and other factors not in our control. These include many if not all of the risks and uncertainties that our ceMSC business was subject to prior to its sale to Mesoblast, including product development, efficacy and regulatory risks. We have received no such payments thus far, nor do we have any expectation of receiving any such payments in the foreseeable future. Our ability to earn royalties from Mesoblast is subject to these same risks and will require performance by Mesoblast that results in its meeting some or all of the milestones referred to above, and is thereafter also dependent upon the commercial success of Mesoblast s ceMSC business. Royalties, if any, are payable to us in cash. Any portion of the second $50 million that

becomes payable to us will be payable, at the discretion of Mesoblast, in Mesoblast ordinary shares, based on a then current valuation of such shares. Any such Mesoblast ordinary shares that we receive will be subject to a one year holding period, with the same limited downside protection for a drop in the Mesoblast share price over the holding period.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

2. Discontinued Operations - continued

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

During fiscal 2014, we completed all of our responsibilities under a separate transition services agreement with Mesoblast and all involvement in our former Therapeutics business has ceased. The only continuing cash flows to us related to our former 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 the first quarter of fiscal 2015 or full fiscal year 2014.

Summarized operating results of discontinued operations are as follows:

	Three Months Ended	
	March 31, 2015 ($000s)	March 31, 2014 ($000s)
Revenue from collaborative research agreements and royalties	$	$
Operating expenses:		
Research and development	$	73
Selling, general and administrative		516
		589
Loss from discontinued operations before income tax expense		(589)
Income tax expense		165
Loss from discontinued operations	$	$ (754)

Revenues from our former Therapeutics business historically consisted primarily of collaborative research agreements and royalties. Because of the disposition of our Therapeutics business in 2013, we will no longer incur related research and development expenses related to these discontinued operations. Our discontinued operations also earned royalty revenues and cost reimbursement under an adult expanded access program. Royalties were earned on the sale of human mesenchymal stem cells sold for research purposes. We recognized this revenue as sales were made.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

3. 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 care, cartilage repair, and orthopedics to harness the ability of cells and novel constructs to promote the body s natural healing. We launched Grafix for commercial distribution in 2010, began distribution of Ovation in early fiscal 2011, and began distribution of Cartiform during 2013. We transitioned Ovation to OvationOS (now branded as BIO(4)) during the second half of 2014. The initial commercial sale of BIO(4) through our collaboration with Stryker occurred in the first quarter of fiscal 2015. We have continued to increase our distribution volume of these products since their respective commercial launches and are developing additional products for future commercialization.

Our Therapeutics segment focused on developing and marketing products to treat medical conditions in the inflammatory and cardiovascular disease areas. Its operations focused on clinical trials and discovery efforts. As disclosed in Note 2 *Discontinued Operations*, in October 2013 we entered into a Purchase Agreement with Mesoblast, pursuant to the terms of which we sold our culture expanded mesenchymal stem cell business, including Prochymal and other related assets.

Given the sale of our former Therapeutics segment, we now have only one operating segment. As such, our financial statements present the assets, liabilities, and results of the former Therapeutics segment as discontinued operations for all periods presented, and our continuing operations now represent what was formerly our Biosurgery segment.

4. Property and Equipment

Property and equipment at March 31, 2015 and December 31, 2014 are as follows:

	March 31, 2015 ($000s)	December 31, 2014 ($000s)
Laboratory and manufacturing equipment	$ 1,395	$ 1,211
Computer hardware, furniture and fixtures	1,486	1,377
Leased assets	228	228

Leasehold improvements		4,417		4,365
		7,526		7,181
Accumulated depreciation and amortization		(5,361)		(5,094)
Property and equipment, net	$	2,165	$	2,087

Depreciation and amortization expense for property and equipment was $267,000 and $214,000 for three months ended March 31, 2015 and 2014, respectively.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

5. Inventory

As of March 31, 2015 and December 31, 2014, inventory for our Biosurgery business consists of the following:

	March 31, 2015 ($000s)	December 31, 2014 ($000s)
Inventory		
Raw materials and supplies	$ 1,088	$ 1,025
Work-in-process	148	19
Finished goods	10,703	9,880
Total Biosurgery inventory	$ 11,939	$ 10,924

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

6. Share-Based Compensation

In April 2006, we adopted our 2006 Omnibus Plan. We amended and restated this plan in 2008 and 2010, and further amended it in 2012 and 2014, 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 3,000,000 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 March 31, 2015, there were 306,906 shares available for future awards under the Amended and Restated 2006 Omnibus Plan.

