OSIRIS THERAPEUTICS, INC.
Form 10-Q
November 06, 2009
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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 September 30, 2009**

**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)

| **Delaware** | **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 o 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 November 5, 2009** |
|---|---|
| Common Stock, par value $0.001 per share | 32,772,331 |

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**PART I FINANCIAL INFORMATION**

**Item 1. Financial Statements - Unaudited**.

**OSIRIS THERAPEUTICS, INC.**

**Condensed Balance Sheets**

**Amounts in thousands**

| | September 30, 2009 Unaudited | December 31, 2008 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash | $ 1,572 | $ 940 |
| Investments available for sale | 101,321 | 61,298 |
| Accounts receivable | 218 | 61,287 |
| Prepaid expenses and other current assets | 2,770 | 2,060 |
| Current assets of discontinued operations | | 3,223 |
| Total current assets | 105,881 | 128,808 |
| | | |
| Property and equipment, net | 3,797 | 394 |
| Restricted cash | 666 | 130 |
| Other assets | 453 | 615 |
| Long-term assets of discontinued operations | | 7,520 |
| Total assets | $ 110,797 | $ 137,467 |
| | | |
| **LIABILITIES AND STOCKHOLDERS DEFICIT** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 16,192 | $ 10,513 |
| Deferred revenue, current portion | 40,660 | 40,471 |
| Capital lease obligations, current portion | 5 | 6 |
| Current liabilities of discontinued operations | 493 | 7,219 |
| Total current liabilities | 57,350 | 58,209 |
| | | |
| Deferred revenue, net of current portion | 54,158 | 84,275 |
| Other long-term liabilities | 2,575 | 3 |
| Total liabilities | 114,083 | 142,487 |
| | | |
| Stockholders deficit: | | |
| Common stock, $.001 par value, 90,000 shares authorized 32,772 and 32,676 shares outstanding in 2009 and 2008 | 33 | 33 |
| Additional paid-in-capital | 272,355 | 269,830 |
| Accumulated other comprehensive income | 358 | 33 |
| Accumulated deficit | (276,032) | (274,916) |
| Total stockholders deficit | (3,286) | (5,020) |
| Total liabilities and stockholders deficit | $ 110,797 | $ 137,467 |

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

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**OSIRIS THERAPEUTICS, INC.**

**Condensed Statements of Operations**

**Unaudited**

**Amounts in thousands, except per share data**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| **Revenue from collaborative research agreements, government contract and royalties** | $ 10,584 | $ 995 | $ 33,779 | $ 3,887 |
| Operating expenses: | | | | |
| Research and development | 16,247 | 18,592 | 53,354 | 54,334 |
| General and administrative | 1,511 | 1,887 | 6,745 | 6,277 |
| | 17,758 | 20,479 | 60,099 | 60,611 |
| Loss from operations | (7,174) | (19,484) | (26,320) | (56,724) |
| Interest income (expense), net | 134 | (419) | 387 | (800) |
| Loss from continuing operations, before income taxes | (7,040) | (19,903) | (25,933) | (57,524) |
| Income tax benefit | 238 | | 2,636 | |
| **Loss from continuing operations** | (6,802) | (19,903) | (23,297) | (57,524) |
| **Discontinued operations:** | | | | |
| Income (loss) from operations of discontinued operations, net of income taxes | (28) | (384) | 1,069 | 6,269 |
| Gain from sale of discontinued operations, net of income taxes | 636 | 25,539 | 21,112 | 25,539 |
| **Income from discontinued operations** | 608 | 25,155 | 22,181 | 31,808 |
| **Net income (loss)** | $ (6,194) | $ 5,252 | $ (1,116) | $ (25,716) |
| **Basic and diluted income (loss) per share** | | | | |
| Loss from continuing operations | $ (0.21) | $ (0.63) | $ (0.71) | $ (1.81) |
| Income from discontinued operations | 0.02 | 0.80 | 0.68 | 1.00 |
| Basic and diluted earnings (loss) per share | $ (0.19) | $ 0.17 | $ (0.03) | $ (0.81) |
| Weighted Average Common Shares (basic and diluted) | 32,764 | 31,808 | 32,731 | 31,799 |

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

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**OSIRIS THERAPEUTICS, INC.**

**Condensed Statement of Stockholders Deficit**

**For the nine months ended September 30, 2009**

**Unaudited**

**Amounts in thousands, except for share and per share data**

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income | Accumulated Deficit | Total Stockholders Deficit |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance at January 1, 2009** | 32,675,920 | $ 33 | $ 269,830 | $ 33 | $ (274,916) | $ (5,020) |
| Exercise of options to purchase common stock ($0.40 - $13.33 per share) | 74,911 | | 575 | | | 575 |
| Issuance of common stock for services rendered by directors ($18.60 per share) | 21,500 | | 400 | | | 400 |
| Share-based payment employee compensation | | | 1,550 | | | 1,550 |
| **Comprehensive Loss:** | | | | | | |
| Net loss for the period | | | | | (1,116) | (1,116) |
| Unrealized gain on investments available for sale | | | | 325 | | 325 |
| **Total Comprehensive Loss** | | | | | | (791) |
| **Balance at September 30, 2009** | 32,772,331 | $ 33 | $ 272,355 | $ 358 | $ (276,032) | $ (3,286) |

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

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**OSIRIS THERAPEUTICS, INC.**

**Condensed Statements of Cash Flows**

**Unaudited**

**Amounts in thousands**

| | Nine Months Ended September 30, 2009 | 2008 |
|---|---|---|
| **Cash flows from operating activities:** | | |
| **Continuing Operations:** | | |
| Loss from continuing operations | $ (23,297) | $ (57,524) |
| **Adjustments to reconcile loss from continuing operations to net cash provided by (used in) continuing operations:** | | |
| Depreciation and amortization | 483 | 1,453 |
| Non cash share-based payments | 1,852 | 1,290 |
| Non cash interest expense | | 130 |
| **Changes in operating assets and liabilities:** | | |
| Accounts receivable | 56,101 | (177) |
| Prepaid expenses and other current assets | (710) | (169) |
| Other assets | 162 | 864 |
| Accounts payable and accrued expenses | 4,670 | (2,950) |
| Deferred revenue | (29,928) | |
| Long-term interest payable and other liabilities | | (839) |
| Net cash provided by (used in) continuing operations | 9,333 | (57,922) |
| **Discontinued Operations:** | | |
| Income from discontinued operations | 22,181 | 31,808 |
| **Adjustments to reconcile income from discontinued operations to net cash (used in) provided by discontinued operations:** | | |
| Non cash impact of the sale of discontinued operations | (26,595) | (27,986) |
| Depreciation and amortization | 210 | 295 |
| Provision for bad debts | 45 | 29 |
| Non cash share-based payments | 98 | 134 |
| **Changes in operating assets and liabilities:** | | |
| Accounts receivable | 1,516 | 844 |
| Inventory and other current assets | 1,707 | 1,066 |
| Accounts payable and accrued expenses | (3,108) | 4,256 |
| Long-term liabilities | | 873 |
| Net cash (used in) provided by discontinued operations | (3,946) | 11,319 |
| Net cash provided by (used in) operating activities | 5,387 | (46,603) |
| | | |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (181) | (4,029) |
| Proceeds from the sale of property and equipment | 17 | 104 |
| Proceeds from sale of discontinued operations, net of transaction costs | 9,797 | 33,636 |
| Proceeds from sale of investments available for sale | 35,578 | 12,353 |
| Purchases of investments available for sale | (50,000) | |
| Net cash (used in) provided by investing activities | (4,789) | 42,064 |
| | | |
| **Cash flows from financing activities:** | | |
| Principal payments on capital lease obligations and notes payable | (5) | (8,277) |
| Restricted cash | (536) | 150 |
| Proceeds from convertible and short-term notes payable | | 17,000 |

| | | | | |
|---|---|---|---|---|
| Proceeds from exercise of stock options | | 575 | | 262 |
| Net cash provided by financing activities | | 34 | | 9,135 |
| | | | | |
| Net increase in cash | | 632 | | 4,596 |
| Cash at beginning of period | | 940 | | 704 |
| | | | | |
| **Cash at end of period:** | $ | 1,572 | $ | 5,300 |

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

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

## 1. Nature of Business

Osiris Therapeutics, Inc. ( we, us, our, or the Company ) is a Delaware corporation headquartered in Columbia, Maryland. We began operations on December 23, 1992. We are a stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic, and cardiovascular areas. Our biologic drug candidates utilize adult human mesenchymal stem cells, or MSCs, which can selectively differentiate, based on the tissue environment, into various tissue lineages, such as muscle, bone, cartilage, marrow stroma, tendon or fat. In addition, MSCs have anti-inflammatory properties and can prevent fibrosis or scarring, which gives MSCs the potential to treat a wide variety of medical conditions. Our operations consist primarily of research, development and clinical activities to bring our biologic drug candidates to the marketplace. We have several research collaboration agreements and a government contract for additional product development.

## 2. Significant Accounting Policies and Recent Accounting Pronouncements

***Unaudited Interim Financial Statements***

The accompanying unaudited 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, 2008.

