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# OSIRIS THERAPEUTICS, INC.

## FORM 10-Q
(Quarterly Report)

Filed 11/05/10 for the Period Ending 09/30/10

| | |
|---|---|
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| Telephone | 443-545-1819 |
| CIK | 0001360886 |
| Symbol | OSIR |
| SIC Code | 2836 - Biological Products, Except Diagnostic Substances |
| Industry | Biotechnology & Drugs |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

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

**For the quarterly period ended September 30, 2010**

**Or**

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

**For the transition period from to**

**Commission File Number: 001-32966**

# OSIRIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

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

| | |
|---|---|
| Large accelerated filer ☐ | Accelerated filer ☒ |
| Non-accelerated filer ☐<br>(Do not check if a smaller reporting company) | Smaller reporting company ☐ |

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

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 4, 2010 |
|---|---|
| Common Stock, par value $0.001 per share | 32,790,019 |

**OSIRIS THERAPEUTICS, INC.**

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**PART I — FINANCIAL INFORMATION**

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

**OSIRIS THERAPEUTICS, INC.**
**BALANCE SHEETS**
**(amounts in thousands)**

| | September 30, 2010 (unaudited) | December 31, 2009 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ 1,088 | $ 1,306 |
| Investments available for sale | 75,168 | 99,409 |
| Accounts receivable | 262 | 1,138 |
| Inventory | 321 | — |
| Prepaid expenses and other current assets | 789 | 948 |
| Total current assets | 77,628 | 102,801 |
| | | |
| Property and equipment, net | 3,266 | 3,734 |
| Restricted cash | 521 | 666 |
| Other assets | 3,142 | 395 |
| Total assets | $ 84,557 | $ 107,596 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 7,057 | $ 9,013 |
| Deferred revenue, current portion | 40,840 | 41,011 |
| Capital lease obligations, current portion | — | 3 |
| Current liabilities of discontinued operations | — | 412 |
| Total current liabilities | 47,897 | 50,439 |
| | | |
| Deferred revenue, net of current portion | 13,543 | 44,173 |
| Other long-term liabilities | 470 | 424 |
| Total liabilities | 61,910 | 95,036 |
| | | |
| Stockholders' equity | | |
| Common stock, $.001 par value, 90,000 shares authorized, 32,790 shares outstanding - 2010, 32,773 outstanding - 2009 | 33 | 33 |
| Additional paid-in-capital | 274,242 | 272,959 |
| Accumulated other comprehensive income (loss) | 5 | (88) |
| Accumulated deficit | (251,633) | (260,344) |
| Total stockholders' equity | 22,647 | 12,560 |
| Total liabilities and stockholders' equity | $ 84,557 | $ 107,596 |

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

**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, | |
|---|---|---|---|---|
| | 2010 | 2009 | 2010 | 2009 |
| **Product sales** | $ 99 | $ — | $ 99 | $ — |
| Cost of goods sold | 34 | — | 34 | — |
| Gross profit | 65 | — | 65 | — |
| **Revenue from collaborative research agreements, government contract and royalties** | 10,659 | 10,584 | 32,340 | 33,779 |
| Operating expenses: | | | | |
| Research and development | 5,460 | 16,247 | 18,476 | 53,354 |
| General and administrative | 1,268 | 1,511 | 4,677 | 6,745 |
| | 6,728 | 17,758 | 23,153 | 60,099 |
| Income (loss) from operations | 3,996 | (7,174) | 9,252 | (26,320) |
| Other income, net | 27 | 134 | 151 | 387 |
| Income (loss) from continuing operations, before income taxes | 4,023 | (7,040) | 9,403 | (25,933) |
| Income tax benefit (expense) | 525 | 238 | (692) | 2,636 |
| **Income (loss) from continuing operations** | 4,548 | (6,802) | 8,711 | (23,297) |
| **Discontinued operations:** | | | | |
| Income (loss) from operations of discontinued operations, net of income taxes | — | (28) | — | 1,069 |
| Gain from sale of discontinued operations, net of income taxes | — | 636 | — | 21,112 |
| **Income from discontinued operations** | — | 608 | — | 22,181 |
| **Net income (loss)** | $ 4,548 | $ (6,194) | $ 8,711 | $ (1,116) |
| **Basic income (loss) per share** | | | | |
| Income (loss) from continuing operations | $ 0.14 | $ (0.21) | $ 0.27 | $ (0.71) |
| Income from discontinued operations | — | 0.02 | — | 0.68 |
| Basic earnings (loss) per share | $ 0.14 | $ (0.19) | $ 0.27 | $ (0.03) |
| **Diluted income (loss) per share** | | | | |
| Income (loss) from continuing operations | $ 0.14 | $ (0.21) | $ 0.26 | $ (0.71) |
| Income from discontinued operations | — | 0.02 | — | 0.68 |
| Diluted earnings (loss) per share | $ 0.14 | $ (0.19) | $ 0.26 | $ (0.03) |
| Weighted Average Common Shares (basic) | 32,789 | 32,764 | 32,781 | 32,731 |
| Weighted Average Common Shares (diluted) | 33,100 | 32,764 | 33,095 | 32,731 |

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

**OSIRIS THERAPEUTICS, INC.**
**CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY**
**For the nine months ended September 30, 2010**
**Unaudited**
**(amounts in thousands, except for share and per share data)**

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance at January 1, 2010** | 32,773,331 | $ 33 | $ 272,959 | $ (88) | $ (260,344) | $ 12,560 |
| Exercise of options to purchase common stock ($0.40 per share) | 5,188 | — | 2 | — | — | 2 |
| Issuance of common stock for services rendered by Directors ($6.46 per share) | 11,500 | — | 74 | — | — | 74 |
| Share-based payment — employee compensation | — | — | 1,207 | — | — | 1,207 |
| **Comprehensive Income:** | | | | | | |
| Net income for the period | — | — | — | — | 8,711 | 8,711 |
| Unrealized gain on investments available for sale | — | — | — | 93 | — | 93 |
| **Total Comprehensive Income** | | | | | | 8,804 |
| **Balance at September 30, 2010** | 32,790,019 | $ 33 | $ 274,242 | $ 5 | $ (251,633) | $ 22,647 |

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

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2010** | **2009** |
| **Cash flows from operating activities:** | | |
| **Continuing operations** | | |
| Income (loss) from continuing operations | $ 8,711 | $ (23,297) |
| **Adjustments to reconcile income (loss) from continuing operations to net cash (used in) provided by operations:** | | |
| Depreciation and amortization | 566 | 483 |
| Non cash share-based payments | 1,281 | 1,852 |
| **Changes in operating assets and liabilities:** | | |
| Accounts receivable | 876 | 56,101 |
| Prepaid expenses and other current assets | (162) | (710) |
| Other assets | (2,747) | 162 |
| Accounts payable and accrued expenses | (1,938) | 4,670 |
| Deferred revenue | (30,801) | (29,928) |
| Net cash (used in) provided by continuing operations | (24,214) | 9,333 |
| **Discontinued operations** | | |
| Income from discontinued operations | — | 22,181 |
| **Adjustments to reconcile income from discontinued operations to net cash used in discontinued operations:** | | |
| Non cash impact of the sale of discontinued operations | — | (26,595) |
| Depreciation and amortization | — | 210 |
| Provision for bad debts | — | 45 |
| **Non cash share-based payments** | — | 98 |
| **Changes in operating assets and liabilities:** | | |
| Accounts receivable | — | 1,516 |
| Inventory and other current assets | — | 1,707 |
| Accounts payable and accrued expenses | (412) | (3,108) |
| Net cash used in discontinued operations | (412) | (3,946) |
| Net cash (used in) provided by operating activities | (24,626) | 5,387 |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (98) | (181) |
| Proceeds from the sale of property and equipment | — | 17 |
| Proceeds from sale of discontinued operations, net | — | 9,797 |
| Proceeds from sale of investments available for sale | 24,598 | 35,578 |
| Purchases of investments available for sale | (236) | (50,000) |
| Net cash provided by (used in) investing activities | 24,264 | (4,789) |
| **Cash flows from financing activities:** | | |
| Principal payments on capital lease obligations and notes payable | (3) | (5) |
| Restricted cash | 145 | (536) |
| Proceeds from the exercise of stock options | 2 | 575 |
| Net cash provided by financing activities | 144 | 34 |
| Net (decrease) increase in cash | (218) | 632 |
| Cash at beginning of period | 1,306 | 940 |
| Cash at end of period | $ 1,088 | $ 1,572 |

