OSIRIS THERAPEUTICS, INC.
Form 10-Q
May 12, 2014
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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, 2014

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 9, 2014**
Common Stock, par value $0.001 per share	34,222,162

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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, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash	$ 2,342	$ 2,416
Investments available for sale	34,650	39,508
Trading securities	16,907	17,086
Trade accounts receivable, net of reserves	11,763	7,459
Other receivables	15,130	15,265
Inventory	2,337	1,929
Prepaid expenses and other current assets	318	355
Current assets of discontinued operations	96	91
Total current assets	83,543	84,109
Property and equipment, net	1,809	1,896
Deferred tax asset	5,737	5,849
Restricted cash	243	243
Total assets	$ 91,332	$ 92,097
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,025	$ 4,842
Capital lease obligations, current portion	45	45
Deferred tax liability	5,737	5,849
Current liabilities of discontinued operations	17	57
Total current liabilities	9,824	10,793
Other long-term liabilities	319	355
Total liabilities	10,143	11,148
Commitments and contingencies		
Stockholders equity		
Common stock, $.001 par value, 90,000 shares authorized, 34,222 shares outstanding - 2014, 34,115 shares outstanding - 2013	34	34
Additional paid-in capital	284,219	282,702
Accumulated other comprehensive (loss) income	55	(33)

Accumulated deficit		(203,119)		(201,754)
Total stockholders equity		81,189		80,949
Total liabilities and stockholders equity	$	91,332	$	92,097

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

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OSIRIS THERAPEUTICS, INC.

STATEMENTS OF COMPREHENSIVE LOSS

Unaudited

(amounts in thousands, except per share data)

	Three Months Ended March 31,	
	2014	**2013**
Product revenues	$ 10,054	$ 4,055
Cost of product revenues	2,212	1,135
Gross profit	7,842	2,920
Operating expenses:		
Research and development	670	957
Selling, general and administrative	7,235	2,404
Fees paid to related parties	149	62
Share based payments to related parties	403	180
	8,457	3,603
Loss from operations	(615)	(683)
Other income (expense), net	(126)	29
Loss from continuing operations, before income taxes	(741)	(654)
Income tax benefit	130	358
Loss from continuing operations	(611)	(296)
Discontinued operations:		
Loss from operations of discontinued operations, net of income taxes of $165 and $358, respectively, in 2014 and 2013	(754)	(2,439)
Net loss	(1,365)	(2,735)
Other comprehensive income		
Unrealized gain on investments available for sale	88	25
Comprehensive loss	$ (1,277)	$ (2,710)
Basic and diluted loss per share		
Loss from continuing operations	$ (0.02)	$ (0.01)
Loss from discontinued operations	(0.02)	(0.07)
Basic and diluted loss per share	$ (0.04)	$ (0.08)
Weighted average common shares (basic and diluted)	34,148	32,912

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

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OSIRIS THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

For the three months ended March 31, 2014

Unaudited

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount				
Balance at January 1, 2014	**34,114,603**	**$ 34**	**$ 282,702**	**$ (33)**	**$ (201,754)**	**$ 80,949**
Exercise of options to purchase common stock ($.40- $12.01 per share)	80,559		634			634
Share-based payment-director services ($14.93 per share)	27,000		403			403
Share-based payment-employee compensation			480			480
Net loss					(1,365)	(1,365)
Unrealized gain on investments available for sale				88		88
Balance at March 31, 2014	**34,222,162**	**$ 34**	**$ 284,219**	**$ 55**	**$ (203,119)**	**$ 80,189**

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

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OSIRIS THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

Unaudited
(amount in thousands)