***Use of Estimates***

The preparation of financial statements in conformity with US GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Due to the inherent uncertainty involved in making those assumptions, actual results could differ from those estimates. We believe that the most significant estimates that affect our financial statements are those that relate to revenue recognition associated with our collaborative agreements, deferred tax assets, and share-based compensation.

***Revenue Recognition***

We generate revenues from collaborative agreements, research licenses, and a government contract. We evaluate 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 stand alone basis, there must be objective and reliable evidence of fair value of the undelivered items, 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.

Revenues from research licenses and government contracts are recognized as earned upon either the incurring of reimbursable expenses directly related to the particular research plan or the completion of certain development milestones as defined within the terms of the agreement. Payments received in advance of research performed are designated as deferred revenue. Non-refundable upfront license fees and certain other related fees are 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 is recognized as revenue as it is earned and received.

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

In October 2008, we entered into a Collaboration Agreement with Genzyme Corporation ( Genzyme ) for the development and commercialization of our biologic drug candidates, Prochymal® and Chondrogen®. Under the agreement, Genzyme has paid to us non-contingent, non-refundable cash payments totaling $130.0 million, with $75.0 million paid during November 2008 and $55.0 million paid on July 1, 2009. The agreement provides Genzyme with certain rights to intellectual property developed by us, and requires that we continue to perform certain development work related to the subject biologic drug candidates. We have evaluated the deliverables related to these payments, and concluded that the various deliverables represent a single unit of accounting. For this reason, we have deferred the recognition of revenue related to the upfront payments, and are amortizing these amounts to revenue on a straight-line basis over the estimated delivery period of the required development services, which extend through the first quarter of 2012. Accordingly, we recognized $10.0 million of revenue in each of the first three fiscal quarters of 2009 related to the amortization of the upfront payments. The balance of these payments has been recorded as $40.0 million of current deferred revenue and $53.3 million of long-term deferred revenue as of September 30, 2009. The agreement also provides for contingent milestone payments of up to $1.25 billion in the aggregate, as well as royalties to be paid to us on any sales by Genzyme. Consistent with our revenue recognition policies, we will recognize revenue from these contingent milestone payments for which we have no continuing performance obligations upon achievement of the related milestone. For any milestone payments for which we have a continuing performance obligation, the milestone payments will be deferred and recognized as revenue over the term of the related performance obligations.

In 2007, we partnered with Genzyme to develop Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies. In January 2008, we were awarded a contract from the United States Department of Defense ( DoD ) pursuant to which we are seeking in partnership with Genzyme to develop and stockpile Prochymal for the repair of gastrointestinal injury resulting from acute radiation exposure. We began recognizing revenue under this contract during the first quarter of 2008. Contract revenue is recognized as the related costs are incurred, in accordance with the terms of the contract. We recognized $2.9 million in revenue from the DoD contract during the nine months ended September 30, 2009 and $1.7 million in revenue during the comparable period of 2008.

In October 2007, we entered into a collaborative agreement with the Juvenile Diabetes Research Foundation ( JDRF ) to conduct a Phase II clinical trial evaluating Prochymal as a treatment for type 1 diabetes mellitus. This collaborative agreement provides for JDRF to provide up to $4.0 million of contingent milestone funding to support the development of Prochymal for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus. The contingent milestone payments under the agreement are amortized to revenue on a straight line basis over the duration of our obligations under the collaborative agreement as they are received and earned. We received $2.0 million of the contingent milestones during 2008 and $0.8 million during 2009. We expect to receive the remaining $1.2 million during the remainder of 2009 and 2010. We are amortizing the funding received, resulting in $0.7 million of revenue to date in 2009 under the agreement with JDRF. The remaining deferred revenue under this agreement has been recorded as $0.7 million of current deferred revenue and $0.8 million of long-term deferred revenue as of September 30, 2009.

We have also entered into several strategic agreements with other pharmaceutical companies focusing on the development and commercialization of our stem cell drug products. For example, in 2003, we entered into an agreement with JCR Pharmaceuticals Co., Ltd. ( JCR ) pertaining to our hematologic malignancies (GvHD) drugs for distribution in Japan.

We also earn royalties on the sale of human mesenchymal stem cells sold for research purposes and recognize the revenue as the sales are made. Our overall revenues include $218,000 and $189,000 of such royalty revenue during the nine months ended September 30, 2009 and 2008,

respectively.

***Research and Development Costs***

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

***Income (Loss) per Common Share***

Basic income (loss) per common share is calculated by dividing net income (loss) 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. All common share equivalents resulting from assumed exercise of outstanding stock options and warrants are excluded from the computation of diluted loss per share as their effect is anti-dilutive.

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

***Investments Available for Sale and Other Comprehensive Income (Loss)***

Investments available for sale consist primarily of marketable securities with maturities varying between three months and one year. Investments available for sale are valued at their fair value, with unrealized gains and losses reported as a separate component of stockholders deficit in accumulated other comprehensive income. Gains or losses on investments available for sale are reclassified to earnings when realized.

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.

***Share-Based Compensation***

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

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

A summary of the combined activity under both of our stock-based compensation plans as of September 30, 2009 and changes during the nine months then ended is presented below.

| | Number of Shares | Weighted Average Exercise Price Per Share at Grant Date | Weighted Average Remaining Term (in Years) | Aggregate Intrinsic Value ($000) |
|---|---|---|---|---|
| Outstanding at January 1, 2009 | 1,211,177 | $ 10.66 | 8.02 | $ 10,592 |
| Granted at market value | 163,000 | 17.87 | | |

| | | | | |
|---|---|---|---|---|
| Exercised | (74,911) | 7.69 | | 490 |
| Forfeited or expired | (243,692) | 14.38 | | 203 |
| Outstanding at September 30, 2009 | 1,055,574 | 11.07 | 7.11 | 2,026 |
| | | | | |
| Exercisable at September 30, 2009 | 542,193 | 7.03 | 5.84 | 1,932 |

The weighted average grant date fair value of options granted during the nine months ended September 30, 2009 was $9.32 per share. We received a total of $575,000 in cash from the exercise of options during the nine months ended September 30, 2009.

Also, during the three months ended March 31, 2009 we granted 21,500 unrestricted shares of common stock to members of our Board of Directors under our Amended and Restated 2006 Omnibus Plan and recognized $400,000 in share-based expense. As of September 30, 2009, 623,000 shares of common stock remain available for future share awards under our Amended and Restated 2006 Omnibus Plan.

Share-based compensation expense (including director compensation) included in our statements of operations for the three and nine months ended September 30, 2009 and 2008 is allocable to our research and development activities, discontinued operations and general and administrative activities, as follows:

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2009 ($000) | 2008 ($000) | 2009 ($000) | 2008 ($000) |
| Research and development | $ 222 | $ 192 | $ 708 | $ 522 |
| Discontinued operations | | 55 | 98 | 134 |
| General and administrative | (141) | 213 | 1,144 | 768 |
| Total | $ 81 | $ 460 | $ 1,950 | $ 1,424 |

As of September 30, 2009, there was approximately $2.1 million of total unrecognized share-based compensation cost related to options granted under our plans, which will be recognized over a weighted-average period of approximately 3 years, as the options vest.

***Supplemental Cash Flow Information***

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2009 ($000) | 2008 ($000) |
| **Supplemental disclosure of cash flows information:** | | |
| Cash paid for interest | $ 8 | $ 577 |
| Cash paid for income taxes | 915 | |

***Significant New Accounting Pronouncements***

In September 2006, the Financial Accounting Standards Board ( FASB ) issued new accounting guidance related to fair value measurements and related disclosures. This new guidance defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. We adopted this new guidance on January 1, 2008, as required for our financial assets and financial liabilities. However, the FASB deferred the effective date of this new guidance for one year as it relates to fair value measurement requirements for nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value on a recurring basis. We adopted these remaining provisions on January 1, 2009. The adoption of this accounting guidance did not have a material impact on our financial statements.

In April 2009, the FASB issued new accounting guidance related to interim disclosures about the fair values of financial instruments. This guidance requires disclosures about the fair value of financial instruments whenever a public company issues financial information for interim reporting periods. This guidance is effective for interim reporting periods ending after June 15, 2009. We adopted this guidance upon its issuance, and it had no material impact on our financial statements. See Note 8 - Fair Value Measurements for these disclosures.

In May 2009, the FASB issued new accounting guidance related to the accounting and disclosures of subsequent events. This guidance incorporates the subsequent events guidance contained in the auditing standards literature into authoritative accounting literature. It also requires entities to disclose the date through which they have evaluated subsequent events and whether the date corresponds with the release of their financial statements. This guidance is effective for all interim and annual periods ending after June 15, 2009. We adopted this guidance upon its issuance and it had no material impact on our financial statements. See Note 9 - Subsequent Events for this new disclosure.

In June 2009, the FASB issued new accounting guidance to improve financial reporting by companies involved with variable interest entities and to provide more relevant and reliable information to users of financial statements. This guidance is effective for fiscal years beginning after November 15, 2009. We are currently evaluating the impact that the adoption of this guidance will have on our financial statements.

In August 2009, the FASB issued new accounting guidance to provide clarification on measuring liabilities at fair value when a quoted price in an active market is not available. This guidance became effective for us on October 1, 2009. We adopted this guidance on October 1, 2009, and it had no material impact on our financial statements.