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

**OSIRIS THERAPEUTICS, INC.**
**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

## 1. Nature of Business

Osiris Therapeutics, Inc. ("we," "us," "our," or the "Company") is a Maryland corporation headquartered in Columbia, Maryland. We began operations on December 23, 1992 and were a Delaware corporation until, with approval of our stockholders; we reincorporated as a Maryland corporation on May 31, 2010. We are a leading stem cell company focused on developing and marketing products to treat serious medical conditions in the inflammatory, autoimmune, 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. Historically, our operations have consisted 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. During 2009, we created a Biosurgery Division, focused on harnessing the ability of cells and novel constructs to promote the body's natural healing.

## 2. Significant Accounting Policies

### *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, 2009.

### *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 standalone 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.

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 made non-contingent, non-refundable cash payments to us, 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 both 2010 and 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 $13.3 million of long-term deferred revenue as of September 30, 2010. 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, and we will complete our work under the contract during the second half of 2010. Contract revenue is recognized as the related costs are incurred, in accordance with the terms of the contract. We recognized $360,000 and $470,000 in revenue from the DoD contract during the three and nine months ended September 30, 2010, respectively, and $55,000 and $2.9 million, respectively, in revenue during the comparable periods of 2009.

In October 2007, we entered into a collaborative agreement with the Juvenile Diabetes Research Foundation ("JDRF") to conduct a Phase 2 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 have received $3.5 million of the contingent milestones to date, and expect to receive the remaining $500,000 during 2010. We are amortizing the funding received, resulting in $210,000 of revenue in each of the three fiscal quarters to date in 2010 under the agreement with JDRF. The remaining deferred revenue under this agreement has been recorded as $840,000 of current deferred revenue and $210,000 of long-term deferred revenue as of September 30, 2010.

We have also entered into 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 hematologic malignancies (GvHD) drugs for distribution in Japan. Under such agreements, we receive fees for licensing the use of our technology. We recognized $1.0 million of revenue during the first fiscal quarter of 2010 from JCR upon the achievement of a milestone event specified in the agreement.

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 $70,000 and $218,000, respectively, of such royalty revenue during the three and nine months ended September 30, 2010.

As discussed in Note 5- *Segment Reporting* below, at the end of the third quarter of 2009, we created a new Biosurgery Division, focused on developing high-end biologic products for use in surgical procedures. We commenced the manufacturing of our first Biosurgery product, a regenerative wound care product, during the first quarter of 2010. During the first and second quarters of 2010, we distributed the product only for initial clinical evaluation. We launched the product for commercial sale during the third quarter of 2010, and revenues on such sales are recognized when legal title to the product has passed to the customer. To date, we have recognized revenues of approximately $100,000 from the sales of Biosurgery products

***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 per Common Share***

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

**OSIRIS THERAPEUTICS, INC.**
**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

Potentially dilutive effects of common share equivalents are calculated based upon the income (loss) from continuing operations. Accordingly, the 1,000,000 shares issuable upon the assumed exercise of our outstanding warrant and all 1,055,074 of our outstanding options as of September 30, 2009 were excluded from the calculation of diluted earnings per share, as their impact on our loss from continuing operations is anti-dilutive. As a result basic and diluted income per share are identical for those periods.

Diluted income per common share for the three months ended September 30, 2010 excludes 884,000 “out-of the money” stock options and the 1,000,000 shares issuable upon the assumed exercise of our outstanding warrant, as their effect is anti-dilutive. Similarly, diluted income per common share for the nine months ended September 30, 2010 excludes 811,179 “out-of the money” stock options and the 1,000,000 shares issuable upon the assumed exercise of our outstanding warrant.

A reconciliation of basic to diluted weighted average common shares outstanding for the applicable periods is as follows:

| | Three months ended September 30, 2010 (000s) | Nine months ended September 30, 2010 (000s) |
|---|---|---|
| Basic weighted average common shares outstanding | 32,789 | 32,781 |
| Dilutive weighted average options outstanding | 311 | 314 |
| Dilutive weighted average warrants outstanding | — | — |
| Diluted weighted average common shares outstanding | 33,100 | 33,095 |

***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 two years. Investments available for sale are valued at their fair value, with unrealized gains and losses reported as a separate component of stockholders’ equity in accumulated other comprehensive income. Gains or losses on investments available for sale are classified as other income 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 differ from original expectations.

**OSIRIS THERAPEUTICS, INC.**
**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

A summary of the combined activity under both of our stock-based compensation plans as of September 30, 2010 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, 2010 | 1,000,762 | $ 10.78 | 7.11 | $ 2,187 |
| Granted at market value | 406,500 | 7.37 | | |
| Exercised | (5,188) | 0.40 | | 33 |
| Forfeited | (44,750) | 12.42 | | — |
| Outstanding at September 30, 2010 | 1,357,324 | 9.74 | 7.11 | 2,298 |
| Exercisable at September 30, 2010 | 659,134 | 8.26 | 5.65 | 2,201 |

The weighted average grant date fair value of options granted during the nine months ended September 30, 2010 was $3.77 per share. We received a total of $2,000 in cash from the exercise of options during the nine months ended September 30, 2010.

As of September 30, 2010, approximately 803,000 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, 2010 and 2009 is allocable to our research and development activities, discontinued operations and general and administrative activities, as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2010 | 2009 | 2010 | 2009 |
| | ($000) | ($000) | ($000) | ($000) |
| Research and development | $ 248 | $ 222 | $ 667 | $ 708 |
| Discontinued operations | — | — | — | 98 |
| General and administrative | 178 | (141) | 614 | 1,144 |
| Total | $ 426 | $ 81 | $ 1,281 | $ 1,950 |

As of September 30, 2010, there was approximately $1.9 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 1.7 years, as the options vest.

***Supplemental Cash Flow Information***

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2010 | 2009 |
| | ($000) | ($000) |
| **Supplemental disclosure of cash flows information:** | | |
| Cash paid for interest | $ — | $ 8 |
| Cash paid for income taxes | 1,635 | 915 |

***Recent Accounting Guidance Not Yet Adopted at September 30, 2010***

In March 2010, ASU 2010-17, *Revenue Recognition—Milestone Method* (Topic 605) *: Milestone Method of Revenue Recognition—a consensus of the FASB Emerging Issues Task Force* (“ASU 2010-17”) was issued and will amend the accounting for revenue arrangements under which a vendor satisfies its performance obligations to a customer over a period of time, when the deliverable or unit of accounting is not within the scope of other authoritative literature, and when the arrangement consideration is contingent upon the achievement of a milestone. The amendment defines a milestone and clarifies whether an entity may recognize consideration earned from the achievement of a milestone in the period in which the milestone is achieved. This amendment is effective on a prospective basis for milestones achieved on or after January 1, 2011, with early adoption permitted. The amendment may be applied retrospectively to all arrangements or prospectively for milestones achieved after the effective date. We expect to prospectively apply the amended guidance to milestones achieved on or after January 1, 2011.