	Quarter ended March 31,	
	2014	**2013**
Cash flows from operating activities:		
Continuing operations		
Loss from continuing operations	$ (611)	$ (296)
Adjustments to reconcile loss from continuing operations to net cash used in operations of continuing operations:		
Unrealized loss on trading securities	179	
Depreciation and amortization	214	146
Non cash share-based payments	883	473
Provision for bad debts		22
Changes in operating assets and liabilities:		
Accounts receivable	(4,204)	(2,244)
Inventory	(408)	(333)
Prepaid expenses, and other current assets	72	141
Lease reserves	(25)	
Accounts payable, accrued expenses, and other current liabilities	(817)	(52)
Net cash used in operating activities of continuing operations	(4,717)	(2,143)
Discontinued operations		
Loss from discontinued operations	(754)	(2,439)
Adjustments to reconcile loss from discontinued operations to net cash used in operations of discontinued operations:		
Depreciation and amortization		39
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	(5)	(61)
Accounts payable and accrued expenses	(40)	19
Net cash used in operations of discontinued operations	(799)	(2,442)
Net cash used in operating activities	(5,516)	(4,585)
Cash flows from investing activities:		
Purchases of property and equipment	(127)	(111)
Proceeds from sale of investments available for sale	5,000	4,000
Purchases of investments available for sale	(54)	(29)
Net cash provided by investing activities	4,819	3,860
Cash flows from financing activities:		
Principal payments on capital lease obligations	(11)	(11)
Proceeds from the exercise of options to purchase common stock	634	169
Net cash provided by financing activities	623	158
Net increase in cash	(74)	(567)
Cash at beginning of period	2,416	1,854
Cash at end of period	$ 2,342	$ 1,287

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, 2014 AND 2013

1. Description of Business and Significant Accounting Policies

Description of Business

Osiris Therapeutics, Inc. (we, us, our, or the Company) is a Maryland corporation headquartered in Columbia, Maryland. We began operations on December 23, 1992 and were a Delaware corporation until, with approval of our stockholders, we reincorporated as a Maryland corporation on May 31, 2010. We are a leading stem cell company focused on developing and marketing products in the 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, cartilage repair, and orthopedics, 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, 2013, 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 (2013 10-K) for the

fiscal year ended December 31, 2013.

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, 2014 AND 2013

1. Description of Business and Significant Accounting Policies - continued

Investments Available for Sale

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

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

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 are required to hold that stock for one year from the date of receipt. We currently intend to dispose of the Mesoblast stock as soon as we are able to do so in December 2014. As such, we have reflected the investment as a current asset in Trading Securities. Mesoblast is a public company and its stock is traded on the Australian stock exchange.

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

Our only derivative instrument is the price guarantee regarding the payment received in restricted shares of Mesoblast stock. We do not hold derivative financial instruments for trading purposes.

Restricted Cash

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

Trade Accounts Receivable

Trade accounts receivable are reported at their net realizable value. We charge off uncollectible receivables when the likelihood of collection is remote. We set credit terms with individual customers, and consider receivables outstanding longer than the time specified in the respective customer s contract, typically 45-days, to be past due. As of March 31, 2014 and December 31, 2013, accounts receivable in the accompanying balance sheets are both reported net of a $78,000 allowance for doubtful accounts, respectively. We believe the reported amounts are fully collectible. Trade accounts receivable balances are not collateralized. We incurred $0 and $21,000 of bad debt expense in the first quarter 2014 and 2013 respectively.

Other Receivables

Other receivables consist of amounts due us from Mesoblast related to the sale of our Prochymal business, primarily the scheduled installment payment of $15.0 million which we received subsequent to the end of the first fiscal quarter of 2014, in April 2014. Other receivables also include reimbursements due us from Mesoblast for goods and services provided to them in connection with the Transition Services Agreement entered into as part of the sale transaction. The Transition Services Agreement has been extended so that we will provide some services to Mesoblast through October 10, 2014, and will continue to be reimbursed for the costs and time incurred.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2014 AND 2013

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 2014 or during fiscal year 2013.

Biosurgery Revenue Recognition

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

Therapeutics Revenue Recognition

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

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

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2014 AND 2013

1. Description of Business and Significant Accounting Policies - continued

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, 2014 and December 31, 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 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.

Diluted loss per common share for the three months ended March 31, 2013 excluded all 2,132,664 shares issuable upon the exercise of options, and all 1,000,000 shares issuable upon the exercise of an outstanding warrant, as their impact on our net loss is anti-dilutive. As a result, basic and diluted weighted average common shares outstanding are identical for the period.