In October 2009, the FASB issued new accounting guidance to modify the revenue recognition associated with multiple-deliverable revenue arrangements. This guidance is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We adopted this guidance on October 1, 2009, and it had no material impact on our financial statements.

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

**3. Collaboration Agreements and Government Contract**

Below is a discussion of each of our material collaborative agreements and other contracts. This discussion is qualified in its entirety by the actual terms and provisions of the respective agreements and contracts. The accounting policies related to each of these contracts, including material impact on our financial statements, is included above under the Revenue Recognition section of Note 2, Significant Accounting Policies and Recent Accounting Pronouncements.

***Collaboration Agreement with Genzyme Corporation*** On October 31, 2008, we entered into a Collaboration Agreement with Genzyme for the development and commercialization of Prochymal and Chondrogen. Under the terms of the agreement, we will retain the rights to commercialize Prochymal and Chondrogen in the United States and Canada, and Genzyme has been granted the exclusive right and license to commercialize Prochymal and Chondrogen in all other countries (the Genzyme Territory ), except with respect to Prochymal for Graft vs. Host Disease ( GvHD ) in Japan, which has previously been licensed to another pharmaceutical company. Genzyme has the right to opt-out of any further Chondrogen development following receipt of the results of the planned Phase II/III clinical trial for Chondrogen. If Genzyme opts-out, all rights to Chondrogen will revert to us with no further obligations between the companies with regard to Chondrogen. In the event that Genzyme does not opt-out but instead participates in the future development efforts for Chondrogen, Genzyme would be entitled to retain rights and licenses to our intellectual property related to Chondrogen in all countries outside the United States and Canada.

As partial consideration for the grant of these rights, the Collaboration Agreement provides for a non-contingent, non-refundable cash payment to us of $130.0 million from Genzyme, with $75.0 million paid in November 2008 and $55.0 million paid on July 1, 2009. The Collaboration Agreement also provides for contingent milestone payments of up to $1.25 billion in the aggregate, in addition to royalties on any sales by Genzyme, to be paid by Genzyme to us, as follows:

*Prochymal:* As respects Prochymal, we are eligible to receive up to $500.0 million in development and regulatory milestone payments and up to $250.0 million in sales based milestone payments, as follows:

- Total development milestones related to GvHD of up to $50.0 million, with $25.0 million payable upon marketing approval from the United States Food & Drug Administration ( FDA ), and $25.0 million payable upon marketing approval from the European Medicines Agency ( EMEA ).

- Total development milestones of up to $180.0 million related to Crohn s disease and Ulcerative Colitis, with $50.0 million payable upon achieving statistically significant endpoint(s) in a Phase III clinical trial for Crohn s disease, $100.0 million payable upon marketing approval by the EMEA for Crohn s disease, $10.0 million payable upon achieving statistically significant endpoint(s) in a

Phase II or Phase III clinical trial for Ulcerative Colitis, and $20.0 million payable upon achieving marketing approval for Ulcerative Colitis by the EMEA.

- Total development milestones of up to $270.0 million related to the development of follow-on indications for Prochymal, with $20.0 million payable upon each success in a Phase II clinical trial for acute myocardial infarction, type 1 diabetes or other follow-on indications, as agreed to by the Company and Genzyme, and $40.0 million payable upon receipt of each marketing approval by the EMEA for Prochymal for chronic obstructive pulmonary disease ( COPD ), acute myocardial infarction, type 1 diabetes mellitus or other follow-on indications, as agreed to by the Company and Genzyme.

- Total sales based milestones of up to $250.0 million for Prochymal, with $100.0 million payable when annual Prochymal sales reach $500.0 million in the Genzyme Territory, and $150.0 million payable when annual Prochymal sales reach $1.0 billion in the Genzyme Territory.

*Chondrogen:* Upon receipt of the results of the planned Phase II/III clinical trial of Chondrogen, Genzyme may elect to opt-out of any further Chondrogen development, at which point all rights to Chondrogen will revert to us with no further obligations between the companies with regard to Chondrogen. If Genzyme does not opt-out, we are eligible to receive up to $500.0 million in development, regulatory and sales based milestone payments for Chondrogen, as follows:

- Total development and regulatory milestones of up to $100.0 million, with $10.0 million payable if Genzyme does not opt-out, $10.0 million payable upon demonstration of disease modification in the current clinical trial program, $40.0 million payable upon marketing approval by either the FDA or EMEA for a pain reduction indication, and $40.0 million payable upon marketing approval by either the FDA or EMEA for a disease modification indication.

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

- Total sales milestones of up to $400.0 million, with $100.0 million payable when annual Chondrogen sales reach $500.0 million in the Genzyme Territory, $150.0 million payable when annual Chondrogen sales reach $1.0 billion in the Genzyme territory, and $150.0 million payable when annual Chondrogen sales reach $2.0 billion in the Genzyme Territory.

We will be solely responsible for ongoing clinical trial costs and future clinical trial costs with respect to both Prochymal and Chondrogen through Phase II clinical trials. We will share with Genzyme all costs of future Phase III and Phase IV clinical trials for agreed-upon indications (assuming in the case of Chondrogen that Genzyme does not opt-out), with us being responsible for 60% of such costs and Genzyme responsible for 40% of such costs.

Assuming successful development and marketing approval (and assuming in the case of Chondrogen that Genzyme does not opt-out), we will be entitled to receive escalating royalties on sales of Prochymal and Chondrogen within the Genzyme Territory.

***Genzyme Partnership and the United States Department of Defense Contract.*** In 2007, we partnered with Genzyme to develop Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies. In January 2008, we were awarded a contract from the DoD pursuant to which we, in partnership with Genzyme, are seeking to develop and stockpile Prochymal for the repair of gastrointestinal injury resulting from acute radiation exposure. Under the terms of the contract, the DoD will provide funding to us for the development of Prochymal for acute radiation syndrome ( ARS ). Under the terms of our partnership with Genzyme, we contribute Prochymal and corresponding safety and efficacy data to the effort and Genzyme lends its vast product development and large-scale commercialization expertise. The agreement provides for Genzyme to receive a royalty of 15% on sales of Prochymal, limited to those sales made under contract to U.S. or allied governmental agencies for emergency preparedness.

***Juvenile Diabetes Research Foundation Agreement.*** In 2007, we entered into a collaborative agreement with the JDRF which provides funding to support the development of Prochymal as a treatment for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus. This collaborative agreement provides for JDRF to provide up to $4.0 million of contingent milestone funding. We initiated a Phase II clinical trial evaluating Prochymal as a treatment for type 1 diabetes in the fourth quarter of 2007, and received $2.0 million of the contingent milestones during 2008 and $0.8 million in September 2009. We expect to receive the remaining $1.2 million of contingent milestones by 2010. Consistent with our revenue recognition policies for such contingent milestones, we began amortizing each milestone payment as it was received and will continue to amortize the payments over the remaining term of our obligations under the agreement. Future milestone payments received will be similarly amortized over the term of our obligations beginning upon their receipt.

***JCR Pharmaceuticals Agreement.*** In 2003, we entered into a strategic alliance with JCR. Under the JCR agreement, we have granted JCR the exclusive right in Japan to use our technology in conjunction with the treatment of hematologic malignancies using hematopoietic stem cell transplants. The JCR agreement entitles us to a licensing fee and to royalties on any resulting revenue. Upon commencement of the agreement, JCR purchased 545,454 shares of our Series B Convertible Preferred Stock for $3.0 million. These shares were converted into 136,363 shares of our common stock concurrent with our initial public offering in August 2006. JCR has also paid us a total of $4.0 million in licensing fees under

the agreement, The JCR agreement also provides for additional contingent milestone payments totaling $3.0 million, which will be recorded as revenue if and when the milestone events occur.

**4. Discontinued Operations & Gain on Sale of Discontinued Operations**

On May 8, 2008, we entered into an Asset Purchase Agreement to sell our Osteocel® business to NuVasive, Inc., a Delaware corporation. Osteocel is a product that we developed and that we manufactured beginning in July 2005, for regenerating bone in orthopedic indications. The agreement provided for the sale to be effected at two closings a technology assets closing, for the transfer of technology and certain other business assets, and a manufacturing assets closing, for the transfer of manufacturing assets and facilities. On July 24, 2008, we held a Special Meeting of Stockholders at which our stockholders overwhelmingly approved the sale of the Osteocel business. The technology assets closing also occurred on that date, at which time we received an initial payment of $35.0 million. In December 2008, we earned another $5.0 million in additional purchase price through the achievement of a production milestone. The agreements with NuVasive were amended several times during 2008, all without altering the potential purchase price of up to $85.0 million.

In March 2009, we entered into further amendments to the Asset Purchase Agreement and the related Manufacturing Agreement, as a result of which the manufacturing assets closing was accelerated and all performance conditions to receipt by us of $30.0 million of contingent milestone payments were removed. As a result, those payments became payable at specified dates, without regard to other conditions; either in cash or in shares of NuVasive stock, at the option of NuVasive The final milestone payment of $15.0 million was conditioned on at least $35.0 million in cumulative Osteocel sales by NuVasive. This final milestone was achieved in October 2009 and we were paid $15.0 million in NuVasive common stock in November 2009.