**OSIRIS THERAPEUTICS, INC.**
**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

The new guidance is consistent with our current revenue recognition policies for arrangements with milestones. As a result, we do not believe the adoption of this ASU will have a material impact on our financial statements.

## 3. Collaboration Agreements and Government Contract

We are a party to several material collaborative agreements and other contracts as fully described in Note 2 of our Annual Report on Form 10-K for the year ended December 31, 2009 ("2009 10-K"). There have not been any material changes to any of these agreements during 2010 that require disclosure. 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.

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

In April 2008, we committed to a plan to sell our entire product line relating to the processing, manufacturing, marketing and selling of Osteocel® and Osteocel® XO, an allograft material containing cancellous bone, used in spinal fusion and other surgical procedures. We refer to these assets as our Osteocel asset disposal group, and on May 2, 2008, we entered into an Asset Purchase Agreement to sell these assets to NuVasive, Inc., a Delaware corporation. Not included among the Osteocel asset disposal group is Osteocel® XC, our second generation product candidate under development for bone repair, utilizing culture expanded mesenchymal stem cells to create a synthetic version of Osteocel.

The Asset Purchase Agreement, which was amended several times, provided for up to $85.0 million of total purchase price, all of which we ultimately earned.

We recognized a pre-tax gain of approximately $23.5 million on the sale of discontinued operations during 2009, essentially all of which was recognized during the first fiscal quarter of that year. Net of taxes, the gain on the sale was approximately $20.5 million during 2009.

As stipulated under the Asset Purchase Agreement, 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.

We eliminated the Osteocel asset 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 group at December 31, 2009 were current liabilities totaling $412,000, all of which were paid during the first quarter of 2010.

Summarized operating results of the Osteocel asset disposal group for the three and nine months ended September 30, 2009 are as follows:

| | Three Months Ended September 30, 2009 ($000) | Nine Months Ended September 30, 2009 ($000) |
|---|---|---|
| Product sales | $ (1) | $ 6,295 |
| Cost of goods sold | 70 | 4,985 |
| Gross profit (loss) | (71) | 1,310 |
| Selling, general & administrative expenses | — | 124 |
| Income (loss) from operations of discontinued operations, before income taxes | (71) | 1,186 |
| Income tax benefit | 43 | 117 |
| Income (loss) from operations of discontinued operations | $ (28) | $ 1,069 |

**OSIRIS THERAPEUTICS, INC.**
**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

## 5. Segment Reporting

At the end of the third quarter of 2009, we created a Biosurgery Division, focused on developing high-end biologic products for use in surgical procedures.

In 2010, we began to manage our business in two reportable operating segments: the Therapeutics segment and the Biosurgery segment. Our Therapeutics segment focuses on developing and marketing products to treat medical conditions in the inflammatory, autoimmune, orthopedic and cardiovascular areas. Its operations have focused on clinical trials and discovery efforts to identify additional medical indications. Our Therapeutics segment does not presently have any products approved for sale and its revenues consist of collaborative research agreements and royalties as described in Note 2- *Significant Accounting Policies* .

Our Biosurgery segment is focused on the development, manufacture and sale of biologic products designed to promote the body's natural healing process and improve surgical outcomes. We commenced the manufacturing of our first Biosurgery product, a regenerative wound care product, during the first quarter of 2010. During the first and second quarters of 2010, we distributed the product only for initial clinical evaluation. We launched the product for commercial sale during the third quarter of 2010, and recognized revenues of approximately $100,000 from the sales of Biosurgery products. Accordingly, we have incurred research, development, manufacturing, general, and administrative costs related to the Biosurgery segment throughout 2010, but have recognized revenue from sales only during the third quarter of 2010. As a result of these start up costs, any measure of segment profitability from our Biosurgery segment for 2010 is not indicative of the segment's expected future results.

Therefore, although we have historically managed our business based primarily on the costs specifically attributable to each of our segments, we expect to begin managing our business based on more traditional measures of segment income as we increase our production and sales levels for our Biosurgery products.

The costs specifically attributable to each of our segments for the three and nine months ended September 30, 2010 are as follows:

| | Three Months Ended September 30, 2010 | | | Nine Months Ended September 30, 2010 | | |
|---|---|---|---|---|---|---|
| | Therapeutics | Biosurgery | Total | Therapeutics | Biosurgery | Total |
| **Product sales** | $ — | $ 99 | $ 99 | $ — | $ 99 | $ 99 |
| Cost of goods sold | — | 34 | 34 | — | 34 | 34 |
| Gross profit | — | 65 | 65 | — | 65 | 65 |
| **Revenue from collaborative research agreements, government contract and royalties** | 10,659 | — | 10,659 | 32,340 | — | 32,340 |
| Operating expenses: | | | | | | |
| Research and development | 4,639 | 821 | 5,460 | 15,231 | 3,245 | 18,476 |
| General and administrative | 1,084 | 184 | 1,268 | 4,185 | 492 | 4,677 |
| | 5,723 | 1,005 | 6,728 | 19,416 | 3,737 | 23,153 |
| Segment income (loss) | $ 4,936 | $ (940) | $ 3,996 | $ 12,924 | $ (3,672) | $ 9,252 |

In general, our total assets, including long-lived assets such as property and equipment, and our capital expenditures are not specifically allocated to any particular operating segment. Accordingly, capital expenditures and total asset information by reportable segment is not presented. The only assets that are allocated to the individual segments are the inventory and accounts receivable specifically related to each segment.

**OSIRIS THERAPEUTICS, INC.**
**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

The assets specifically attributable to each of our segments as of September 30, 2010 are as follows:

| | September 30, 2010 ($000) | |
|---|---|---|
| | Biologic Drug Candidates | Biosurgery |
| **Segment assets:** | | |
| Accounts receivable | $ 168 | $ 94 |
| Inventory | — | 321 |
| **Total segment assets** | **$ 168** | **$ 415** |

## 6. Income Tax (Benefit) Expense

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

The tax expense for the nine months ended September 30, 2010 reflects an effective tax rate of 7.4% 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.

During the three and nine months ended September 30, 2010 and 2009, we recognized the following income tax expense (benefit):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2010 | 2009 | 2010 | 2009 |
| | ($000) | ($000) | ($000) | ($000) |
| Tax expense (benefit) to continuing operations | $ (525) | $ (238) | $ 692 | $ (2,636) |
| Tax expense of operations of discontinued operations | — | 43 | — | 117 |
| Tax expense (benefit) of sale of discontinued operations | — | (660) | — | 2,317 |
| Total income tax expense (benefit) | $ (525) | $ (855) | $ 692 | $ (202) |

At September 30, 2010, the balance of our net operating loss and tax credit carryforwards is $92.8 million. During the quarter ended September 30, 2010, we released a portion of valuation allowance in the amount of $2.9 million to reflect our expectation of being able to utilize net operating loss and tax credit carryforwards in 2011. Our remaining deferred tax assets have been fully reserved in both 2010 and 2009 since their ultimate future realization cannot be assured.