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 2014 and 2013, revenues from one of the distributors of our Biosurgery products, Stability Biologics, comprised approximately 58% and 64%, respectively, of our total Biosurgery product revenues. As of March 31, 2014 and December 31, 2013, receivables from this distributor comprised 20% and 57%, respectively, of our trade receivables. We expect all of our reported receivables to be fully collected. As discussed under *Trade Accounts Receivable*, we have not incurred any bad debt expense for the three months ended March 31, 2014.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2014 AND 2013

1. Description of Business and Significant Accounting Policies - continued

Recently Adopted Accounting Guidance at March 31, 2014

In July 2013, the Financial Accounting Standards Board (FASB) issued an Accounting Standards Update (ASU) related to the presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The ASU requires an unrecognized tax benefit, or a portion of an unrecognized tax benefit, to be presented in the financial statements as either a reduction to a deferred tax asset or separately as a liability depending on the existence, availability and/or use of an operating loss carryforward, a similar tax loss, or a tax credit carryforward. This ASU was adopted at January 1, 2014. This ASU did not have an impact on our consolidated financial statements as we currently do not have any unrecognized tax benefits in the same jurisdictions in which we have tax loss or credit carryovers.

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 had received at December 31, 2013, payment of $20 million in cash, and $15 million in Mesoblast ordinary shares, which were delivered to us upon completed delivery of the ceMSC assets. The remaining $15 million of the initial consideration was received in cash on April 9, 2014. The Mesoblast shares received by us are subject to a one year holding period from the date of receipt, but are afforded limited downside protection for a drop in the Mesoblast share price over the holding period. We have evaluated this downside protection, and determined that it meets the criteria of a derivative instrument. The fair value of the protection at the time of the disposition of our Therapeutics business was $1.7 million. We recognized the price protection derivative as an asset at March 31, 2014 and December 31, 2013 at its then fair value of $2.0 million and $1.7 million respectively, which has been reflected in the calculation of the gain on sale of the Therapeutics business.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2014 AND 2013

2. Discontinued Operations - continued

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 also be subject to a one year holding period, with the same limited downside protection described above.

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

As a result of the disposal of our Therapeutics segment, we have presented the assets, liabilities, and results of the segment s operations as a discontinued operation for all periods presented. Our only continuing involvement in our former Therapeutics business is to wind down our prior research and development activities and to assist Mesoblast absorb this business under a Transition Services Agreement entered into as part of the Purchase Agreement. 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 2014 or full fiscal year 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 approximately $600,000, including legal, accounting and advisory fees, and income tax expense of $1.7 million.

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

	March 31, 2014 ($000s)	December 31, 2013 ($000s)

Current assets:		
Accounts receivable	$ 96	$ 91
Current liabilities:		
Accounts payable and accrued expenses	$ 17	$ 57

Summarized operating results of discontinued operations are as follows:

	March 31, 2014 ($000s)	March 31, 2013 ($000s)
Revenue from collaborative research agreements and royalties	$	$ 186
Operating expenses:		
Research and development	73	2,024
Selling, general and administrative	516	243
	589	2,267
Loss from discontinued operations before income tax expense	(589)	(2,081)
Income tax expense	165	358
Loss from operations of discontinued operations	$ (754)	$ (2,439)

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2014 AND 2013

2. Discontinued Operations - continued

Revenues from our former Therapeutics business have historically consisted primarily of collaborative research agreements and royalties. Because of the disposition of our Therapeutics business in 2013, we will no longer incur related research and development expenses related to these discontinued operations. Our discontinued operations 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.

3. Segment Reporting

Historically, 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 and OvationOS during 2013. We have continued to increase our distribution volume of these products since their respective commercial launches and are developing additional products for future commercialization.

Our Therapeutics segment focused on developing and marketing products to treat medical conditions in the inflammatory and cardiovascular disease areas. Its operations have focused on clinical trials and discovery efforts. As disclosed in Note 2 *Discontinued Operations*, 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, 2014 and December 31, 2013 are as follows:

	March 31, 2014 ($000)	December 31, 2013 ($000)
Laboratory and manufacturing equipment	$ 706	$ 663
Computer hardware, furniture and fixtures	1,021	889
Leased assets	228	228
Leasehold improvements	4,262	4,260
	6,217	6,050
Accumulated depreciation and amortization	(4,408)	(4,154)
Property and equipment, net	$ 1,809	$ 1,896

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2014 AND 2013

5. Inventory

As of March 31, 2014 and December 31, 2013, inventory for our Biosurgery business consists of the following:

	March 31, 2014 ($000)	December 31, 2013 ($000)
Inventory		
Raw materials and supplies	$ 460	$ 387
Work-in-process	428	22
Finished goods	1,449	1,520
Total Biosurgery inventory	$ 2,337	$ 1,929

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 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 March 31, 2014, there were 14,281 shares available for future awards under the Amended and Restated 2006 Omnibus Plan. At our 2014 Annual Meeting of Stockholders, held on May 6, 2014, an amendment to the Amended and Restated 2006 Omnibus Plan was approved that, among other things, increased the maximum number of shares that may be awarded under the Plan to 3,000,000 shares.