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**OSIRIS THERAPEUTICS, INC.**

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The Asset Purchase Agreement, as amended, provides for up to $85.0 million of total purchase price, as follows:

| Payments | | Amount ($000) | Payment Date |
|---|---|---|---|
| Initial cash payment | $ | 35,000 | July 2008 |
| Cumulative sales to NuVasive of 75,000 ccs of Osteocel, paid in cash | | 5,000 | Paid in January 2009 |
| Accelerated Manufacturing Assets Closing, paid in cash | | 5,000 | Paid in March 2009 |
| Installment paid in stock | | 12,500 | Paid in June 2009 |
| Installment paid in stock | | 12,500 | Paid in September 2009 |
| Milestone payment due upon NuVasive achieving at least $35.0 million in cumulative sales of Osteocel, paid in stock | | 15,000 | Paid in November 2009 |
| | | | |
| Total possible purchase price | $ | 85,000 | |

The $30.0 million of payments that became payable at specified dates (March, June and September 2009, respectively) as a result of the March 2009 amendments, net of direct expenses of approximately $0.2 million, were recorded as a component of the gain on the sale of discontinued operations in the first quarter of 2009. The $12.5 million payments due June 30, 2009 and September 30, 2009 were paid in shares of common stock issued by NuVasive. We have since sold all of these shares of NuVasive common stock and received approximately $25.3 million in the aggregate in cash. At September 30, 2009, the $12.5 million in stock received on September 30, 2009 is shown as a component of Investments Available for Sale on our balance sheet. The requisite events related to the final $15.0 million contingent milestone were achieved in October 2009, and we will recognize the corresponding milestone payment, paid in stock in early November 2009, as a component of the gain on the sale of discontinued operations in the fourth quarter of 2009. Title to the fixed assets to be transferred to NuVasive passed on April 9, 2009.

Concurrent with the March 2009 amendments to the Asset Purchase Agreement with NuVasive, we executed a Supply Agreement with AlloSource to facilitate the complete transfer of the Osteocel business, pursuant to which we transferred to AlloSource our entire Osteocel work-in-process inventory at specified prices on the date of the manufacturing assets closing with NuVasive. The aggregate purchase price for the Osteocel work-in-process inventory was approximately $3.7 million, paid by AlloSource in cash installments over the 90-days following the execution of the Supply Agreement.

As stipulated under the March 2009 amendments, we ceased manufacturing Osteocel on March 28, 2009. As a result of this cessation of manufacturing, we committed to a workforce reduction of the approximately 80 employees involved in the Osteocel business. Employees directly affected by the workforce reduction received notification on March 30, 2009, and the workforce reduction was substantially completed in the second quarter of 2009. All of the affected employees received severance benefits, comprised principally of severance, benefits continuation costs and outplacement services. Total one-time termination benefits for the reduction in force totaled approximately $1.4 million, which was recorded as a component of the gain on the sale of discontinued operations in the first quarter of 2009.

Also in connection with the March 2009 amendments, we relieved NuVasive of its obligation to assume the lease for our Columbia, Maryland facility. As a result of the combination of our cessation of Osteocel manufacturing and retaining the lease obligations for the Columbia, Maryland facility, we conducted an analysis of our future minimum lease payments for the facility, related to unutilized space, and recorded an impairment charge of approximately $3.2 million related to our future minimum lease payments. Additionally, we recorded an impairment of the leasehold improvements specifically related to Osteocel production of approximately $3.0 million. Both of these impairments were recorded as components of the gain on the sale of discontinued operations in the first quarter of 2009.

Also as a result of acceleration of the manufacturing assets closing, during the first quarter of 2009 we reversed approximately $2.5 million of concessionary pricing reserves for future Osteocel production that had been established under the original Manufacturing Agreement.

The fair value of the property that we transferred on the date of the manufacturing assets closing in April 2009, including both the manufacturing assets transferred to NuVasive and the inventory transferred to AlloSource, was approximately $5.1 million.

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**OSIRIS THERAPEUTICS, INC.**

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As detailed above, we recognized a gain of approximately $21.1 million, net of income taxes, on the sale of discontinued operations during the nine months ended September 30, 2009. In connection with this transaction, we recognized a gain on the sale of discontinued operations of $30.4 million during the fiscal year ended December 31, 2008, as detailed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

We eliminated the Osteocel asset disposal group from our ongoing operations as a result of the disposal transaction and have presented the group s assets, liabilities, and the results of the group s operations as a discontinued operation for all periods.

The net assets allocable to the Osteocel asset disposal group included on our balance sheet at September 30, 2009 and December 31, 2008 were as follows:

| | 2009 ($000) | 2008 ($000) |
|---|---|---|
| Accounts receivable, net | $ | $ 1,516 |
| Inventory and other current assets | | 1,707 |
| Current assets of discontinued operations | | 3,223 |
| Property and equipment, net | | 7,520 |
| Liabilities of discontinued operations | (493) | (7,219) |
| Net assets (liabilities) of discontinued operations | $ (493) | $ 3,524 |

Summarized operating results of the Osteocel asset disposal group are as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2009 ($000) | 2008 ($000) | 2009 ($000) | 2008 ($000) |
| Product sales | $ (1) | $ 2,872 | $ 6,295 | $ 19,338 |
| Cost of goods sold | 70 | 3,035 | 4,985 | 11,602 |
| Gross profit (loss) | (71) | (163) | 1,310 | 7,736 |
| Selling, general & administrative expenses | | 221 | 124 | 1,467 |
| | (71) | (384) | 1,186 | 6,269 |

| | | | | |
|---|---|---|---|---|
| Income (loss) from operations of discontinued operations, before income taxes | | | | |
| Income tax expense (benefit) | (43) | | 117 | |
| Income (loss) from operations of discontinued operations | $ (28) | $ (384) | $ 1,069 | $ 6,269 |

**5. Earnings (Loss) Per Common Share**

Basic earnings (loss) per common share is computed based on the weighted average number of shares of common stock outstanding during the period. Dilutive shares are computed using the treasury stock method and include the incremental effect of shares that would be issued upon the assumed exercise of stock options and warrants. All common share equivalents resulting from assumed exercise of outstanding stock options and warrants are excluded from the computation of diluted loss per share as their effect is anti-dilutive. For the nine months ended September 30, 2009, these common share equivalents are comprised of 409,023 common stock equivalents related to in-the-money stock options , 133,169 common stock equivalents related to out-of-the-money stock options, and 226,592 common stock equivalents related to an outstanding warrant. For the three months ended September 30, 2009, such common share equivalents are comprised of 329,133 common stock equivalents related to in-the-money stock options , 213,060 common stock equivalents related to out-of-the-money stock options, and 9,455 common stock equivalents related to an outstanding warrant.

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

## 6. Income Tax (Benefit) Expense

The tax benefit for the nine months ended September 30, 2009 reflects an effective tax rate for continuing operations of 9.9% compared to a U.S. statutory tax rate of 35%. The effective tax rate reflects our estimated annual effective tax rate, which reflects our expectation that a portion of our income will be subject to the Federal alternative minimum tax in 2009. During the three and nine months ended September 30, 2009, we recognized the following income tax expense (benefit):

| | Quarter Ended September 30, 2009 ($000) | Nine Months Ended September 30, 2009 ($000) |
|---|---|---|
| Tax benefit to continuing operations | $ (235) | $ (2,633) |
| Tax expense (benefit) of operations of discontinued operations | (43) | 117 |
| Tax expense (benefit) of sale of discontinued operations | (663) | 2,314 |
| Total income tax expense (benefit) | $ (941) | $ (202) |

We have not recognized any deferred tax assets or liabilities in our financial statements since we cannot assure their future realization. Because realization of deferred tax assets is dependent upon future earnings, a full valuation allowance has been recorded on the net deferred tax assets, which relate primarily to net operating loss carry-forwards and research and development and orphan drug tax credit carry-forwards. In the event that we become profitable within the next several years, we have net deferred tax assets of approximately $55.5 million that may be utilized prior to us having to recognize any income tax expense or make payments to the taxing authorities. However, utilization of our net operating loss and tax credit carry-forwards in any one year may be limited under Internal Revenue Code Sections 382 and 383. In addition, even if certain of our net deferred tax assets are not subject to limitations, we may be subject to the Federal alternative minimum tax in future years.

## 7. Investments Available for Sale

On September 30, 2009, NuVasive, Inc. paid us the $12.5 million milestone payment in freely tradable shares of its common stock, as provided for under the amended Asset Purchase Agreement. The number of shares delivered to us was determined based upon the average closing price of NuVasive s common stock over a ten-day period. This average price was less than the fair value of NuVasive s common stock at September 30, 2009 and we recorded an unrealized gain of $298,000 at September 30, 2009, as a component of Other Comprehensive Income. We began selling the NuVasive common stock on September 30, 2009, and have since sold all the shares and have received approximately $12.7 million in aggregate cash, which as been invested in accordance with our Investment Policy.