**OSIRIS THERAPEUTICS, INC.**
**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

## 7. Investments Available for Sale

Investments available for sale consisted of the following as of September 30, 2010 and December 31, 2009:

| | September 30, 2010 $000 | | | |
|---|---|---|---|---|
| | | Unrealized | | |
| | Cost | Gain | Loss | Fair Value |
| **Cash equivalents:** | | | | |
| Money market funds & certificates of deposit | $ 13,728 | $ — | $ (3) | $ 13,725 |
| Commercial paper | 9,597 | — | — | 9,597 |
| | 23,325 | 0 | (3) | 23,322 |
| **Short term investments:** | | | | |
| Corporate notes and bonds | 47,641 | 12 | (8) | 47,645 |
| US government agencies | 4,197 | 4 | — | 4,201 |
| | 51,838 | 16 | (8) | 51,846 |
| **Total investments available for sale** | **$ 75,163** | **$ 16** | **$ (11)** | **$ 75,168** |

| | December 31, 2009 $000 | | | |
|---|---|---|---|---|
| | | Unrealized | | |
| | Cost | Gain | Loss | Fair Value |
| **Cash equivalents:** | | | | |
| Money market funds & certificates of deposit | $ 23,706 | $ 1 | $ — | $ 23,707 |
| Commercial paper | 19,393 | — | — | 19,393 |
| | 43,099 | 1 | — | 43,100 |
| **Short term investments:** | | | | |
| Common stock | 573 | — | (84) | 489 |
| Corporate notes and bonds | 42,586 | 36 | (44) | 42,578 |
| US government agencies | 13,239 | 6 | (3) | 13,242 |
| | 56,398 | 42 | (131) | 56,309 |
| **Total investments available for sale** | **$ 99,497** | **$ 43** | **$ (131)** | **$ 99,409** |

The following table summarizes maturities of our investments available for sale as of September 30, 2010 and December 31, 2009:

| | September 30, 2010 ($000) | | December 31, 2009 ($000) | |
|---|---|---|---|---|
| | Cost | Fair Value | Cost | Fair Value |
| **Maturities:** | | | | |
| Within 3-months | $ 63,160 | $ 63,159 | $ 28,330 | $ 28,240 |
| Between 3—12 months | 4,508 | 4,510 | 65,824 | 65,819 |
| Between 1—2 years | 7,495 | 7,499 | 5,343 | 5,350 |
| **Total investments available for sale** | **$ 75,163** | **$ 75,168** | **$ 99,497** | **$ 99,409** |

Realized gains and losses and investment income earned on investments available for sale were $27,000 and $151,000, respectively, for the three and nine months ended September 30, 2010, and have been included as a component of “Other income, net” in the accompanying financial statements.

**OSIRIS THERAPEUTICS, INC.**
**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

## 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.

When quoted prices in active markets for identical assets are available, we use these quoted market prices to determine the fair value of financial assets and classify these assets as Level 1. In other cases where a quoted market price for identical assets in an active market is either not available or not observable, we obtain the fair value from a third party vendor that uses pricing models, such as matrix pricing, to determine fair value. These financial assets would then be classified as Level 2. In the event quoted market prices were not available, we would determine fair value using broker quotes or an internal analysis of each investment's financial statements and cash flow projections. In these instances, financial assets would be classified based upon the lowest level of input that is significant to the valuation. Thus, financial assets might be classified in Level 3 even though there could be some significant inputs that may be readily available. To date, we have never had any assets that were required to be classified as Level 3.

Effective January 1, 2010, we adopted the FASB's updated guidance related to fair value measurements and disclosures, which requires a reporting entity to disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and to describe the reasons for the transfers. In addition, in the reconciliation for fair value measurements using significant unobservable inputs, or Level 3, a reporting entity should disclose separately information about purchases, sales, issuances and settlements. The updated guidance also requires that an entity should provide fair value measurement disclosures for each class of assets and liabilities and disclosures about the valuation techniques and inputs used to measure fair value for both recurring and non-recurring fair value measurements for Level 2 and Level 3 fair value measurements. The guidance is effective for interim or annual financial reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances and settlements in the roll forward activity in Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. Therefore, the Company has not yet adopted the guidance with respect to the roll forward activity in Level 3 fair value measurements. The adoption of the updated guidance for Levels 1 and 2 fair value measurements did not have an impact on the Company's consolidated results of operations or financial condition, as there were no transfers to or from Levels 1 and 2 to date in 2010.

**OSIRIS THERAPEUTICS, INC.**
**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)**
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009**

Assets and liabilities measured at fair value on a recurring basis are summarized below as of September 30, 2010 and December 31, 2009:

| | September 30, 2010 ($000s) | | | |
|---|---|---|---|---|
| | Level I | Level II | Level III | Total |
| **Assets** | | | | |
| Cash Equivalents | $ 12,878 | $ — | $ — | $ 12,878 |
| Government Obligations | 2,203 | — | — | 2,203 |
| Certificates of Deposit | — | 847 | — | 847 |
| Agency Obligations | — | 43,229 | — | 43,229 |
| Corporate Debt Securities & Commercial Paper | — | 15,081 | — | 15,081 |
| Municipal Securities | — | — | — | — |
| Foreign Bonds | — | 930 | — | 930 |
| Common Stock | — | — | — | — |
| **Short Term Investments Available for Sale** | **$ 15,081** | **$ 60,087** | **$ —** | **$ 75,168** |

| | December 31, 2009 ($000s) | | | |
|---|---|---|---|---|
| | Level I | Level II | Level III | Total |
| **Assets** | | | | |
| Cash Equivalents | $ 18,456 | $ — | $ — | $ 18,456 |
| Government Obligations | 11,367 | — | — | 11,367 |
| Certificates of Deposit | — | 5,251 | — | 5,251 |
| Agency Obligations | — | 38,691 | — | 38,691 |
| Corporate Debt Securities & Commercial Paper | — | 23,795 | — | 23,795 |
| Municipal Securities | — | 101 | — | 101 |
| Foreign Bonds | — | 1,259 | — | 1,259 |
| Common Stock | — | 489 | — | 489 |
| **Short Term Investments Available for Sale** | **$ 29,823** | **$ 69,586** | **$ —** | **$ 99,409** |

## 9. Subsequent Events

We evaluated our September 30, 2010 financial statements for subsequent events through the date the financial statements were issued. We are not aware of any subsequent events which would require recognition or disclosure in the financial statements.

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

### Cautionary Statements About 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. Statements included or incorporated herein which are not historical facts are forward-looking statements. When used in this Quarterly Report, the words *estimates, expects, anticipates, projects, plans, intends, believes, forecasts* and variations of such words or similar expressions are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying forward-looking statements.

Forward-looking statements reflect management's current views with respect to future events and performance and are based on currently available information and management's assumptions regarding future events. While management believes that its assumptions are reasonable, forward-looking statements are subject to various known and unknown risks and uncertainties and actual results may differ materially from those expressed or implied herein. In connection with the "safe harbor provisions" of the Private Securities Litigation Reform Act of 1995, the Company notes that certain factors, among others, which could cause future results to differ materially from the forward-looking statements, expectations and assumptions expressed or implied herein are discussed in greater detail in our Annual Report on Form 10-K under Part I - Item 7; "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Item 1A "Risk Factors," and may be discussed elsewhere herein or in other documents we file with the Securities and Exchange Commission, or SEC. Examples of forward-looking statements may include, without limitation, statements regarding any of the following: our product development efforts; our clinical trials and anticipated regulatory requirements, and our ability to successfully navigate these requirements; the success of our product candidates in development; status of the regulatory process for our 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 (MSCs) and biologic drug candidates (including Prochymal® and Chondrogen®); our cash needs; patents, trademarks and other proprietary rights; the safety and ability of our potential products to treat disease; our ability to supply a sufficient amount of our product candidates and, if approved, products to meet demand; our costs to comply with governmental regulations; our relationship with collaborating partners; our ability to maintain and benefit from our collaborative arrangements; our ability to benefit from government contracts; our plans for sales and marketing; our plans regarding facilities; types of regulatory frameworks we expect will be applicable to our potential products; and results of our scientific research.

Readers are cautioned that all forward-looking statements attributable to us or persons acting on our behalf apply only as of the date of this Quarterly Report and are expressly qualified in their entirety by the cautionary statements included herein. We undertake no obligation to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances and do not intend to do so.