In connection with the stock options exercised during the three months ended March 31, 2014, we received cash proceeds of $634,000. At March 31, 2014, there was $4.5 million of total unrecognized compensation costs related to non-vested stock options, which is expected to be recognized through fiscal 2018.

A summary of stock option activity for the three months ended March 31, 2014 is as follows:

	Number of Shares		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life		Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2014	1,233,767	$	10.61	6.3-years	$	7,992
Granted	488,500	$	15.37			
Exercised	(80,559)	$	(7.87)		$	507
Forfeited or canceled	(160,000)	$	(21.63)			
Balance, March 31, 2014	1,481,708	$	11.15	7.5-years	$	4,851
Exercisable at March 31, 2014	509,958	$	10.03	5.7-years	$	2,238

The weighted fair value of options granted during the three months ended March 31, 2014 was $8.11 per share.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2014 AND 2013

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, 2014 and 2013, the tax benefit from continuing operations was $130,000 and $358,000 million, respectively. This benefit is attributable to the losses from continuing operations that were expected to be utilized by discontinued operations.

8. Investments Available for Sale

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

	March 31, 2014 $000 Unrealized				December 31, 2013 $000 Unrealized			
	Cost	Gain	Loss	Fair Value	Cost	Gain	Loss	Fair Value
Cash equivalents:								
Money market funds & certificates of deposit	$ 111	$	$	$ 111	$ 655	$	$	$ 655
Commercial paper & corporate securities	9,135	26	(9)	9,152	6,354	23	(10)	6,367
	9,246	26	(9)	9,263	7,009	23	(10)	7,022
Investments:								
Common stock and municipal securities	13,538	30	(15)	13,553	12,507	9	(24)	12,492
Agency obligations & Mutual Funds	5,474	23	(4)	5,493	10,781	5	(35)	10,750
US & International government agencies	6,337	4		6,341	9,244			9,244
	25,349	57	(19)	25,387	32,532	14	(59)	32,486
Investments available for sale	**$ 34,595**	**$ 83**	**$ (28)**	**$ 34,650**	**$ 39,541**	**$ 37**	**$ (69)**	**$ 39,508**

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.

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

	March 31, 2014 $000		December 31, 2013 $000	
	Cost	Fair Value	Cost	Fair Value
Maturities:				
Within 3-months	$ 3,590	$ 3,612	$ 12,664	$ 12,664
Between 3 12 months	4,444	4,452	1,623	1,610
More than 1 year	26,561	26,586	25,254	25,234
Investments available for sale	$ 34,595	$ 34,650	$ 39,541	$ 39,508

Realized gains and investment income earned on investments available for sale were $54,000 and $18,000, respectively, for the three months ended March 31, 2014 and 2013, and have been included as a component of Other income, 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, 2014 AND 2013

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 and our derivative instrument.

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

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

When quoted prices in active markets for identical assets are available, we use these quoted market prices to determine the fair value of financial assets and classify these assets as Level 1. In other cases where a quoted market price for identical assets in an active market is either not available or not observable, we obtain the fair value from a third party vendor that uses pricing models, such as matrix pricing, to determine fair value. These financial assets would then be classified as Level 2. In the event quoted market prices were not available, we would determine fair value using broker quotes or an internal analysis of each investment s financial statements and cash flow projections. In these instances, financial assets would be classified based upon the lowest level of input that is significant to the valuation. Thus, financial assets might be classified in Level 3 even though there could be some significant inputs that may be readily available.