Investments available for sale consisted of the following as of September 30, 2009 and December 31, 2008:

| | September 30, 2009 ($000) | | December 31, 2008 ($000) | |
|---|---|---|---|---|
| | Cost | Fair Value | Cost | Fair Value |
| **Cash equivalents:** | | | | |
| Money market funds & certificates of deposit | $ 29,244 | $ 29,245 | $ 33,436 | $ 33,436 |
| Commercial paper | 18,694 | 18,692 | 11,187 | 11,195 |
| | 47,938 | 47,937 | 44,623 | 44,631 |
| **Short term investments:** | | | | |
| Auction rate certificates | | | 3,100 | 3,100 |
| Common stock | 10,470 | 10,766 | | |
| Corporate notes and bonds | 4,173 | 4,180 | 1,921 | 1,921 |
| US government agencies | 38,382 | 38,438 | 11,621 | 11,646 |
| | 53,025 | 53,384 | 16,642 | 16,667 |
| | | | | |
| **Total investments available for sale** | **$ 100,963** | **$ 101,321** | **$ 61,265** | **$ 61,298** |

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

The following table summarizes maturities of our investments available for sale as of September 30, 2009 and December 31, 2008:

| | September 30, 2009 ($000) | | December 31, 2008 ($000) | |
|---|---|---|---|---|
| | Cost | Fair Value | Cost | Fair Value |
| **Maturities:** | | | | |
| Within 3-months | $ 60,373 | $ 60,840 | $ 46,826 | $ 46,832 |
| Between 3 12 months | 34,697 | 34,376 | 10,208 | 10,190 |
| Between 1 2 years | 5,893 | 6,105 | 4,231 | 4,276 |
| **Total investments available for sale** | **$ 100,963** | **$ 101,321** | **$ 61,265** | **$ 61,298** |

**8. 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 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 carry no investments classified as Level 3.

Assets and liabilities measured at fair value on a recurring basis are summarized below:

| | September 30, 2009 ($000) | | | December 31, 2008 ($000) | | |
|---|---|---|---|---|---|---|
| | Level 1 | Level 2 | Total | Level 1 | Level 2 | Total |
| Assets: | | | | | | |
| Overnight securities included in Cash | $ | $ | $ | $ 929 | $ | $ 929 |
| Investments available for sale | 101,321 | | 101,321 | 61,298 | | 61,298 |
| Total assets | $ 101,321 | $ | $ 101,321 | $ 62,227 | $ | $ 62,227 |

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**OSIRIS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008**

**9. Subsequent Events**

We evaluated our September 30, 2009 financial statements for subsequent events through the date the financial statements were available to be issued, which was November 4, 2009. NuVasive, Inc. has advised us that, in the latter part of October 2009, it achieved at least $35.0 million in cumulative sales of Osteocel, which triggered its obligation under the Asset Purchase Agreement for payment of the final milestone payment of $15.0 million. NuVasive has further advised us that pursuant to its rights under the Asset Purchase Agreement, it intends to make this payment through delivery of shares of its common stock having equivalent value. Upon receipt (anticipated on November 6, 2009), we will record this payment as a component of gain from the sale of discontinued operations during the fourth quarter of 2009. We are not aware of any other subsequent events which would require recognition or disclosure in the financial statements.

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

**Forward-Looking Information**

This Quarterly Report includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Forward-looking statements include statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, compensation arrangements, financing needs, plans or intentions relating to acquisitions, business trends and other information that is not historical information and, in particular, may appear under the headings Risk Factors in our Annual Report on Form 10-K under Part I Item 1A, Part II Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and the other documents we file with the United States Securities and Exchange Commission, or SEC, including, among others, this and other of our quarterly reports on Form 10-Q and any amendments thereto. 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. Examples of forward-looking statements include, but are not limited to, statements regarding the following: our product development efforts; our clinical trials and anticipated regulatory requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for mesenchymal stem cells and biologic drug candidates (including the anticipated timeline and clinical strategy for Prochymal and Chondrogen); our cash needs; patents and proprietary rights; ability of our potential products to treat disease; our plans for sales and marketing; our plans regarding facilities; types of regulatory frameworks we expect will be applicable to our potential products; results of our scientific research; our ability to benefit from the sale of our Osteocel business and to earn milestone payments; and our ability to benefit from our collaborations with Genzyme and other collaborations and to earn milestone payments and perform under and derive royalty and other revenue thereunder. Risks and uncertainties related to the sale of our Osteocel assets and related transactions include typical business transactional risks, the risk of changing relationships with customers, suppliers or employees; and the risk that we may not be able to fully perform or generate or receive contingent milestone payments. Risks and uncertainties related to our Collaboration Agreement with Genzyme for the development and commercialization of Prochymal and Chondrogen include, among others: typical business transactional risks; risks related to product development and clinical trial design, performance and completion; uncertainty of the success of Prochymal and Chondrogen in clinical trials and their ability to treat disease; Genzyme s early termination and opt-out rights; the ability of Osiris and Genzyme to successfully navigate regulatory requirements and to manufacture and commercialize products; and the uncertainty as to our ability, and the ability and willingness of Genzyme to successfully perform our respective obligations under the collaborative arrangement, and our ability to earn milestone and royalty payments thereunder. All forward-looking statements, including, without limitation, management s examination of historical operating trends, are based upon our current expectations and various assumptions. Our expectations, beliefs and projections are expressed in good faith and we believe there is a reasonable basis for them. However, there can be no assurance that management s expectations, beliefs or projections will result or be achieved, and you should not unduly rely on forward-looking statements.

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, 2008, and our unaudited Condensed Financial Statements for the three and nine months ended September 30, 2009 and other disclosures included in this Quarterly Report on Form 10-Q. Our Condensed Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles 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, 2008 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.

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.

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

**Introduction and Overview**

The following is a discussion and analysis of our financial condition and results of operations for the three and nine month periods ended September 30, 2009 and 2008. You should read this discussion together with the accompanying unaudited condensed financial statements and notes and with our Annual Report on Form 10-K for the year ended December 31, 2008. Historical results and any discussion of prospective results may not indicate our future performance. See Forward Looking Information.

We are a stem cell therapeutic company headquartered in Columbia, Maryland, focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic, and cardiovascular areas. We were incorporated in Delaware in April 2002. Our

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predecessor company was organized in 1992. Our lead biologic drug candidate, Prochymal®, is being evaluated in Phase III clinical trials for four indications, including acute and steroid refractory GvHD, Crohn s disease and acute radiation syndrome, and is the only stem cell therapeutic currently granted both Orphan Drug and Fast Track status by the U.S. Food and Drug Administration ( FDA ). Prochymal is also being developed for the repair of heart tissue following a heart attack, the protection of pancreatic islet cells in patients with type 1 diabetes mellitus, and the treatment of patients with COPD. Our pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen for osteoarthritis in the knee.

As discussed more fully in Note 3 to the accompanying Condensed Financial Statements, on October 31, 2008, we entered into a Collaboration Agreement with Genzyme Corporation ( Genzyme ) for the global development and commercialization of our biologic drug candidates, Prochymal and Chondrogen. Under the terms of the Collaboration Agreement, we retain the right to commercialize Prochymal and Chondrogen in the United States and Canada, and Genzyme is granted the exclusive right and license to commercialize the products in all other countries (except with respect to GvHD in Japan where Prochymal has previously been licensed to another pharmaceutical company). In July 2007, we separately partnered with Genzyme for the development of effective countermeasures to nuclear terrorism and other radiological emergencies. In January 2008, we were awarded a contract from the U.S. Department of Defense ( DoD ), pursuant to which we are seeking, in partnership with Genzyme, to develop and stockpile Prochymal for the repair of gastrointestinal injury resulting from acute radiation exposure. Additionally, we have partnered with the Juvenile Diabetes Research Foundation ( JDRF ) for the development of Prochymal as a treatment for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus.

In April 2008, we committed to a plan to sell our assets related to Osteocel, a product that we produced and marketed beginning in July 2005, for regenerating bone in orthopedic indications. On May 8, 2008, we entered into an Asset Purchase Agreement to sell those assets, including our entire product line relating to the processing, manufacturing, marketing and selling of Osteocel and Osteocel XO, to NuVasive, Inc. The first of two scheduled closings in connection with this transaction, the technology assets closing , occurred on July 24, 2008, at which time we received an initial payment of $35.0 million. Concurrent with the technology assets closing, we entered into a Manufacturing Agreement with NuVasive, under which we continued to manufacture Osteocel until March 28, 2009 when all manufacturing activities ceased. In March 2009, we entered into amendments to the Asset Purchase Agreement and amendments to the related Manufacturing Agreement that stipulated that all of our responsibilities would be considered fulfilled upon consummation of the second and final closing, the manufacturing assets closing. The manufacturing assets closing occurred on April 9, 2009. Upon execution of the amendments, we received $5.0 million of additional purchase price in cash and on June 30 and September 30, 2009, we received $12.5 million in NuVasive s common stock. NuVasive has advised us that, in the latter part of October 2009, it achieved $35.0 million in cumulative sales of Osteocel, which triggered its obligation under the Asset Purchase Agreement for payment of the final milestone payment of $15.0 million. NuVasive has further advised us that it intends to make this payment in stock in early November 2009.