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our audited Financial Statements and related notes thereto and other disclosures included as part of our Annual Report on Form 10-K for the year ended December 31, 2009, and our unaudited Condensed Financial Statements for the three and nine months ended September 30, 2010 and 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, 2009 under Part I — Item 1A "Risk Factors" and in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2010 under Part II — Item 1A "Risk Factors." There may be other factors that may cause our actual results to differ materially from the forward-looking statements.

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

### 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, 2010 and 2009. 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, 2009. Historical results and any discussion of prospective results may not indicate our future performance. See "Cautionary Statements About Forward-Looking Information."

We are a leading stem cell company headquartered in Columbia, Maryland and focused on developing and marketing products to treat serious medical conditions in the inflammatory, autoimmune, orthopedic, and cardiovascular areas. We believe our stem cell products have significant therapeutic potential because of their ability to regulate inflammation, promote tissue regeneration and prevent pathological scar formation. We were incorporated in Maryland in March 2010. Our predecessor company was organized in 1992. We have two business segments, Therapeutics and Biosurgery. Our Therapeutics business is focused on developing biologic stem cell drug candidates from a readily available and non-controversial source — adult bone marrow. Our Biosurgery division works to harness the ability of cells and novel

constructs to promote the body's natural healing with the goals of improving surgical outcomes and offering better treatment options for patients and physicians.

Our lead biologic drug candidate, Prochymal (remestemcel-L), is being evaluated in a number of indications, including acute graft versus host disease ("GvHD"), Crohn's disease, acute myocardial infarction, type 1 diabetes, pulmonary disease and gastrointestinal injury resulting from radiation exposure (animal rule). Prochymal is the only stem cell therapeutic currently granted both Orphan Drug and Fast Track status by the United States Food and Drug Administration ("FDA"). Our pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen for osteoarthritis in the knee.

In the fourth quarter of 2008, we entered into a collaboration agreement with Genzyme Corporation for the development and commercialization of Prochymal and Chondrogen. Under the terms of the agreement, we retained the rights to commercialize Prochymal and Chondrogen in the United States and Canada and Genzyme has been granted exclusive rights to commercialize Prochymal and Chondrogen in all other countries, except with respect to GvHD in Japan, where Prochymal has previously been licensed to another pharmaceutical company. Under the agreement, we were paid $130.0 million for these rights. The 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.

We have also 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 U.S. Department of Defense, 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. 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 had produced and marketed since July 2005, for regenerating bone in orthopedic indications. On May 8, 2008, we entered into an Asset Purchase Agreement to sell our entire product line relating to the processing, manufacturing, marketing and selling of Osteocel to NuVasive, Inc. The total proceeds from the sale of Osteocel were $85.0 million, all of which has been received by us. The assets and operations related to Osteocel are reported as discontinued operations in the condensed financial statements included in this Quarterly Report on Form 10-Q for all periods.

In August 2009, we announced the creation of a Biosurgery Division focused on developing and marketing high-end biological products for use in surgical procedures. We intend to build on the success of our first generation implantable product, Osteocel, which generated over $40 million of revenue for us before being sold for $85.0 million in 2008. We introduced our first biologic product from the Biosurgery Division during March 2010 for clinical evaluation and began commercial sales during the third fiscal quarter of 2010.

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 including 49 U.S. and 299 foreign patents owned or licensed. We have 23 U.S. patent applications pending and 73 foreign patent applications pending.

Our two biologic drug candidates utilize human mesenchymal stem cells, or MSCs. MSCs can selectively differentiate, based on the tissue environment, into various tissue lineages such as bone, muscle, fat, tendon, ligament, cartilage and bone marrow stroma. In addition, MSCs have anti-inflammatory properties and can prevent fibrosis or scarring. These characteristics give MSCs the potential to treat a wide variety of medical conditions. We believe that our biologic drug candidates have advantages over other stem cell therapeutics in development for 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 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.

- **U niversal 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 leading to serious medical complications and can even be fatal. 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 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.

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

| Drug Candidate | Indication | Status |
|---|---|---|
| **Prochymal** | Acute GvHD | Phase 3 |
| | Treatment-Resistant Acute GvHD | Expanded Access |
| | Biologics Refractory Crohn's Disease | Phase 3 |
| | Type I Diabetes Mellitus | Phase 2 |
| | Acute Myocardial Infarction | Phase 2 |
| | Pulmonary Disease | Phase 2 |
| | Acute Radiation Syndrome | Phase 3 (Animal Rule) |
| | | |
| **Chondrogen** | Osteoarthritis & Cartilage Protection | Phase 2 |

***Prochymal,*** our lead biologic drug candidate, is being evaluated in Phase 3 trials for a number of indications including acute graft versus host disease ("GvHD"), Crohn's disease, acute myocardial infarction, type 1 diabetes, pulmonary disease and gastrointestinal injury resulting from radiation exposure (animal rule). Prochymal is the only stem cell therapeutic currently designated by the FDA as both an Orphan Drug and Fast Track product.

*Prochymal for Treatment-Resistant GvHD*

GvHD is a life threatening immune system reaction that commonly affects one or more of the following organs: skin, gastrointestinal tract, and liver, in patients who have received a bone marrow transplant. Although in the U.S. there are no drugs approved for treating GvHD, the disease is commonly treated off-label with steroids. GvHD that does not respond to this treatment is known as steroid refractory GvHD. A large majority of steroid refractory GvHD patients die within six months. In a Phase 2 trial for treatment refractory GvHD, we enrolled patients that did not respond to treatment with steroids and at least one second line therapy. Of these patients, all responded to treatment with Prochymal, and 59% achieved complete resolution of their disease. Prochymal has been granted Fast Track status by FDA as well as Orphan Drug status by FDA and the European Medicines Agency for GvHD.

In May 2008, we received clearance from the FDA to initiate an expanded access treatment program making Prochymal available to children with life threatening GvHD. Under the program, children, 2 months to 17 years of age, with Grades B-D acute GvHD that hasn't responded to steroids are eligible for treatment. Upon completion of enrollment of the two Phase 3 trials evaluating Prochymal in adults with GvHD, as described below, the expanded access program was broadened to include patients 18 to 70 years of age. The expanded access programs for Prochymal in treating adult and pediatric patients with refractory GvHD are ongoing.

In February 2010, we reported the results of a study evaluating Prochymal as a rescue therapy in 59 pediatric patients with severe, treatment-resistant acute GvHD. The trial enrolled patients with Grades B-D acute GvHD who had failed steroids and other immunosuppressive agents. Patients in the study received two intravenous infusions of Prochymal per week for a total of four weeks. Patients who experienced a partial response by day 28 were eligible for continued treatment. GvHD assessments were used in the study to detect improvements in patients treated with Prochymal. At study entry, 88% of children had Grade C/D GvHD, the most severe forms of GvHD and were unresponsive to an average of three lines of therapy. Overall response to treatment with Prochymal at 28 days was 63%. Response to Prochymal at day 28 significantly improved survival over those patients who progressed (78% vs. 9%, $p<0.05$). Patients in the trial were treated at 31 pediatric transplant centers across the U.S., Canada, Europe and New Zealand.

In September 2009, we announced the preliminary results for the two Phase 3 trials evaluating Prochymal in adults with GvHD, as described below. While the trials did not reach significance in their primary endpoints, the studies did reveal several important findings:

- The primary endpoint for the steroid-refractory GvHD trial (durable complete response) for the per protocol population approached statistical significance (40% Prochymal vs. 28%, standard of care, $p=0.087$, $n=179$);
- Prochymal significantly improved response in steroid-refractory liver (76% vs. 47%, $p=0.03$) and gastrointestinal GvHD (82% vs. 68%, $p=0.03$);
- In the sickest patients—those with GvHD affecting all three organs, skin, liver and gastrointestinal tract—treatment with Prochymal resulted in a 63% overall response rate, while none of the placebo-treated patients responded ($p<0.05$);
- Children receiving Prochymal had an overall response rate of 64% compared to 36% in patients receiving placebo; and
- In children with steroid-refractory GvHD, Prochymal more than doubled complete response rates (64% vs. 29%) and reduced disease progression by half (21% vs. 43%).