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

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

Contractual life: 1.0 year

Volatility: 40%

Risk-free interest rate: 0.13%

Expected dividends: $0

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2014 AND 2013

9. Fair Value - continued

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

	March 31, 2014 ($000s)
Balance at beginning of period	$ 1,685
Change in Fair Value	286
Balance at end of period	$ 1,971

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

	March 31, 2014 ($000s)			
	Level I	Level II	Level III	Total
Assets				
Investments available for sale				
Cash & Cash Equivalents	$ 111	$	$	$ 111
Investments: Available for Sale Securities				
Government Obligations		6,341		6,340
Mutual Funds		3,987		3,987
Agency Obligations		1,506		1,506
Corporate Debt Securities & Commercial Paper		9,152		9,152
Municipal Securities		13,553		13,554
Investments available for sale	111	34,539		34,650
Derivative and securities received in business disposition				
Restricted shares of Mesoblast common stock	14,936			14,936
Price protection on restricted Mesoblast shares			1,971	1,971
Derivative and securities received in business disposition	**14,936**		**1,971**	**16,907**

Total assets	**$** 15,047	**$** 34,540	**$** 1,971	**$** 51,558

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (continued)

THREE MONTHS ENDED MARCH 31, 2014 AND 2013

9. Fair Value - continued

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

10. Subsequent Events

We evaluated our March 31, 2014 financial statements for subsequent events through the date the consolidated financial statements were issued. On April 9, 2014, we received a $15.0 million milestone payment related to the disposition of the Therapeutics product as detailed in *Note 2 - Discontinued Operations*. We are not aware of any other subsequent events which would require recognition or disclosure in the consolidated 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, 2013.

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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; the success of our product candidates in development; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and commercialization strategy for marketed Biosurgery products (including Grafix®, Ovation®, OvationOS ™ and Cartiform®); our cash needs; patents, trademarks and other proprietary rights; the safety and ability of our products perform as intended or expected; our ability to supply a sufficient amount of our marketed products or product candidates and, if or insofar as approved or otherwise commercially available, products to meet demand; our costs to comply with governmental regulations; our plans for or success of sales and marketing; our plans regarding facilities; our ability to establish and maintain reimbursement for our commercially available products; types of regulatory frameworks we expect will be applicable to our products and potential products; and results of our scientific research.

Readers are cautioned that all forward-looking statements attributable to us or persons acting on our behalf apply only as of the date of this 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, 2013, and our unaudited condensed financial statements for the three month period ended March 31, 2014 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, 2013 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, 2014 and 2013 and significant factors that could affect our prospective financial condition and results of operations. You should read this discussion together with our financial statements and notes included in Item 1. Financial Statements.

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

We are a leading stem cell company headquartered in Columbia, Maryland and focused on developing and marketing products to treat conditions in the wound care, orthopedic and sports medicine markets. We currently market and distribute Grafix and Ovation for acute and chronic wounds, Cartiform, a viable cartilage mesh for cartilage repair and OvationOS, a viable bone matrix for bone growth. We believe our

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products have significant therapeutic potential because of their ability to regulate inflammation, promote tissue regeneration and prevent pathological scar formation.

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

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

In October 2013, we sold our Therapeutics business to a wholly-owned subsidiary of Mesoblast Limited (ASX: MSB; USOTC: MBLYT) in a transaction that is worth up to $100 million plus royalties. The agreement with Mesoblast provides for the receipt by us of $50 million in initial consideration for closing and delivery of the assets, and for up to an additional $50 million in payments, but only upon Mesoblast achieving certain clinical and regulatory milestones. In addition, we are entitled to earn single to low double-digit cash royalties on future sales by Mesoblast of Prochymal and other products utilizing the acquired ceMSC technology. Mesoblast has assumed all future development costs and efforts. As of December 31, 2013, of the $50 million in initial consideration, we had received $35 million, comprised of $20 million in cash and $15 million of Mesoblast stock, which is restricted from resale until December 2014. We received the remainder of the initial consideration, in the amount of $15 million, in cash, on April 9, 2014. We have entered into a separate transition services agreement with Mesoblast to assure a seamless transition, and once we fulfill our duties under this agreement, will be able to focus our full attention on our Biosurgery business. We extended the term of this agreement to October 2014, but still expect to complete all our responsibilities under it during fiscal 2014.

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

Financial Operations Overview

Revenue

We 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 and Ovation for acute and chronic wounds, Cartiform, a viable cartilage mesh for cartilage repair and OvationOS 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 and in those situations, title instead passes to the customer when the product is used in a surgical procedure. Due to the nature of the products and the manufacturing process, we generally do not allow sales returns.