In connection with the stock options exercised during the three months ended March 31, 2015, we received cash proceeds of $328,000. At March 31, 2015, there was $5.4 million of total unrecognized compensation costs related to non-vested stock options, which is expected to be recognized through fiscal 2019.

A summary of stock option activity for the three months ended March 31, 2015 is as follows:

	Number of Shares		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life		Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2014	1,608,557	$	12.01	7.92 years	$	6,774
Granted	207,000	$	17.97			
Exercised	(44,625)	$	7.10		$	419
Forfeited or canceled	(57,750)	$	14.35			
Balance, March 31, 2015	1,713,182	$	12.68	8.08 years	$	8,837
Exercisable at March 31, 2015	556,807	$	10.39	5.97 years	$	4,409

The weighted fair value of options granted during the three months ended March 31, 2015 was $8.66 per share.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

7. Income Taxes

We calculate our interim tax provision in accordance with the guidance for accounting for income taxes in interim periods. At the end of each interim period, we estimate the annual effective tax rate and apply that tax rate to our ordinary quarterly pre-tax income from continuing operations. The tax expense or benefit related to significant, unusual or extraordinary discrete events during the interim period is recognized in the interim period in which those events occurred. In addition, the effect of changes in enacted tax laws or rates or tax status is recognized in the interim period in which the change occurs. For the period ended March 31, 2015, the tax expense from continuing operations was $612,000. For the period ended March 31, 2014, the tax benefit from continuing operations was $130,000.

8. Investments Available for Sale

Investments available for sale consisted of the following as of March 31, 2015 and December 31, 2014:

	March 31, 2015 ($000s)				December 31, 2014 ($000s)			
	Cost	Unrealized Gain	Unrealized Loss	Fair Value	Cost	Unrealized Gain	Unrealized Loss	Fair Value
Cash equivalents:								
Money market funds & certificates of deposit	$ 110	$	$	$ 110	$ 1,043	$	$	$ 1,043
Corporate debt securities & commercial paper	10,795	37	(39)	10,793	12,835	21	(24)	12,832
	10,905	37	(39)	10,903	13,878	21	(24)	13,875
Investments:								
Municipal securities	11,640	2	(124)	11,518	12,400	13	(47)	12,366
Agency obligations	7,257	18	(31)	7,244	5,401	12	(28)	5,385
US & international government agencies	5,709		(7)	5,702	5,680	1	(2)	5,679
	24,606	20	(162)	24,464	23,481	26	(77)	23,430
Investments available for sale	**$ 35,511**	**$ 57**	**$ (201)**	**$ 35,367**	**$ 37,359**	**$ 47**	**$ (101)**	**$ 37,305**

The cash equivalents detailed above 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.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

8. Investments Available for Sale - continued

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 March 31, 2015 and December 31, 2014:

	Less than 12 Months		12 Months or More		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
March 31, 2015 ($000s)						
Municipal securities	$ 8,709	$ (66)	$ 1,024	$ (58)	$ 9,733	$ (124)
Agency obligations	4,442	(31)			4,442	(31)
Corporate debt securities & commercial paper	5,212	(39)			5,212	(39)
US & international government agencies	3,070	(7)			3,070	(7)
Total temporarily impaired	**$ 21,433**	**$ (143)**	**$ 1,024**	**$ (58)**	**$ 22,457**	**$ (201)**

	Less than 12 Months		12 Months or More		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
December 31, 2014 ($000s)						
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)**

The following table summarizes maturities of our investments available for sale as of March 31, 2015 and December 31, 2014:

	March 31, 2015 ($000s)	December 31, 2014 ($000s)

	Cost	Fair Value	Cost	Fair Value
Maturities:				
Within 3 months	$ 2,303	$ 2,286	$ 3,056	$ 3,056
Between 3 12 months	11,514	11,474	12,658	12,660
More than 1 year	21,694	21,607	21,645	21,589
Investments available for sale	**$ 35,511**	**$ 35,367**	**$ 37,359**	**$ 37,305**

Realized gains (losses) and investment interest income net of management fees earned on investments available for sale were $151,000 and $54,000, respectively, for the three months ended March 31, 2015 and 2014, and have been included as a component of Other income (expense), net in the accompanying financial statements.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

9. Fair Value

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

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

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

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

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

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

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.

