

OSIRIS THERAPEUTICS, INC.

Form 10-Q

August 11, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2008

or

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

For the transition period from to

Commission File Number: 001-32966

OSIRIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

7015 Albert Einstein Drive, Columbia, Maryland

(Address of principal executive offices)

71-0881115

(I.R.S. Employer Identification No.)

21046

(Zip Code)

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443-545-1800

(Registrant's telephone number, including area code)

None

(Former name, former address and former fiscal year, if changed since last report)

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

Large accelerated filer ☐

Accelerated filer ☒

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

Smaller reporting company ☐

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

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 August 7, 2008
Common Stock, par value \$0.001 per share	31,808,030

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OSIRIS THERAPEUTICS, INC.

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[Table of Contents](#)**PART I FINANCIAL INFORMATION****Item 1. Financial Statements - Unaudited.****OSIRIS THERAPEUTICS, INC.****Condensed Balance Sheets****Unaudited**

Amounts in thousands

	June 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash	\$ 2,353	\$ 704
Investments available for sale	4,662	17,460
Accounts receivable	1,544	549
Prepaid expenses and other current assets	2,097	1,583
Current assets of discontinued operations	10,675	8,445
Total current assets	21,331	28,741
Property and equipment, net	1,032	2,020
Restricted cash	280	280
Other assets	825	1,404
Long-term assets of discontinued operations	8,172	4,596
Total assets	\$ 31,640	\$ 37,041
LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 21,271	\$ 11,535
Notes payable, current portion	18,391	6,521
Capital lease obligations, current portion	283	886
Current liabilities of discontinued operations	3,974	2,552
Total current liabilities	43,919	21,494
Note payable, net of current portion	2,500	1,200
Other long-term liabilities	16	11
Total liabilities	46,435	22,705
Stockholders (deficit) equity:		
Common stock, \$0.001 par value, 90,000 shares authorized 31,771 and 31,648 shares outstanding in 2008 and 2007	32	32
Additional paid-in-capital	258,197	255,728
Accumulated other comprehensive loss	(632)	
Accumulated deficit	(272,392)	(241,424)

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Total stockholders' (deficit) equity		(14,795)		14,336
Total liabilities and stockholders' (deficit) equity	\$	31,640	\$	37,041

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

Table of Contents**OSIRIS THERAPEUTICS, INC.****Condensed Statements of Operations****Unaudited****Amounts in thousands, except per share data**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenue from government contracts, collaborative research agreements and royalties	\$ 2,530	\$ 295	\$ 2,892	\$ 574
Operating expenses:				
Research and development	19,048	10,440	35,742	18,934
General and administrative	1,782	1,501	4,390	3,007
Total operating expenses	20,830	11,941	40,132	21,941
Loss from operations	(18,300)	(11,646)	(37,240)	(21,367)
Interest expense, net	(172)	(418)	(381)	(761)
Loss from continuing operations	(18,472)	(12,064)	(37,621)	(22,128)
Income from operations of discontinued operations	3,104	1,606	6,653	169
Net loss	\$ (15,368)	\$ (10,458)	\$ (30,968)	\$ (21,959)
Basic and diluted net loss per share				
Loss from continuing operations	\$ (0.58)	\$ (0.43)	\$ (1.19)	\$ (0.80)
Income from discontinued operations	0.10	0.06	0.21	0.01
Net loss	\$ (0.48)	\$ (0.37)	\$ (0.98)	\$ (0.79)
Weighted Average Common Shares (basic and diluted)	31,769	27,914	31,754	27,649

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

Table of Contents**OSIRIS THERAPEUTICS, INC.****Condensed Statement of Stockholders (Deficit) Equity****For the six months ended June 30, 2008****Unaudited****Amounts in thousands, except for share and per share data**

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders (Deficit) Equity
Balance at January 1, 2008	31,648,437	\$ 32	\$ 255,728	\$	\$ (241,424)	\$ 14,336
Induced conversion of convertible notes into common stock (\$14.00 per share)	87,524		1,500			1,500
Exercise of options to purchase common stock (\$0.40 - \$0.80 per share)	13,069		5			5
Issuance of common stock for services rendered by directors (\$12.01 per share)	21,500		258			258
Share-based payment employee compensation			706			706
Comprehensive Loss:						
Net loss for the period					(30,968)	(30,968)
Unrealized loss on investments available for sale				(632)		(632)
Total Comprehensive Loss						(31,600)
Balance at June 30, 2008	31,770,530	\$ 32	\$ 258,197	\$ (632)	\$ (272,392)	\$ (14,795)

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

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OSIRIS THERAPEUTICS, INC.