In July 2010, we announced that the Biologics and Genetic Therapies Directorate of Health Canada has completed its initial evaluation and accepted for full review our New Drug Submission of Prochymal for the treatment of GvHD. Health Canada has notified us that the application has been granted Priority Review, shortening the scheduled examination period from 300 to 180 days. Heath Canada also informed us that it plans to add Prochymal to its Register of Innovative Drugs, subject to a final review upon approval. This registration would confer eight years of market exclusivity, beginning on the date of Prochymal's approval for commercial sale in Canada. This registration also generally provides that, during such period of market exclusivity, no submission for a generic version of Prochymal would be approved by Health Canada for GvHD.

*Phase 3 Clinical Trial—Steroid Refractory Acute GvHD*

Our Phase 3 trial evaluated the safety and efficacy of Prochymal in conjunction with standard of care for the treatment of patients who had failed to respond to corticosteroid treatment for acute GvHD. This clinical trial was a double-blind, placebo-controlled study. Patients six months to 70 years of age were randomized to receive Prochymal or placebo at a 2:1 ratio in addition to standard of care. The trial completed enrollment with 260 patients in 2009 and treated 244 patients from 72 leading bone marrow transplant centers in the United States, Canada, Europe and Australia.

The primary endpoint, durable complete response, for the per-protocol population in the Phase 3 trial evaluating Prochymal in steroid-refractory GvHD approached but did not reach statistical significance, with 40% of patients receiving Prochymal, as compared to 28% of placebo patients, achieving a durable complete response. The per-protocol patient population refers to the group of patients that met all of the study protocol requirements, such as inclusion and exclusion criteria. The addition of Prochymal to standard of care significantly improved response in steroid-refractory liver (76% vs. 47%, $p=0.03$) and gastrointestinal (82% vs. 68%, $p=0.03$) GvHD. In the sickest patients—those with GvHD affecting all three organs—skin, liver and gastrointestinal tract—treatment with Prochymal resulted in a 63% overall response rate, while none of the placebo-treated patients responded ($p<0.05$). Prochymal also demonstrated a positive safety profile relative to placebo.

*Phase 3 Clinical Trial—First Line Treatment of Acute GvHD.*

Our previous Phase 2 trial for treatment of newly diagnosed acute GvHD completed enrollment in 2009 and indicated that patients were twice as likely to have total clinical resolution of their disease when Prochymal was added to steroid therapy, compared to reported results for treatment with steroids alone. Twenty-nine of 31 patients, or 94%, responded in the Phase 2 trial, after receiving two infusions of Prochymal, with 24 patients, or 77% achieving a complete response, meaning the patients had experienced total clinical resolution of the disease. At six months, 61% of all patients treated with Prochymal still had a durable response requiring no additional immunosuppressive therapy, clinical intervention, or increased steroid use. Of these, 95% were alive at six months.

The Phase 3 trial to evaluate Prochymal as a first line treatment for GvHD is a randomized, double blind, placebo controlled study that completed enrollment in 2009 with 192 patients from 52 leading transplant centers across the United States, Canada and Australia. Patients received a total of six infusions during the first four weeks of the study. The majority of patients enrolled in this trial were suffering from skin GvHD, which was well-controlled with steroids, particularly when given at a uniform controlled dose as prescribed in the protocol. The high response rates diminished the potential for Prochymal to demonstrate an effect.

*Phase 3 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 received Fast Track designation from the FDA for the development of Prochymal for patients with moderate to severe biologics refractory Crohn's disease.

We completed a Phase 2 trial in 2006 studying Prochymal as a treatment for moderate to severe Crohn's disease that is refractory to steroids and other immunosuppressants. Four leading centers in the United States enrolled ten patients for the prospective, randomized, open label trial. Patients with moderate to severe Crohn's disease with a Crohn's Disease Activity Index ("CDAI") of at least 220 who had previously failed treatment with steroids and other immunosuppressive agents were given two infusions of Prochymal, seven days apart. The average CDAI at baseline was 341 for patients enrolled in the study. Patients had suffered from Crohn's disease for an average of 14.2 years, and 80% of the patients required prior surgical intervention to treat their Crohn's disease prior to study entry. Within 14 days of treatment with Prochymal, one-third of the patients had a reduction of CDAI of greater than 100 points. Mean IBDQ scores improved significantly from baseline to Day 28 (113 to 146, $p=0.008$) and one-third of the patients reported IBDQ scores of at least 170, indicating they had achieved clinical remission of their disease. There were no infusional toxicities, and no treatment-related severe adverse events.

As a result of the encouraging data from the Phase 2 trial, a Phase 3 trial evaluating Prochymal for the treatment of refractory moderate to severe Crohn's disease was initiated. The placebo-controlled, double-blind study was designed to enroll 270 patients, 18 to 70 years of age with a CDAI greater than 250. The primary endpoint of this trial is the proportion of patients with CDAI of less than 150 (clinical remission) at day 28. Patients were enrolled at approximately 60 leading centers in the U.S. and Canada.

In April 2010, we announced that we would resume enrollment in our Phase 3 Crohn's program, following its suspension in 2009 over concerns about the trial design. The Crohn's program had initially consisted of two linked trials — one aimed at inducing remission (Protocol 603) and the other at maintaining response (Protocol 610) in patients who had failed other available treatments for the disease. The primary endpoint for Protocol 603, which included a placebo and two Prochymal dose arms, is the proportion of patients experiencing disease remission within 28 days of initiation of therapy with Prochymal, compared to those patients receiving placebo. For a patient to reach the primary end-point of disease remission, their CDAI score must fall to below 150. Concerns that the trial design would make it difficult to detect a treatment effect led to the April 2009 suspension. The trial remained blinded following suspension, however, to permit an interim analysis of the 207 patients enrolled in the study at that time. The findings of the interim analysis showed that the majority of patients enrolled prior to suspension had failed at least two immunomodulators and two biological agents before commencement of treatment in the trial. The trial design requires patients to complete a "washout" period prior to study entry, to ensure that residual benefit from prior therapy does not influence their response. There were no differences in average Crohn's Disease Activity Index (CDAI) scores at entry, which exceeded 350 in all arms prior to treatment, indicating the patients had very debilitating disease. For the primary endpoint of disease remission, the interim analysis revealed that one dose arm for Prochymal approached statistical significance in the intent to treat (ITT) population, and reached significance in the per protocol population. Additionally, the analysis showed that Prochymal continued to demonstrate a benign safety profile with no significant differences in any of the pre-defined safety outcomes compared to placebo. These results showed that, despite the initial concerns, the effect size or the difference between the Prochymal and placebo response rates, of one dose arm of Prochymal is consistent with the original statistical assumptions of the protocol and is significantly outperforming placebo. As a result, enrollment in this clinical trial evaluating Prochymal for patients with treatment resistant Crohn's disease was resumed.

The decision to resume enrollment was made following discussions with the Food and Drug Administration (FDA) about the results of the interim analysis. Enrollment is now ongoing with the best-performing Prochymal dose arm as determined by the interim analysis and the placebo arm, according to the pre-specified adaptive trial design. The trial has been repowered to compensate for the statistical penalty incurred by the interim analysis in the ITT population. The follow-on maintenance trial (Protocol 610) has been discontinued to remove the potential for bias.