We do not currently hold any assets in this category.

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.

The price protection derivative related to the Mesoblast 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 shares at a price of $15 million. Significant inputs to the model include the following:

Fair value of underlying Mesoblast stock: $15,000,000

Contractual life: 1.0 year

Volatility: 40%

Risk-free interest rate: 0.13%

Expected dividends: $0

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

9. Fair Value - continued

The price protection related to Mesoblast shares ended in December 2014. There were no transfers in and out of Level 3 during the first quarter of fiscal 2015. The following table represents a rollforward of the fair value of Level 3 instruments, comprised solely of the limited price protection derivative related to the Mesoblast stock issued to us in connection with the sale of our former Therapeutics business:

	March 31, 2015 ($000s)	December 31, 2014 ($000s)
Balance at beginning of period	$	$ 1,685
Fair value upon receipt of Mesoblast stock		
Change in fair value		2,252
Settlements		(3,937)
Balance at end of period	$	$

Assets and liabilities measured at fair value on a recurring basis are summarized below as of March 31, 2015 and December 31, 2014:

	March 31, 2015 ($000s)			
	Level I	Level II	Level III	Total
Assets				
Investments: Available for Sale Securities				
Cash & cash equivalents	$ 110	$	$	$ 110
US & international government agencies		5,702		5,702
Agency obligations		7,244		7,244
Corporate debt securities & commercial paper		10,793		10,793
Municipal securities		11,518		11,518
Total investments available for sale	110	35,257		35,367
Securities received in business disposition				
Restricted shares of Mesoblast common stock	8,162			8,162
Total securities	8,162			8,162

Total assets	**$ 8,272**	**$ 35,257**	**$**	**$ 43,529**

	December 31, 2014 ($000s)			
	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
Certificates of deposit				
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 securities	10,591			10,591
Total assets	$ 11,634	$ 36,262	$	$ 47,896

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2015 AND 2014

10. Subsequent Events

We evaluated our March 31, 2015 financial statements for subsequent events through the date the consolidated financial statements were issued. We are not aware of any subsequent events that would require recognition of disclosure in the financial statements. Furthermore, there have been no material changes, outside of the normal course of business, to any of the contractual obligations disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

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ITEM 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

CAUTIONARY STATEMENTS ABOUT FORWARD-LOOKING INFORMATION

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Statements included or incorporated herein which are not historical facts are forward looking statements. When used in this Quarterly Report, the words *estimates, expects, anticipates, projects, plans, intends, believes, forecasts* and variations of such words or similar expressions are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying forward looking statements.

Forward looking statements reflect management s current views with respect to future events and performance and are based on currently available information and management s assumptions regarding future events. While management believes that its assumptions are reasonable, forward-looking statements are subject to various known and unknown risks and uncertainties and actual results may differ materially from those expressed or implied herein. In connection with the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, we note that certain factors, among others, which could cause future results to differ materially from the forward-looking statements, expectations and assumptions expressed or implied herein are discussed in greater detail in our Annual Report on Form 10-K under Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 1A Risk Factors, and may be discussed elsewhere herein or in other documents we file with the Securities and Exchange Commission, or SEC. Examples of forward-looking statements may include, without limitation, statements regarding any of the following: our product development efforts; 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 activities and projected expenditures, including our anticipated timeline and commercialization strategy for marketed Biosurgery products (including Grafix®, BIO4™ and Cartiform®); and Biosurgery products under development; our cash needs; patents, trademarks and other proprietary rights; the safety and ability of our products perform as intended or expected; our ability to supply a sufficient amount of our marketed products or product candidates and, if or insofar as approved or otherwise commercially available, 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 attributable to us or persons acting on our behalf apply only as of the date of this Quarterly Report and are expressly qualified in their entirety by the cautionary statements included herein. We undertake no obligation to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances and do not intend to do so.