During the third quarter of fiscal 2010, we launched Grafix for limited commercial distribution, as the first product in our then newly established Biosurgery business. We began distribution of a second Biosurgery product, Ovation, in early fiscal 2011. These products follow our first generation Biosurgery product, Osteocel, which we sold to Nuvasive, Inc. in 2008 for approximately $80 million in aggregate consideration. We have continued to increase our distribution volume for Grafix and our other current Biosurgery products throughout fiscal 2011, 2012 and 2013, and continuing during the first quarter of fiscal 2104, both through in-house personnel as well as through our expanding distributor network. The increase in product revenue and gross profit since commercial launch is due to volume increases. We anticipate continuing to increase our organizational focus on the development and commercialization of Biosurgery products in the foreseeable future.

Research and Development Costs

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

Consistent with our historic focus on the development of biologic drug candidates with potential uses in multiple indications, many of our historic costs are not attributable to a specifically identified product. We use our employee and infrastructure resources across several projects. Accordingly, we do not account for internal research and development costs on a project-by-project basis. From inception in December 1992 through March 31, 2014, we incurred aggregate research and development costs of approximately $437 million.

Biosurgery research and development expenses for the comparable periods were $670,000 and $957,000 during the first quarter of fiscal 2014 and 2013, which includes costs incurred for a study, Protocol 302, which began during the second quarter of Fiscal 2012 and was designed to allow for the collection of data necessary to obtain the permanent HCPCS Q-codes for Grafix, which are required for Medicare and Medicaid reimbursement when treatment is performed in the outpatient setting.

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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. Generally, we have experienced a decrease in general and administrative costs as the result of our continued cost cutting

efforts and the refinement of many of our general business processes, as well as a reduction in share-based compensation expense. During the first quarter of fiscal 2014, we hired 48 additional regional sales representatives, increasing our total internal sales force to approximately 60 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 our distribution efforts for 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, 2014 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, other than as disclosed herein.

Results of Operations

Comparison of Three Months Ended March 31, 2014 and 2013

Product Revenues & Gross Profit

During the first quarter of fiscal 2014, our revenue from product distribution more than doubled to $10.1 million, 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 both Grafix and Ovation, and during the first quarter of fiscal 2014 we realized product revenue from the limited distribution of OvationOS, a viable bone matrix for bone growth, and Cartiform, a viable cartilage mesh for cartilage repair. Although revenue from the distribution of these two new products is still less than 20% of

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our total product revenue, we believe OvationOS and Cartiform will contribute to our future growth and are complementary products to both Grafix and Ovation, simplifying the sales efforts. Our gross profit increased in the first quarter of fiscal 2014 to 78% compared to 72% in the comparable period of the prior year, primarily as the result of operational efficiencies as we more heavily utilize our production facilities. During the first quarter of fiscal 2014, we continued to operate our manufacturing facilities at our Columbia, Maryland location using one shift and have capacity to facilitate further growth without substantial increases in our clean room and manufacturing facilities. We expect to start manufacturing using a second shift during the second quarter of fiscal 2014.

Research and Development Expenses

Research and development expenses in the first quarter of fiscal 2014 were $670,000 compared to $957,000 in the same period of fiscal 2013. The reduction in R&D expenses reflect the completion of our Protocol 302 study evaluating the efficacy of Grafix for the treatment of diabetic foot ulcers compared to the standard of care. We expect to start further studies of Grafix in additional indications during fiscal 2014, and our R&D costs are expected to increase over the first quarter experience.

Selling, General and Administrative Expenses

Selling, general and administrative expenses rose to $7.2 million during the first quarter of fiscal 2014 compared to $2.4 million in the same period of fiscal 2013. The significant majority of these cost increases were incurred in sales and marketing efforts to increase our product distribution and to build up our infrastructure in the areas of reimbursement for public and private health care providers. During the first quarter of fiscal 2014, we increased the size of our in-house direct sales force five-fold, primarily for Grafix, and invested in training and more extensive product support capabilities. We also hired a senior marketing director and a team of reimbursement specialists. Selling, general and administrative costs were 72.0% of product revenue in the first quarter of fiscal 2014 compared to 59.3% during the same period in fiscal 2013. We will continue to heavily invest in our sales, marketing and reimbursement capabilities throughout the remainder of fiscal 2014 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 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. We carry the Mesoblast stock and the related derivative as Trading Securities. The derivative is valued at approximately $1.9 million at the end of the first quarter of fiscal 2014. This amount will be fully amortized into Other Income (Expense), Net by the time the restriction on our ability to sell the Mesoblast stock lapses in December 2014. Other Income (Expense), Net in the same period of fiscal 2013 consisted solely of the net investment gains on our investments available for sale.