*Phase 2 Clinical Trial—Acute Myocardial Infarction.*

Prochymal is also being evaluated as a therapy to improve heart function in patients who have suffered a heart attack. Based on statistics published in 2005 by the American Stroke Association and the American Heart Association, approximately 700,000 individuals in the United States each year experience their first heart attack. According to these same statistics, approximately 20% of these patients suffer extensive damage to their heart muscle leading to heart failure within six years. In preclinical studies in animal models, Prochymal targeted the damaged area of the heart following a single intravenous infusion. These studies also indicate that Prochymal prevents scar formation that typically occurs after a heart attack and improves cardiac function eight to ten weeks after its administration.

Positive two-year data was reported for a Phase 1 clinical trial evaluating the safety and efficacy of the intravenous administration of Prochymal in patients who experienced their first acute myocardial infarction ("AMI"). In the 53-patient, double-blind, placebo-controlled trial, patients receiving the therapy had significantly lower rates of adverse events, such as cardiac arrhythmias, as well as significant improvements in heart, lung and global function. Administration of Prochymal was found to be well tolerated at all dose levels. In December 2009, results from the study were published in the *Journal of the American College of Cardiology* . Based on these positive findings, we received approval from the FDA to initiate a Phase 2 trial.

A Phase 2 double-blind, placebo-controlled trial to evaluate the safety and efficacy of Prochymal in conjunction with standard of care to improve heart function in patients who experience a first heart attack is currently enrolling patients. The trial is being conducted at leading institutions and academic research centers in the United States and Canada. Target enrollment is 220 patients and those participating will be randomized to Prochymal or placebo at a 1:1 ratio.

*Phase 2 Clinical Trial—Early Onset Type 1 Diabetes Mellitus.*

In early 2010, enrollment was completed for 63 patients in our Phase 2, double-blind, placebo-controlled study evaluating Prochymal for the treatment of early onset type 1 diabetes in individuals 12 to 35 years old. We believe that based upon their mechanism of action, MSCs may home to the pancreas and inhibit the local immune and inflammatory responses, preventing the destruction of pancreatic islets and promoting the repair of pancreatic tissue damage. Patients were enrolled within 2 to 20 weeks of being diagnosed with type 1 diabetes and received three infusions of Prochymal over the course of 60 days. The primary efficacy endpoint, the measurement of C-peptide produced after glucose stimulation, will be measured at one year. 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. To date, we received $3.5 million from JDRF to fund clinical costs, and expect to receive the remaining $500,000 during the fourth quarter of 2010.

*Phase 2 Clinical Trial—Chronic Obstructive Pulmonary Disease*

Enrollment in the 62-patient Phase 2 clinical trial evaluating the safety and efficacy of Prochymal in conjunction with standard of care for improving pulmonary function in patients with moderate to severe Chronic Obstructive Pulmonary Disease ("COPD") was completed in the second half of 2008. Patients in the double-blind, placebo-controlled study 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, systemic inflammation and quality of life assessments. In addition, exacerbations and hospitalizations due to COPD will be monitored for both safety and efficacy. Patients were evaluated over the course of two years following initial Prochymal or placebo infusion.

At the six-month interim analysis, the trial met its primary goal of demonstrating the safety of Prochymal in patients with compromised pulmonary function. Prochymal significantly decreased systemic inflammation in patients when compared to those receiving placebo, as determined by C-reactive protein (CRP). Despite this reduction in inflammation, however, pulmonary function in patients receiving Prochymal was not significantly improved compared to those receiving placebo.

*Phase 3 Development—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 and stockpiling of Prochymal for the treatment of acute radiation syndrome (“ARS”). Assuming FDA approval of Prochymal for ARS, the DoD may exercise purchase options for up to 20,000 doses of Prochymal at a price of $10,000 per dose.

***Chondrogen*** is our biologic drug candidate for the treatment of osteoarthritis and the reduction of pain in the knee. In 2006, we completed enrollment of a randomized double-blind, placebo controlled Phase 1/2 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 1/2 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 that 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 upfront payments to us 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 2010 and 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.

In 2003, we entered into an agreement with JCR Pharmaceuticals ("JCR"), granting it exclusive rights to Prochymal for the treatment of GvHD and other hematological malignancies in Japan. During the first quarter of 2010, we achieved a $1 million milestone from JCR for development progress in Japan. The collaboration with JCR also provides for additional milestone payments of up to $8.5 million for regulatory and sales milestones, as well as royalty payments on sales of the drug in Japan.

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 $470,000 in revenue under the terms of this contract in the first three fiscal quarters of 2010, 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 2 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 $630,000 in revenue during the first nine months of 2010 under this agreement.

*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, 2010, we incurred aggregate research and development costs of approximately $385 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:

- 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.

*Other Income (Expense), Net*

Investment income consists of interest earned on our cash and investments available for sale and realized gains and losses incurred on the sale of these investments. Interest expense consists of interest incurred on capital leases. We do not expect to incur material interest expense in the 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*

Historically, 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 and research and development carry-forwards. In the event that we become profitable within the next several years, we have net deferred tax assets (before a 100% valuation allowance) of approximately $92.8 million that may be utilized prior to us having to recognize any income tax expense or make payments to the taxing authorities other than the alternative minimum tax. The income tax accounting for the upfront fees we received from Genzyme Corporation require us to recognize revenue for income tax purposes several years earlier than we recognize this revenue for financial statement purposes, resulting in current income tax liabilities that we expect to exceed our ultimate aggregate income tax expense. During the third quarter of 2010, we released a portion of the valuation allowance in the amount of $2.9 million to reflect our expectation of being able to utilize net operating loss and tax credit carryforwards in 2011.

In fiscal 2010 and 2009, we recorded a provision for income taxes to recognize the U.S. Federal alternative minimum tax on our taxable income.

The tax provision for the three and nine months ended September 30, 2010, reflects an effective tax rate for continuing operations of 7.4% 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 2010.

**Critical Accounting Policies**

There have been no material changes in our critical accounting policies, estimates and judgments during the nine months ended September 30, 2010 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2009, other than as disclosed herein.

**Results of Operations**

***Comparison of Three Months Ended September 30, 2010 and 2009***

*Revenues from Collaborative Research Licenses & Grants*

Revenues from collaborative research licenses and grants were $10.7 million for the three months ended September 30, 2010 compared to $10.6 million for the third quarter of fiscal 2009. During the three months ended September 30, 2010, we recognized $10.0 million in revenue from our collaborative agreement with Genzyme and $210,000 from our collaborative agreement with JDRF. Our revenues for the three month period also include $360,000 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, 2009 consisted of $10.0 million from the Genzyme agreement, $465,000 from the JDRF collaboration and $55,000 from the DoD contract, plus other minor royalties.

*Biosurgery Product Sales*

During the three months ended September 30, 2010, we launched commercial sales of wound care products manufactured by our Biosurgery Division and recognized $99,000 in revenue and gross profit of $65,000. We are continuing to distribute the majority of these products for clinical evaluation and expect commercial sales to ramp up slowly until we obtain reimbursement approvals.

*Research and Development Expenses*

Research and development expenses for the three months ended September 30, 2010 were $5.5 million as compared to research and development expenses of $16.2 million for the same period of 2009. The third quarter 2010 expenses include $821,000 of development and initial manufacturing costs associated with our Biosurgery Division. The reduction in research and development expenses during the third quarter of 2010 when compared to the comparable period of the prior year reflects the completion of enrollment in our Phase 3 clinical trials and the associated reduction in site and patient costs, and reductions in our contract manufacturing activities as a result of the need for fewer clinical batches of Prochymal. We also incur research and development expenses in connection with the preparation of our applications for marketing approval as we work towards the commercialization of Prochymal for an initial indication.

*General and Administrative Expenses*

General and administrative expenses were $1.3 million for the three months ended September 30, 2010 compared to $1.5 million for the comparable period in fiscal 2009. The non cash charge for share-based compensation allocated to general and administrative expenses during the fiscal quarter ended September 30, 2010 was $178,000 as compared to a credit of $141,000 for the same period last year (reflecting forfeitures of options related to employee turnover).