You should read the following management s discussion and analysis of our financial condition and results of operations in conjunction with our audited financial statements and related notes thereto and other disclosures included as part of our Annual Report on Form 10-K for the year ended December 31, 2014, and our unaudited condensed financial statements for the three months period ended March 31, 2015 and other disclosures included in this Quarterly Report on Form 10-Q, and our Current Reports on Form 8-K during this periods and since then to date.

Our condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, and are presented in U.S. dollars.

There are a number of risks and uncertainties that could cause our actual results to differ materially from the forward-looking statements contained in this report. Some of the important factors that could cause our actual results to differ materially from the forward-looking statements we make in this report are set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 under Part I Item 1A Risk Factors. There may be other factors that may cause our actual results to differ materially from the forward-looking statements.

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

Company Overview

The following is a discussion and analysis of our financial condition, results of operations, liquidity and capital resources for each of the three months ended March 31, 2015 and 2014 and significant factors that could affect our prospective financial condition and results of operations. You should read this discussion together with our financial statements and notes included in Item 1. Financial Statements.

Osiris Therapeutics, Inc., based in Columbia, Maryland, is the world leader in researching, developing and marketing cellular regenerative medicine products that improve health and lives of patients and lower overall healthcare costs. The company continues to advance its research and development 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, including Cartiform®, BIO4 , and Grafix®. During the fourth fiscal quarter of 2014, we entered into an exclusive distribution agreement with a subsidiary of Stryker Corporation for the marketing and distribution of BIO4, previously branded and sold by us as OvationOS®, and entered into an agreement with Arthrex, Inc. for the marketing and distribution of Cartiform. The initial commercial sales of BIO4 and Cartiform through our partnerships began in the first quarter of fiscal 2015. We develop and are responsible for the manufacture or processing of each of these products.

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Osiris, Grafix, and Cartiform are registered trademarks of Osiris Therapeutics, Inc. BIO4 is a trademark of Stryker Corporation. More information can be found on the company s website, www.Osiris.com.

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

We are a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of regenerative medicine products. We have developed an intellectual property portfolio to protect our technology and commercial interests.

From 2010 to 2013, we operated in two business segments, Biosurgery and Therapeutics. In October 2013, we sold our Therapeutics segment for up to $100.0 million in initial and contingent consideration, and we are now focused on our Biosurgery business. Our Biosurgery business works to harness the ability of cells and novel constructs to promote the body s natural healing with the goals of improving surgical outcomes and offering better treatment options for patients and physicians. Our Therapeutics business historically focused on developing biologic stem cell drug candidates from a readily available and non-controversial source adult bone marrow. These activities ceased completely following fulfillment in the second half of fiscal 2014 of our remaining obligations in connection with the sale of our Therapeutics business.

The three pillars of our business strategy are to continue our history of innovation, bring about commercial transformation, and ensure differentiation of our company. To innovate, we seek to make new products available to address unmet medical needs through research and development (R&D) and commercial efforts in our areas of focus in wound care, orthopedics and sports medicine. Disease targets for products commercialized or in development include diabetic foot ulcers, venous stasis ulcers, dermal burns, and sports medicine products for motion preservation. Our commercial transformation is defined by establishing a proprietary sales infrastructure and driving long-term revenue growth. To differentiate, we seek to identify and introduce barriers to entry, through means such as superior science, clinical data and intellectual property rights. Since 2010, we have launched commercial distribution of several Biosurgery products, including Grafix, BIO4, and Cartiform.

Over the last six quarters, we have experienced significant growth in revenues from our Biosurgery products. We have also made a significant investment in increasing our sales force, and expect to incur additional research and development expenses associated with efforts to obtain pre-marketing approval from the FDA for expanded indications for Grafix. As we continue with this transition, and the transition of Ovation to Bio4, we face all of the risks and uncertainties to which our business is generally subject. Thus, while we have demonstrated some limited success thus far in the pursuit of our new Biosurgery strategy, we recognize that we operate in a competitive and challenging business environment and that our continued execution on this strategy will face a number of challenges. As a result, we may experience variability in our overall results, and in our quarter to quarter revenues.