Income Taxes

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 fiscal 2014, we will utilize our remaining $3.5million of net operating losses and begin to use part of our $74 million of tax credits to offset the taxable income tax from discontinued operations. We will maintain our full valuation allowance until operations from our Biosurgery business (continuing operations) provides evidence of sufficient future earnings.

Liquidity and Capital Resources

Liquidity

At March 31, 2014, we had $2.3 million in cash and $34.7 million in investments available for sale. Other receivables at March 31, 2014 include $15 million that was paid to us in cash by Mesoblast in April 2014, and trading securities include $15 million of Mesoblast stock which we will be able to sell starting in December 2014. At March 31, 2014, the fair market value of the Mesoblast stock was $14.9 million and we recognized a $465,000 decrease in the market value as a component of Other income (expense) net. 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 2014 was $4.7 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 used in operating activities of continuing operations during the first fiscal quarter of fiscal 2013 was $2.1 million, and reflects our net loss of $296,000, and net increases in our trade receivables and inventory, partially offset by non cash charges.

Net cash provided by investing activities was $4.8 million and $3.9 million, respectively, during first fiscal quarter of fiscal 2014 and 2013, and in each year primarily reflects proceeds from the sales of our investments to fund our operations.

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Net cash provided by financing activities was $623,000 and $158,000, respectively, during first fiscal quarter of fiscal 2014 and 2013. 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 did receive $15 million of Mesoblast Limited ordinary shares which are restricted from sale for a period of twelve months. Mesoblast has provided us with limited price protection in the event that the value of the shares when the restrictive period expires is lower than the price when the shares were issued. In the event the price is lower, Mesoblast will pay us the difference, 50% of which will be paid in cash and the balance in either cash or additional Mesoblast shares, at the sole discretion of Mesoblast. In the event Mesoblast issues additional shares in this regard, the new shares would be subject to a new twelve month restriction period, but would not have price protection. We account for this as a derivative instrument.

Equity Price Risk and Foreign Currency Exchange Rate Risk

We conduct clinical trial activities in areas that operate in a functional currency other than the United States dollar (USD). As a result, when the USD rises and falls against the functional currencies of these other nations, our costs will either increase or decrease by the relative change in the exchange rate. Foreign currency gains and losses were not material during the first quarter of fiscal 2014 or 2013, and at the present time, we have elected not to hedge our exposure to foreign currency fluctuations.

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

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price risk (and the foreign currency risk) will persist. There is no corresponding mitigation of the foreign currency exchange rate risk, and a devaluation of the Australian Dollar will directly impact the value of the Mesoblast shares to us.

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 due to the material weakness in our internal control over financial reporting described below, our disclosure controls and procedures were not effective as of March 31, 2014. 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.

As further described in our Annual Report on Form 10-K for our fiscal year ended December 31, 2013, as filed with the Securities and Exchange Commission on March 31, 2014, 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. This occurred notwithstanding that we had retained a nationally known outside public accounting firm, which we understand to be PCAOB certified, to advise us on, and to analyze and to perform the tax accounting functions related to, these matters. This material weakness was identified in connection with our assessment of the effectiveness of internal control over financial reporting as of December 31, 2013, and has been determined not to have been remediated as of March 31, 2014.

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

With the oversight of our management and the audit committee of our board of directors, we have since taken steps and plan to take additional measures to remediate the underlying causes of the material weakness described above. Because the identified material weakness has not yet been remediated, however, this control deficiency could result in a material misstatement of the financial statements that would not be prevented or detected. See the risk factor in our 2012 Form 10-K contained in Part I, Item 1A under the heading Risk Factors *We have identified a material weakness in our internal control over financial reporting and we may be unable to develop, implement and maintain appropriate controls in future periods. If the material weakness is not remediated, then it could result in a material misstatement to the financial statements.*

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, 2014 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, 2013 as filed with the Securities and Exchange Commission on March 31, 2014.

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

None.

Item 3. Defaults Upon Senior Securities .

None.

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Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information .

None.

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, 2014, 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 (furnished 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 12, 2014 /s/ PHILIP R. JACOBY, JR.

Philip R. Jacoby, Jr.
Chief Financial Officer (Principal Financial)