We are a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. We have developed an extensive intellectual property portfolio to protect our technology in the United States and a number of foreign countries, including 49 U.S. and 268 foreign patents owned or licensed. We believe that our biologic drug candidates have advantages over other stem cell therapeutics in development for at least the following reasons:

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

- **Ability to Mass Produce.** Through our proprietary manufacturing methods, we can grow mesenchymal stem cells ( MSCs ) in a controlled fashion to produce up to 10,000 treatments of our biologic drug candidates from a single bone marrow donation. Our ability to produce a large quantity of treatments from one donation provides us with manufacturing efficiencies and product consistency that are

essential to commercialization.

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

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

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

| Product/Candidate | Indication | Status |
|---|---|---|
| **Prochymal** | Steroid Refractory Acute GvHD | Phase III |
| | First Line Treatment of Acute GvHD | Phase III |
| | Biologics Refractory Crohn s Disease | Phase III |
| | Type I Diabetes Mellitus | Phase II |
| | Acute Myocardial Infarction | Phase II |
| | Chronic Obstructive Pulmonary Disease | Phase II |
| | Acute Radiation Syndrome | Phase III (Animal Rule) |
| | | |
| **Chondrogen** | Osteoarthritis & Cartilage Protection | Phase II |

***Prochymal*** is our lead biologic drug candidate and is being evaluated in Phase III clinical trials for four indications, including the first line treatment of acute GvHD, steroid refractory acute GvHD, biologics refractory Crohn s disease, and acute radiation syndrome, and is the only stem cell therapeutic currently designated by the FDA as both an Orphan Drug and Fast Track product.

On September 8, 2009, we announced preliminary results for our two Phase III GvHD trials (steroid refractory acute GvHD and first line treatment of acute GvHD), noting that while Prochymal showed significant improvements in response rates in difficult-to-treat lever and gastrointestinal GvHD, neither trial reached its primary endpoint.

Key findings from the GvHD trials include:

- There was no statistical difference between Prochymal and placebo on the primary endpoints for either the steroid-refractory (35% vs. 30%, n=260) or the first-line (45% vs. 46%, n=192) GvHD trials.

- The primary endpoint for the steroid-refractory GvHD trial (durable complete response) for the per-protocol population approached statistical significance (40% vs. 28%, p=0.087, n=179).

- In patients with steroid-refractory liver GvHD, treatment with Prochymal significantly improved response (76% vs. 47%, p=0.026, n=61) and durable complete response (29% vs. 5%, p=0.046).

- Prochymal significantly improved response rates in patients with steroid-refractory gastrointestinal GvHD (88% vs. 64%, p=0.018, n=71).

- In pediatric patients, Prochymal showed a strong trend of improvement in response rates (86% vs. 57%, p=0.094, n=28).

The data are still preliminary and further analysis is ongoing to gain a full appreciation of the results of these rigorous, double-blind, placebo-controlled trials.

*Phase III Clinical Trial Steroid Refractory Acute GvHD*

GvHD is a life threatening immune system reaction that commonly affects the skin, gastrointestinal tract, and liver in patients who have received a bone marrow transplant. Our Phase III trial to evaluate Prochymal as a treatment for steroid refractory GvHD is a randomized, double blind, placebo controlled study. The trial has completed enrollment with a total of 244 patients. The trial is investigating patient response to eight infusions of Prochymal administered twice per week for four consecutive weeks. The primary trial endpoint is complete resolution of GvHD for at least 28 day duration. Each patient is also monitored for safety for up to 180 days after their first treatment with Prochymal. Six-month survival is a key secondary endpoint. This trial is being conducted in 72 centers in the United States, Canada, Europe and Australia.

*Phase III Clinical Trial First Line Treatment of Acute GvHD.*

In April 2008, we completed enrollment in our Phase III trial evaluating Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD. This randomized, double blind, placebo controlled study completed enrollment with a total of 192 patients. All patients are being followed-up for safety until day 365 post-randomization. The trial is investigating patient response to a total of six infusions during the first four weeks of the study. The primary trial endpoint is the proportion of patients who achieve a complete response at day 28 and who survive to day 90 without the addition of a second line therapy. The study is being conducted at approximately 50 centers in the United States and Canada.

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*Phase III Clinical Trial Biologics Refractory Crohn s Disease.*

Based on our clinical observations of the effects of Prochymal on the gastrointestinal symptoms of patients with GvHD, we are developing Prochymal for the treatment of Crohn s disease. Crohn s disease is a chronic condition that results in inflammation of the gastrointestinal tract. We completed patient enrollment in a Phase II trial for Crohn s disease under an Investigational New Drug ( IND ) exemption for Crohn s disease. We received Fast Track designation from the FDA for the development of Prochymal for patients with moderate to severe Crohn s disease that is refractory to standard therapies, including biologics.

On March 27, 2009, we announced that we had elected to end enrollment at 207 patients in our Phase III clinical trial evaluating Prochymal for the treatment of moderate to severe Crohn s disease that is refractory to biological therapy and immunosuppressives. We ended enrollment because we believe that there was a design flaw in the trial resulting in significantly higher than expected placebo response rates. The decision was made after the trial s final scheduled interim analysis showed that one of the two Prochymal dose arms had crossed a futility boundary. The dose arm was unlikely to achieve the primary endpoint of remission. This analysis continued to show no serious safety concerns with the therapy and safety was not a factor in the decision to stop enrollment. After careful discussion with the United States Food and Drug Administration, we elected to discontinue enrollment rather than attempt to re-power the trial. We will keep the trial blinded and expect data for use in designing future trials in Crohn s disease and to bolster Prochymal s overall safety database. The Prochymal Crohn s program consisted of two separate but related trials. The first trial, described above, evaluates patients initial response to two dose levels of Prochymal as compared to placebo. This trial was originally designed to enroll 270 subjects. Patients responding to the initial therapy were then eligible to participate in a second, trial evaluating Prochymal as a maintenance therapy. Because the current standard for determining response of Crohn s patients is largely subjective, there may have been response bias in order to meet the eligibility requirements for continuation of therapy in the maintenance trial. Accordingly, enrollment in the second trial has also ended.

*Phase II Clinical Trial Acute Myocardial Infarction.*

Prochymal is also being evaluated for the repair of heart muscle in patients who have suffered a heart attack. In February 2009, we reported positive two-year data on the Phase I clinical trial for Prochymal to evaluate its safety and efficacy to restore heart function in patients experiencing a first time myocardial infarction (MI). Based on these positive findings, we have received approval from the FDA to initiate a Phase II trial. We recently initiated this Phase II trial, which is expected to include approximately 220 patients to be treated at approximately 40 sites in the United States and Canada. The first patient in the Phase II trial was treated in April 2009.

*Phase II Clinical Trial Early Onset Type 1 Diabetes.*

We initiated a Phase II, 60 patient, placebo controlled study in the United States for the treatment of early onset type 1 diabetes in individuals 12 to 30 years old. Primary efficacy will be measured at one year the primary endpoint is the marker of insulin response in response to glucose stimulation. We have entered into a collaborative agreement with the Juvenile Diabetes Research Foundation ( JDRF ) for this study. This agreement provides for JDRF to fund $4.0 million of clinical study costs for 2008 through 2010. During 2008, we received $2.0 million from JDRF to fund clinical costs. We received a $750,000 milestone payment from JDRF during the third quarter of 2009 and expect to receive the remaining $1.2 million during 2009 and 2010.

*Phase II Clinical Trial Chronic Obstructive Pulmonary Disease*

We are evaluating the safety and efficacy of Prochymal in conjunction with standard of care for improving pulmonary function in patients with moderate to severe COPD in a Phase II clinical trial. This trial of 62 enrolled patients is a double-blind, placebo-controlled study. Patients were randomized to either Prochymal or placebo at a 1:1 ratio and received 4 infusions over the course of 90 days. Measurements used in the trial to detect potential improvements in subjects treated with Prochymal include pulmonary function tests, exercise capability, and quality of life assessments. In addition, exacerbations and hospitalizations due to COPD will be monitored for both safety and efficacy. Patients will be evaluated over the course of two years following initial Prochymal or placebo infusion. On June 23, 2009, we announced the interim six-month data from this trial. The six-months data showed that the trial met its primary goal of demonstrating the safety of Prochymal in patients with compromised pulmonary function at the six-month evaluation point; Prochymal significantly decreased systemic inflammation in patients when compared to those receiving placebo, as determined by C-reative protein; and despite the reduction in inflammation, pulmonary function in patients receiving Prochymal was not significantly improved compared to those receiving placebo.

*Phase III Clinical Trial Animal Rule Acute Radiation Syndrome.*

In 2007, we partnered with Genzyme Corporation to develop Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies. In January 2008, we were awarded a contract from the United States Department of Defense ( DoD ) for the development of Prochymal for the treatment of acute radiation syndrome ( ARS ). We are carrying out this contract in collaboration with Genzyme.

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***Chondrogen*** is our biologic drug candidate for the treatment of osteoarthritis and the reduction of pain in the knee. We completed enrollment of a randomized double-blind, placebo controlled Phase I/II clinical trial evaluating Chondrogen for safety and preliminary efficacy based upon regeneration of meniscus at six-months. In November 2007, we reported one-year data for the Phase I/II Chondrogen trial. The data continued to show improvements in joint condition that correlated with a clinically and statistically significant improvement in pain in patients with osteoarthritis (OA) who received Chondrogen as compared to those treated with the control, hyaluronic acid (HA). Patients receiving the control were 3.5 times more likely to experience degenerative bone changes associated with OA as compared to those receiving Chondrogen. The effects were dose dependent and pain scores improved from six months to one year following treatment, suggesting Chondrogen caused a biological modification of patients OA.