Financial Operations Overview

Revenue

We produce human tissue-based products in our Columbia, Maryland facility and distribute these products through a network of independent distributors as well as through the efforts of employee sales personnel. We presently produce and distribute Grafix for acute and chronic wounds, Cartiform, a viable cartilage mesh for cartilage repair and BIO4 for bone growth. All of these products are cryo-preserved and stored in special freezers at -80 degrees Celsius. Customers have the product shipped to them on dry ice. Legal title usually passes to the customer when the product leaves our shipping dock. We do have consignment inventory at certain hospital sites or clinic facilities. 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 consigned products, revenue is recognized when we receive appropriate notification that the product has been used in a surgical procedure. Due to the nature of the products and the manufacturing process, we generally do not allow sales returns.

During the third quarter of fiscal 2010, we launched Grafix as the first product in our then newly established Biosurgery segment, for limited commercial distribution. We began distribution of a second product, Ovation, in early fiscal 2011. We transitioned our Ovation product to OvationOS (now branded as BIO4) during the second half of fiscal 2014. These products followed our first generation Biosurgery product, Osteocel, which we sold to Nuvasive, Inc. in 2008 for approximately $80 million in aggregate consideration. We have continued to increase our distribution volume for Grafix and our other current Biosurgery products throughout fiscal 2012 to 2015 through both in-house personnel as well as through our expanding distributor network. The increase in product revenue and gross profit since commercial launch is due to volume increases. We anticipate continuing to increase our organizational focus on the development and commercialization of Biosurgery products in the foreseeable future.

We have committed to the FDA that, before marketing Grafix for certain expanded indications, we will submit a Biologics License Application (BLA) to the FDA and seek pre-marketing approval for such added indications.

Research and Development Costs

Our research and development costs consist of expenses incurred in identifying, developing and testing biologic tissue based products. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers for independent monitoring and analysis of our clinical trials, costs of contract research and manufacturing, costs of facilities, and the costs of manufacturing clinical trial materials and quality control supplies. Our historic research and development costs included these and other costs specific to our efforts focused on our biologic drug candidates, including costs of manufacture of clinical batches of our biologic drug candidates.

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Consistent with our historic focus on the development of biologic drug candidates with potential uses in multiple indications, many of our historic costs are not attributable to a specifically identified product. We use our employee and infrastructure resources across several projects. Accordingly, we do not account for internal research and development costs on a project-by-project basis. From inception in December 1992 through March 31, 2015, we incurred aggregate research and development costs of approximately $445 million.

Biosurgery research and development expenses were $1.6 million and $670,000 during the first quarter of fiscal 2015 and 2014, respectively, which includes costs incurred for studies in using Grafix in the treatment of venous leg ulcers and diabetic foot ulcers.

We expect our research and development expenses to continue to be substantial in the future, as we continue our clinical trial activity for our existing Biosurgery products if and as they advance through the development cycle, and if and as we invest in additional product opportunities and research programs. Clinical trials and preclinical studies are time-consuming and expensive. Our expenditures on current and future preclinical and clinical development programs are subject to many uncertainties. We test our products in several preclinical studies, and we then conduct clinical trials for those candidates that we determine to be the most promising. As we obtain results from clinical trials, we may elect to discontinue or delay trials for some product candidates in order to focus our resources on more promising product candidates. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, size of trial and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

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

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of the costs associated with our selling and marketing efforts and well as our general management, including salaries, sales commissions, allocations of facilities and related costs, and professional fees such as legal and accounting expenses. Beginning in fiscal 2012, we incurred additional general and administrative expenses related to increased distribution efforts for our Biosurgery products. During the fiscal 2014, we hired 100 additional employees in our sales and marketing department, increasing our total internal sales force to approximately 110 employees. We expect future expense increases to continue as a result of hiring additional operational, financial, accounting, facilities engineering and information systems personnel as we continue to increase distribution of our Biosurgery products. We did not experience any significant reductions in our general and administrative expenses as the result of the sale of our Therapeutics business.