*Other Income (Expense), Net*

Investment income, net was $27,000 for the three months ended September 30, 2010, compared to $134,000 in the corresponding period in fiscal 2009. Our investments available for sale consist of relatively short-term, investment grade securities with a focus on avoiding market risk. Interest expense was immaterial in both periods.

*Income (Loss) from Discontinued Operations*

Our Osteocel operations were sold during fiscal 2009 for $85.0 million, all of which was received during 2009. During the third quarter of fiscal 2009, we recognized $608,000 of income from discontinued operations. The income from discontinued operations in the third fiscal quarter of 2009 was primarily the effect of the decrease in the estimated effective income tax rate for the full fiscal year.

***Comparison of Nine Months Ended September 30, 2010 and 2009***

*Revenues from Collaborative Research Licenses & Grants*

Revenues from collaborative research licenses and grants were $32.3 million for the nine months ended September 30, 2010 compared to $33.8 million for the first nine months of fiscal 2009. During the nine months ended September 30, 2010, we recognized $30.0 million in revenue from our collaborative agreement with Genzyme, $1.0 million from our collaboration with JCR, and $630,000 from our collaborative agreement with JDRF. Our revenues for the nine month period also include $470,000 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 for the nine months ended September 30, 2009 consisted of $30.0 million from the Genzyme agreement, $630,000 from the JDRF collaboration and $2.9 million from the DoD contract, plus other royalties.

*Research and Development Expenses*

Research and development expenses for the nine months ended September 30, 2010 were $18.5 million as compared to research and development expenses of $53.4 million for the same period of 2009. The first nine months of 2010 expenses include $3.2 million of development and initial manufacturing costs associated with our Biosurgery Division. The reduction in research and development expenses during the first nine months of 2010 when compared to the comparable period of the prior year reflects the completion of enrollment in several of our Phase 3 clinical trials and the associated reduction in site and patient costs, and reductions in our contract manufacturing activities as a result of the need for fewer clinical batches of Prochymal. . We also incur research and development expenses in connection with the preparation of our applications for marketing approval as we work towards the commercialization of Prochymal for an initial indication.

*General and Administrative Expenses*

General and administrative expenses were $4.7 million for the nine months ended September 30, 2010 compared to $6.7 million for the comparable period in fiscal 2009. The decrease in general and administrative expenses is primarily attributable to reductions in incentive compensation, non cash share-based compensation expense and reductions in our legal expenses related to our intellectual property. The non cash charge for share-based compensation, including share grants to members of our Board of Directors, allocated to general and administrative expenses during the nine months ended September 30, 2010 was $614,000 as compared to $1.1 million for the same period last year

*Other Income (Expense), Net*

Investment income, net was $151,000 for the nine months ended September 30, 2010, compared to $386,000 in the corresponding period in fiscal 2009. Our investments available for sale consist of relatively short-term, investment grade securities with a focus on avoiding market risk. Interest expense was immaterial in both periods.

***Income from Discontinued Operations***

Our Osteocel operations were sold during fiscal 2009 for $85.0 million, all of which was received during 2009. During the first nine months of fiscal 2009, we recognized $22.2 million of income from discontinued operations.

**Liquidity and Capital Resources**

***Liquidity***

At September 30, 2010, we had $76.3 million in cash and investments available for sale. We did not have any outstanding debt at any time during fiscal 2010 to date, or during all of fiscal 2009. Although there can be no assurance, we believe that we have sufficient liquidity on hand as of September 30, 2010 to fund our operations through the commercialization of our first biological drug candidate.

***Cash Flows***

***Comparison of Nine Months Ended September 30, 2010 and 2009***

Cash used in operating activities of continuing operations for the nine months ended September 30, 2010 was $24.2 million compared cash provided by continuing operations of $9.3 million in the corresponding fiscal period of the prior year. The 2010 income from continuing operations of $7.3 million was offset by net decreases in working capital, primarily accounts payable, accrued expenses, and deferred revenue. Cash provided by operating activities of continuing operations during the first nine months of 2009 reflect our loss from continuing operations of $23.3 million, which was increased primarily by a reduction in deferred revenue, which was offset by $56.1 million in net reductions in accounts receivable, primarily reflecting the $55.0 million payment to us from Genzyme.

Cash used by operating activities of discontinued operations for the first nine months of fiscal 2010 was $412,000, compared to cash used in operating activities of discontinued operations of $3.9 million in the same period of the prior year. The 2010 amount represents the final settlement of the current liabilities of discontinued operations that had been outstanding as of December 31, 2009. The 2009 amount reflects the cash portion of the income from discontinued operations generated in 2009, offset by a decrease in receivables and inventory.

Cash provided by investing activities during the first nine months of 2010 was $24.3 million compared to net cash used in investing activities of $4.8 million in the same period of the prior year. The 2010 amount primarily reflects the net sale of investments and minor property and equipment purchases. In the comparable period of fiscal 2009, we made net purchases of $14.4 million of investments and realize $9.9 million in net proceeds from the sale of our Osteocel business.

Cash provided by financing activities during the first nine months of 2010 was $144,000, and primarily reflects reductions in restricted cash used to collateralize letters of credit. Cash provided by financing activities during the first nine months of 2009 was $34,000, and consisted of the $536,000 increase in restricted cash to collateralize letters of credit, offset by the proceeds from the issuance of common stock pursuant to option exercises.

***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 3 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 Genzyme and JCR collaboration agreements;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including possible litigation costs and liabilities; and
- the costs of expanding our work force consistent with expanding our business and operations and status as a public company.

**Off-Balance Sheet Arrangements.**

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

**Item 3. Quantitative and Qualitative Disclosures About Market Risk** .

*Interest Rate Risk*

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

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

*Foreign Current Exchange Rate Risk*

We conduct clinical trial activities in areas that operate in a functional currency other than the United States dollar (USD). As a result, when the USD rises and falls against the functional currencies of these other nations, our costs will either increase or decrease by the relative change in the exchange rate. Foreign currency gains and losses were not significant during the three and nine months ended September 30, 2010 or 2009, and at the present time, we have elected not to hedge our exposure to foreign currency fluctuations.

*Derivative Instruments*

We do not enter into hedging or derivative instrument arrangements.

**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, 2010 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, 2009, as filed with the Securities and Exchange Commission on March 12, 2010 (the “Annual Report”), except as previously reported in Part II Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 filed on August 6, 2010, pursuant to when the risk factors found in our Annual Report under the subheadings “Certain provisions of Delaware law and of our charter and bylaws contain provisions that could delay and discourage takeover attempts and any attempts to replace our current management by stockholders” and “Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions”, both under the heading “Risks Related to our Common Stock” , were replaced in response to our reincorporation in Maryland.

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

None.

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

None.

**Item 4.** ( **Removed and Reserved** ).

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

None.

**Item 6. Exhibits.**

| Exhibit Number | Description of Exhibit |
|---|---|
| 31.1.1 | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002). |
| 31.2.1 | Certification of Principal Financial Officer pursuant 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. |

**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 5, 2010

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

Date: November 5, 2010

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

**Exhibit 31.1.1**

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

I, C. Randal Mills, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2010 of Osiris Therapeutics, Inc.;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 5, 2010

/s/ C. RANDAL MILLS
C. Randal Mills, Ph.D.
President & Chief Executive Officer

**Exhibit 31.2.1**

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

I, Philip R. Jacoby, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2010 of Osiris Therapeutics, Inc.;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 5, 2010

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

**Exhibit 32.1**

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

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

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2010

/s/ C. RANDAL MILLS
C. Randal Mills, Ph.D.
President & Chief Executive Officer

Date: November 5, 2010

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

This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the United States Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.