**Financial Operations Overview**

*Revenue*

In 2008, we entered into a Collaboration Agreement with Genzyme for the development and commercialization of Prochymal and Chondrogen, and providing for non-contingent, non-refundable up front payments of $130.0 million and contingent milestone payments. This Collaboration Agreement has multiple deliverables, and consistent with our accounting policy for such transactions, we are amortizing the up front payments into revenue on a straight-line basis over the estimated completion period of the deliverables, which extend through the first quarter of 2012. We recognized $10.0 million of revenue in each of the first three quarters of 2009 related to this agreement. Contingent milestone payments earned and for which we have no continuing performance obligations will be recognized as revenue upon achievement of the related milestone, while milestone payments for which we have a continuing performance obligation will be deferred when received and amortized to revenue over the term of the related performance obligations.

Under the DoD contract awarded to us in January 2008, we are seeking, in partnership with Genzyme, to develop Prochymal for the repair of gastrointestinal injury resulting from acute radiation exposure. Under the terms of the contract, the DoD provides funding to us for development. We recognized $2.9 million in revenue under the terms of this contract in the first nine months of 2009, on a cost reimbursement basis.

In prior years, we have entered into strategic agreements with others for the development and commercialization of select stem cell biologic drug candidates for specific indications and geographic markets. In 2007, we entered into a collaborative agreement with the JDRF to conduct a Phase II clinical trial evaluating Prochymal as a treatment for type 1 diabetes mellitus. Under this collaborative agreement, JDRF will provide up to $4.0 million of contingent milestone funding to support the development of Prochymal for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus. The contingent milestone payments under the agreement are amortized into revenue on a straight line basis over the duration of our obligations under the collaborative agreement as they are received and earned. We recognized $0.7 million in revenue during the first nine months of 2009 under this agreement.

In 2003, we entered into an agreement with a foreign pharmaceutical company granting it exclusive rights to Prochymal for the treatment of GvHD in Japan.

*Research and Development Costs*

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

Consistent with our focus on the development of biologic drug candidates with potential uses in multiple indications, many of our costs are not attributable to a specifically identified product. We use our employee and infrastructure resources across several projects. Accordingly, we do not account for internal research and development costs on a project-by-project basis. From inception in December 1992 through September 30, 2009, we incurred aggregate research and development costs of approximately $358 million.

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

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

As a result of 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 biologic drug candidates.

*General and Administrative Expenses*

General and administrative expenses consist primarily of the costs associated with our general management, including salaries, allocations of facilities and related costs, and professional fees such as legal and accounting expenses. We have increased our general and administrative expense for legal and accounting compliance costs, investor relations and other activities associated with operating as a publicly traded company and strengthened our administrative capabilities as we approach the commercial launch of Prochymal for an initial indication. Continued increases will also likely result from the hiring of additional operational, financial, accounting, facilities engineering and information systems personnel.

*Interest Income (Expense), Net*

Interest income consists of interest earned on our cash and investments available for sale. Interest expense consists of interest incurred on capital leases and other debt financings. We pay interest on our promissory notes, capital leases and convertible long-term debt. We do not expect to incur material interest expense in the near future as we had extinguished all of our outstanding debt as of December 31, 2008, and have invested our excess cash in investments available for sale.

*Income Taxes*

During the nine months ended September 30, 2009, we recognized an income tax benefit to continuing operations of $2.6 million, and income tax expense of $2.4 million against the income from discontinued operations. We have not recognized any deferred tax assets or liabilities in our financial statements above these amounts since we cannot assure their future realization. Because realization of deferred tax assets is dependent upon future earnings, a full valuation allowance has been recorded on the net deferred tax assets, which relate primarily to net operating loss carry-forwards and research and development and orphan drug tax credit carry-forwards. In the event that we become profitable within the next several years, we have net deferred tax assets of approximately $140 million that may be utilized prior to us having to recognize any income tax expense or make payments to the taxing authorities. However, utilization of our net operating loss and tax credit carry-forwards in any one year may be limited under Internal Revenue Code Sections 382 and 383, and may expire prior to our ability to utilize them. In addition, even if certain of our net deferred tax assets are not subject to limitations, we may be subject to the Federal alternative minimum tax in future years.

The tax benefit for the nine months ended September 30, 2009, reflects an effective tax rate for continuing operations of 9.9% compared to a U.S. statutory tax rate of 35%. The effective tax rate reflects our estimated annual effective tax rate, which reflects our expectation that a portion of our income will be subject to the Federal alternative minimum tax in 2009.

**Critical Accounting Policies**

There have been no material changes in our critical accounting policies, estimates and judgments during the nine months ended September 30, 2009 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2008, other than as disclosed herein.

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**Results of Operations**

***Comparison of Three Months Ended September 30, 2009 and 2008***

*Revenues from Continuing Operations*

Revenues from continuing operations were $10.6 million for the three months ended September 30, 2009 compared to $1.0 million for the third quarter of fiscal 2008. During the three months ended September 30, 2009, we recognized $10.0 million in revenue from our collaborative agreement with Genzyme and $0.4 million from our collaborative agreement with JDRF. Our revenues for the three month period also include $0.1 million from our contract with the DoD to develop Prochymal for the treatment of acute radiation syndrome, plus royalties on MSCs sold for research purposes. Revenues from continuing operations for the three months ended September 30, 2008 were $1.0 million, and consisted primarily of revenue recognized on our contract with DoD to develop Prochymal as a medical countermeasure to nuclear terrorism.

*Research and Development Expenses*

Research and development expenses for the three months ended September 30, 2009 were $16.2 million as compared to research and development expenses of $18.6 million for the same period last year. At September 30, 2009, we were conducting three Phase III clinical trials in several inflammatory disease indications, and Phase II clinical trials for acute myocardial infarction, type 1 diabetes mellitus, and COPD. In addition, we were conducting animal studies in accordance with the FDA Animal Rule for acute radiation syndrome. The reduction in research and development expenses during the third quarter of 2009 when compared to the comparable period of the prior year reflects the completion of enrollment in our three Phase III clinical trials and the associated reduction in site and patient costs. We also incur research and development expenses in connection with the preparation of our biologic license application as we prepare filings with the FDA towards the commercialization of Prochymal for an initial indication.

*General and Administrative Expenses (excluding discontinued operations)*

General and administrative expenses were $1.5 million for the three months ended September 30, 2009 compared to $1.9 million for the comparable period in fiscal 2008. The decrease in general and administrative expenses is primarily attributable to reductions in our non cash share-based compensation expense related to the departure of two officers during the fiscal quarter, partially offset by increases in our professional staff in the areas of intellectual property and business development and increases in legal costs related to our intellectual property portfolio. The non cash charge for share-based compensation allocated to general and administrative expenses during the fiscal quarter ended September 30, 2009 was ($0.1) million as compared to $0.5 million for the same period last year.

*Interest Income (Expense), Net*

Interest income, net was $0.1 million for the three months ended September 30, 2009 compared to net interest expense of $0.4 million in the corresponding period in fiscal 2008. During 2009, we have not had any short or long-term debt, and interest expense consists of financing charges on capital leases for equipment. We earn interest income on our investments available for sale.

***Income (Loss) from Discontinued Operations***

Loss from operations of the Osteocel asset disposal group was $28,000 for the three months ended September 30, 2009 compared to a loss of $0.4 million for the comparable period of fiscal 2008. Osteocel manufacturing activities ceased in March 2009 and the loss incurred during the third quarter of 2009 reflect miscellaneous costs associated with the wind-down of this business.

Also during the third quarter of 2009, we reported a gain from the sale of discontinued operations of $0.6 million, which reflects the decrease in the estimated annual effective income tax rate for the full fiscal year.

***Comparison of Nine Months Ended September 30, 2009 and 2008***

*Revenues from Continuing Operations*

Revenues from continuing operations were $33.8 million for the nine months ended September 30, 2009 compared to $3.9 million for the first nine months of fiscal 2008. During the nine months ended September 30, 2009, we recognized $30.0 million in revenue from our collaborative agreement with Genzyme and $0.7 million from our collaborative agreement with JDRF. Our revenues for this nine month period also include $2.9 million from our contract with the DoD to develop Prochymal for the treatment of acute radiation syndrome, plus $0.2 million in royalties on MSCs sold for research purposes. Revenues from continuing operations for the nine months ended September 30, 2008 were $3.9 million, and consisted primarily of the recognition of milestone payments received from JDRF as provided for under our collaborative agreement to develop Prochymal for the treatment of Type 1 diabetes, and revenue recognized on our contract with DoD to develop Prochymal as a medical countermeasure to nuclear terrorism.

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*Research and Development Expenses*

Research and development expenses for the nine months ended September 30, 2009 were $53.4 million, as compared to research and development expenses of $54.3 million for the same period last year. Our rate of spending on our Phase III clinical trials are slowing down as we complete enrollment in these trials and incur lower patient treatment and site costs.