Other Income (Expense), Net

Other income consists of interest earned on our cash and investments available for sale, realized gains and losses incurred on the sale of these investments, and the unrealized gains and losses incurred on our trading securities (which we account for using the fair value method), net of interest expense. 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.

Critical Accounting Policies

There have been no material changes in our critical accounting policies, estimates, and judgments during the three months ended March 31, 2015 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, other than as disclosed herein.

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Results of Operations

Comparison of Three Months Ended March 31, 2015 and 2014

Product Revenues & Gross Profit

During the first quarter of fiscal 2015, our revenue from product distribution increased to $21 million, compared to $10 million in the first quarter of fiscal 2014, as we continued to focus on the commercialization of our Biosurgery products. The increase in revenue was achieved through the expansion of our in-house sales and marketing team, as well as increases from our product distributors. We experienced growth in sales of Grafix, BIO4, and Cartiform during the first quarter of fiscal 2015. Although revenue from the distribution of BIO4 and Cartiform is still less than 20% of our total product revenue, we believe that these two new products will contribute to our future growth and are complementary products to Grafix, simplifying the sales efforts. Our gross profit margin was 78% for both first quarters of fiscal 2015 and 2014. During the first quarter of fiscal 2014, we operated our manufacturing facilities at our Columbia, Maryland location using one shift and we began using a second shift during the second quarter of fiscal 2014. We have capacity to facilitate further growth without substantial increases in our clean room and manufacturing facilities.

Research and Development Expenses

Research and development expenses in the first quarter of fiscal 2015 were $1.6 million compared to $670,000 in the same period of fiscal 2014. The increase in research and development expenses is primarily due to increased investments in research and development activities as we further our research into using Grafix in the treatment of venous leg ulcers. We also began a multicenter, open-label, single-arm study to evaluate the safety and efficacy of Grafix for the treatment of complex diabetic foot wounds with exposed tendon and/or bone during the fourth quarter of fiscal 2014, and we expect this to be completed mid-way through 2015. We continue to make substantial investments in research and development activities during fiscal 2015, as we further our research into using Grafix for expanded indications.

Selling, General and Administrative Expenses

Selling, general and administrative expenses rose to $12.8 million during the first quarter of fiscal 2015 compared to $7.2 million in the same period of fiscal 2014. The significant majority of these cost increases were incurred because of increased commissions due to higher sales volume, and sales and marketing efforts to increase our product distribution and to build our infrastructure in the areas of reimbursement for public and private health care providers. Selling, general and administrative costs were 61.1% of product revenue in the first quarter of fiscal 2015 compared to 72.0% during the same period in fiscal 2014. We will continue to heavily invest in our sales, marketing and reimbursement capabilities throughout the remainder of fiscal 2015 and also expect to incur additional costs to augment our human resources, finance and information technology capabilities to support our expanding sales force.

Other Income (Expense), Net

Other income, net in the first quarter of fiscal 2015 primarily consisted of the net realized investment income earned on our investments available for sale of $151,000.

Other expense, net in the first quarter of fiscal 2014 consisted of the net realized investment income earned on our investments available for sale of $54,000, together with the unrealized loss of approximately $465,000 on the market value decrease of the Mesoblast stock we received in connection with the sale of our Therapeutics business, as well as the $286,000 increase in the fair value of the derivative from the limited price protection afforded us on the Mesoblast stock. The derivative was valued at approximately $1.9 million at the end of the first quarter of fiscal 2014. The price protection ended in December 2014, although Mesoblast committed to us to purchase the Mesoblast ordinary shares held by us for no less than $15 million during the first half of fiscal 2015. Therefore, as of December 31, 2014, we no longer had a derivative instrument.

Income Taxes

Due to taxable income expected from continuing operations, we recognized income tax expense in 2015. Due to taxable income expected from discontinued operations for income tax accounting purposes and a net loss from continuing operations, we recognized both an income tax expense and benefit, respectively, in 2014. In fiscal 2015, we will utilize part of our $70 million of tax credits to offset the taxable income up to the federal alternative minimum tax threshold. We will maintain our full valuation allowance until operations from our Biosurgery business (continuing operations) provides evidence of sufficient future earnings.