*General and Administrative Expenses (excluding discontinued operations)*

General and administrative expenses were $6.7 million for the nine months ended September 30, 2009 compared to $6.3 million for the comparable period in fiscal 2008. The non cash charge for share-based compensation allocated to general and administrative expenses during the first nine months of this fiscal year was $1.1 million as compared to $0.8 million for the same period last year.

*Interest Income (Expense), Net*

Interest income, net was $0.4 million for the nine months ended September 30, 2009 compared to net interest expense of $0.8 million in the corresponding period in fiscal 2008. During 2009, we have not had any short or long-term debt, and interest expense consists of financing charges on capital leases for equipment. We earn interest income on our investments available for sale.

***Income from Discontinued Operations***

Income from operations of the Osteocel asset disposal group was $1.1 million for the nine months ended September 30, 2009 compared to earnings of $6.3 million for the comparable period of fiscal 2008. Osteocel manufacturing activities ceased in March 2009.

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2009 ($000)** | **2008 ($000)** |
| Product sales | $ 6,295 | $ 19,338 |
| Cost of goods sold | 4,985 | 11,602 |
| Gross profit | 1,310 | 7,736 |
| | | |
| Selling, general & administrative expenses | 124 | 1,467 |
| Income from operations of discontinued operations before tax | 1,186 | 6,269 |
| Income tax | 117 | |
| Income from operations of discontinued operations | $ 1,069 | $ 6,269 |

In April 2008, we committed to a plan to sell our biologic tissue business, consisting of the Osteocel asset disposal group. On May 8, 2008 we entered into an Asset Purchase Agreement for the sale of the Osteocel asset disposal group to NuVasive, Inc., and on July 24, 2008, the first of two scheduled closings, the technology assets closing, occurred and we received a $35.0 million payment. During the fourth quarter of 2008, we earned additional purchase price of $5.0 million upon the achievement of production milestones. Concurrent with the technology assets closing, we entered into a Manufacturing Agreement with NuVasive, under which we continued to manufacture Osteocel until March 28, 2009 when all manufacturing activities ceased. In March 2009, we entered into amendments to the Asset Purchase Agreement and amendments to the related Manufacturing Agreement which stipulated that, upon consummation of the second and final closing (the manufacturing assets closing ) under the Asset Purchase Agreement all of our responsibilities would be deemed fulfilled. The manufacturing assets closing occurred on April 9, 2009. Upon execution of the amendments, we received $5.0 million of additional purchase price in cash and then received an additional $12.5 million in NuVasive common stock on June 30, 2009 and September 30, 2009. We subsequently sold all the shares of NuVasive common stock and received proceeds of approximately $25.3 million in cash. We are also entitled to receive a contingent milestone payment of $15.0 million in early November 2009, as a result of achievement by NuVasive of cumulative sales revenue from Osteocel of at least $35.0 million. NuVasive has advised that this payment will be made in shares of NuVasive stock.

**Liquidity and Capital Resources**

***Liquidity***

The current global financial crisis which has included, among other things, significant reductions in available capital and liquidity from banks and other providers of credit, substantial reductions and/or fluctuations in equity and currency values worldwide, significant decreases in consumer confidence and consumer and business spending, and concerns that the worldwide economy may enter into a prolonged recessionary period may materially adversely affect our access to capital. In addition, the current global financial crisis may materially adversely affect the liquidity and access to capital of parties with which we from time to time collaborate, which may in turn adversely impact their ability or desire to participate or perform under their collaborations with us. These potential effects of the current global financial crisis

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are difficult to forecast and mitigate. Should additional capital be required to pursue our business plan, but not be available, as a result of the global economic crisis or otherwise, our business and financial condition would be materially and adversely affected.

At September 30, 2009, we had $102.9 million in cash and investments available for sale. We presently estimate that we have sufficient liquidity on hand as of September 30, 2009 to fund our operations through the anticipated date of initial commercialization of Prochymal for an initial indication.

***Cash Flows***

***Comparison of Three Months Ended September 30, 2009 and 2008***

Cash provided by operating activities of continuing operations for the three months ended September 30, 2009 was $40.7 million compared to cash used by operating activities of continuing operations of $31.1 million in the same quarter of the prior year. The third quarter 2009 loss from continuing operations of $6.8 million was offset by the $55.2 million reduction in receivables, reflecting the payment from Genzyme Corporation of the balance of the non-contingent, non-refundable upfront fees, net of amortization of deferred revenue and other minor changes in working capital. Cash used by operating activities of continuing operations during the third fiscal quarter of 2008 reflect our loss from continuing operations of $19.9 million, which was increased primarily by the $12.7 reduction in payables and accrued expenses.

Cash used by operating activities of discontinued operations for the third quarter of fiscal 2009 was $2.1 million compared to cash provided by operating activities of discontinued operations of $5.2 million in the same period of the prior year. The 2009 amounts reflect the net increase in the gain on sale of discontinued operations of $0.6 million, which resulted primarily from the cumulative effect of the reduction in our estimated effective income tax rate for 2009, offset by decreases in both receivables and payables as we wrap up the final accounts of the Osteocel business.

Cash used in investing activities during the third quarter of 2009 was $38.2 million compared to cash provided by investing activities of $33.4 million in the same period of the prior year. The 2009 amount reflects the purchase of $50.0 million of short-term investments from the proceeds of the Genzyme payment, net of $11.8 million of sales of short-term investments to fund operating activities. The 2008 amounts reflect the net cash proceeds from the sale of our Osteocel business in July 2008.

Cash provided from financing activities during the third quarter of 2009 was $0.1 million, which reflects the proceeds from the exercise of stock options. Cash used in financing activities during the third quarter of 2008 was $4.6 million, which was primarily the result of the net payment of short-term debt.

***Comparison of Nine Months Ended September 30, 2009 and 2008***

Cash provided by operating activities of continuing operations for the nine months ended September 30, 2009 was $9.3 million compared to cash used in operating activities of continuing operations of $57.9 million. The 2009 amount reflects the loss from continuing operations of $23.3 million, increased by the $29.9 million of net amortization of deferred revenue, which was offset by the collection of $56.1 million of receivables (primarily the $55.0 payment from Genzyme) and $4.7 million increase in payables. Non cash expenses of $2.3 million were incurred during the first nine months of 2009. The 2008 amounts reflect the loss from continuing operations of $57.5 million, reduced by non cash expenses of $2.7 million and net changes in working capital.

Cash used by operating activities of discontinued operations during the first three quarters of fiscal 2009 was $3.9 million which reflects the wrapping up of the business activities of our former Osteocel activities. During the comparable period of the prior year, $11.3 million of cash was provided by the operating activities of discontinued operations.

Cash used in investing activities during the nine months ended September 30, 2009 was $4.8 million compared to cash provided by investing activities of $42.1 million in the same period of the prior year. The 2009 amounts reflect the purchase of $50.0 million in short-term investments, offset by the sale of $35.6 million of short-term investments to fund operations and the net cash proceeds from the sale of discontinued operation of $9.8 million. The 2008 amounts reflect the net cash proceeds of $33.6 million from the sale of our Osteocel business, the sale of $12.4 million of short-term investments, net of $4.0 million of property additions.

Cash provided by financing activities during the first three quarters of fiscal 2009 was $34,000, reflecting the $0.6 million proceeds from the exercise of stock options, offset by the $0.5 million increase in restricted cash used to collateralize a letter of credit used in lieu of a security deposit on our facilities lease. Cash provided by financing activities during the same period of the prior year was $9.1 million, consisting primarily of borrowing of $10.5 million of convertible promissory notes and $6.5 million of short-term promissory notes, netted against $8.3 million of debt payments.

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***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, particularly regarding the number of patients required for our Phase III trials;
- the timing of and the costs involved in obtaining regulatory approvals for our biologic drug candidates, which could be more lengthy or complex than obtaining approval for a new conventional drug, given the FDA s limited experience with late-stage clinical trials and marketing approval for stem cell therapeutics;
- the timing and achievement of contingent milestone payments under the NuVasive agreement and the Genzyme collaboration agreement;
- 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 status as a public company.

As of December 31, 2008, we had completely extinguished our outstanding debt. As a result of our financial position and forecasts as of that date, we believe that we have sufficient liquidity on hand to fund our operations through the anticipated date of initial commercialization of Prochymal for an initial indication.

**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**.

Due to the short duration of our investment portfolio and the high quality of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

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

We do not enter into hedging or derivative instrument arrangements.

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**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 September 30, 2009 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, 2008, filed with the Securities and Exchange Commission on March 16, 2009.

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

None.

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

None.

**Item 4.** **Submission of Matters to a Vote of Security Holders**.

None.

**Item 5.** **Other Information**.

None.

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**Item 6.** **Exhibits.**

| Exhibit Number | Description of Exhibit |
|---|---|
| 10.1 | Employment Separation Agreement and Release dated September 8, 2009 by and between the Registrant and Richard W. Hunt (Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant with the SEC on September 11, 2009) |
| 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 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). |
| 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. |

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**SIGNATURES**

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: November 6, 2009

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

Date: November 6, 2009

/s/ MATTHEW NEUMAYER
Matthew Neumayer
Corporate Controller (Principal Accounting Officer)