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Liquidity and Capital Resources

Liquidity

At March 31, 2015, we had $3.7 million in cash and $35.4 million in investments available for sale. Other receivables at March 31, 2015 include the difference of $6.8 million between the market value of the Mesoblast shares and the guaranteed payment of $15 million. At March 31, 2015, the market value of the Mesoblast stock was $8.2 million. We have not had any outstanding debt at any time since fiscal 2008.

Cash Flow

Net cash used in operating activities of continuing operations during the first quarter of fiscal 2015 was $359,000 and primarily reflects our net income of $1.4 million, net increases in our trade receivables and inventory, partially offset by the decrease in prepaid assets and other current assets and non cash charges.

Net cash used in operating activities of continuing operations during the first quarter of fiscal 2014 was $4.8 million, and primarily reflects our net loss from continuing operations of $611,000, net increases in our trade receivables and inventory, partially offset by non cash charges.

Net cash provided by investing activities during the first quarter of fiscal 2015 and 2014 was $1.5 million and $4.9 million, respectively, and in each year primarily reflects proceeds from the sales of our investments to fund our operations.

Net cash provided by financing activities during the first quarter of fiscal 2015 and 2014 was $371,000 and $623,000 respectively. The cash provided by financing activities is primarily the net proceeds from the exercise of stock options by our employees.

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 need for (whether or not anticipated) and the timing of, and the costs involved in, obtaining regulatory approvals for our Biosurgery products, which could be costly and time consuming; the costs of maintaining, expanding and protecting our intellectual property portfolio, including possible litigation costs and liabilities; and

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

We have not had any outstanding debt at any time since fiscal 2008.

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.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Risk

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

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

Derivative Instruments

Generally, we do not enter into hedging or derivative instrument arrangements. In connection with the sale of our Therapeutics business, we received $15 million of Mesoblast Limited ordinary shares which were initially restricted from sale for a period of twelve months. Mesoblast provided us with limited price protection in the event that the value of the shares when the restrictive period expired was lower than the price when the shares were issued. In December 2014, the price protection for the Mesoblast ordinary shares expired, although Mesoblast agreed to

pay us no less than $15 million in cash for the stock prior to the end of the first half of fiscal 2015. Accordingly, we no longer have a derivative instrument as of December 31, 2014.

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Foreign Currency Exchange Rate Risk

We conduct clinical trial activities in areas that operate in a functional currency other than the United States dollar (USD). As a result, when the USD rises and falls against the functional currencies of these other nations, our costs will either increase or decrease by the relative change in the exchange rate. Foreign currency gains and losses were not material during the first quarter of fiscal 2015 or 2014, and at the present time, we have elected not to hedge our exposure to foreign currency fluctuations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures. An evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Quarterly Report on Form 10-Q was made under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (a) are effective to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is timely recorded, processed, summarized and reported and (b) include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. There have not been any changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we receive threats or may be subject to routine litigation matters related to our business. However, we are not currently a party to any material pending legal proceedings.

Item 1A. Risk Factors.

There have not been any material changes in the risk factors previously disclosed under the heading Risk Factors in Part I Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 as filed with the Securities and Exchange Commission on March 20, 2015.

Item 2. **Unregistered Sales of Equity Securities and Use of Proceeds**.

None.

Item 3. **Defaults Upon Senior Securities**.

None.

Item 4. **Mine Safety Disclosures.**

None.

Item 5. **Other Information**.

None.

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Item 6. Exhibits.

Exhibit Number	Description of Exhibit
31.1.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002).
31.2.1*	Certification of Principal Financial Officer pursuant o Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002).
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	*The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, formatted in Extensible Business Reporting Language (XBRL), include: (i) the Condensed Statements of Income, (ii) the Condensed Balance Sheets, (iii) the Condensed Statements of Cash Flows, and (iv) related notes (filed herewith).*

* filed herewith.

SIGNATURE

Pursuant to the requirements 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.

Date: May 11, 2015

/s/ PHILIP R. JACOBY, JR.
Philip R. Jacoby, Jr.
Chief Financial Officer (Principal Financial Officer)

Date: May 11, 2015

/s/ GREGORY I. LAW
Gregory I. Law
Vice President of Finance (Principal Accounting Officer)