Condensed Statements of Cash Flows

Unaudited

Amounts in thousands

	Six Months Ended June 30,	
	2008	2007
Cash flows from operating activities:		
Continuing Operations:		
Loss from continuing operations	\$ (37,621)	\$ (22,128)
Adjustments to reconcile loss from continuing operations to net cash used in continuing operations:		
Depreciation and amortization	940	821
Non cash share-based payments	887	827
Non cash interest expense	130	120
Changes in operating assets and liabilities:		
Accounts receivable	(995)	75
Prepaid expenses and other current assets	(513)	(107)
Other assets	560	328
Accounts payable and accrued expenses	9,736	(2,334)
Deferred revenue		(476)
Long-term interest payable and other liabilities	9	200
Net cash used in continuing operations	(26,867)	(22,674)
Discontinued Operations:		
Income from discontinued operations	6,653	169
Adjustments to reconcile income to net cash provided by (used in) discontinued operations:		
Depreciation and amortization	149	52
Non cash share-based payments	78	22
Changes in operating assets and liabilities:		
Accounts receivable	(1,684)	(561)
Inventory and other current assets	(546)	(95)
Accounts payable and accrued expenses	1,422	204
Net cash provided by (used in) discontinued operations	6,072	(209)
Net cash used by operating activities	(20,795)	(22,883)
Cash flows from investing activities:		
Purchases of property and equipment	(3,676)	(2,322)
Proceeds from sale of investments available for sale	12,353	24,797
Purchases of investments available for sale		(18,730)
Net cash provided by investing activities	8,677	3,745
Cash flows from financing activities:		
Principal payments on capital lease obligations and notes payable	(2,238)	(584)
Restricted cash		11
Proceeds from convertible and short-term notes payable	16,000	
Proceeds from issuance of common stock	5	20,059
Payment of debt financing fees		(400)
Net cash provided by financing activities	13,767	19,086

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Net increase in cash	1,649	(52)
Cash at beginning of period	704	714
Cash at end of period:	\$ 2,353	\$ 662

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

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Amounts in thousands, except for share and per share data

1. Basis of Presentation

The accompanying unaudited condensed financial statements of Osiris Therapeutics, Inc. (the "Company") have been prepared in accordance with generally accepted accounting principles in the United States and the rules and regulations of the United States Securities and Exchange Commission (the "SEC"), for interim financial information. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles for complete financial statements and should be read in conjunction with the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007. The interim financial statements are unaudited, but in the opinion of management all adjustments, consisting only of normal recurring accruals, considered necessary for a fair statement of the results of these interim periods have been included. The interim financial statements for the three and six months ended June 30, 2007 and the balance sheet at December 31, 2007 have been reclassified to report our Osteocel business unit as discontinued operations, as discussed in Note 3 to these condensed financial statements. The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year.

2. Significant Accounting Policies and Recent Accounting Pronouncements

Use of Estimates

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

Revenue Recognition

Our revenue recognition policies are in accordance with SEC Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*.

In January 2008, we were awarded a contract from the United States Department of Defense ("DoD") pursuant to which we are seeking to develop and stockpile Prochymal for the repair of gastrointestinal injury resulting from radiation exposure. We began recognizing revenue under this contract during the first quarter of fiscal year 2008. Contract revenue is recognized as the related costs are incurred, in accordance with the

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terms of the contract. During the three months ended June 30, 2008, we recognized \$0.5 million in revenue from the DoD contract.

In October 2007, we entered into a collaborative agreement with the Juvenile Diabetes Research Foundation (JDRF) to conduct a Phase II clinical trial evaluating Prochymal as a treatment for type 1 diabetes. This collaborative agreement provides for JDRF to provide up to \$4.0 million in funding to support the development of Prochymal for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus. During the three months ended June 30, 2008, we recognized \$2.0 million in revenue upon the achievement of certain milestones delineated in our agreement with JDRF.

Loss per Common Share

Basic loss per common share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share adjusts basic loss per share for the potentially dilutive effects of common share equivalents, using the treasury stock method. All common share equivalents resulting from assumed conversion of convertible debt and outstanding stock options and warrants are excluded from the computation of diluted loss per share as their effect is antidilutive.

Investments Available for Sale

Investments Available for Sale consist primarily of investment grade auction rate certificates. They are valued at estimated fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in Accumulated Other Comprehensive Loss.

Securities 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. Management reviews criteria such as the magnitude and duration of the decline, as well as the reasons for the decline, to predict

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whether the loss in value is other than temporary. Once a decline in value is determined to be other than temporary, the value of the security is reduced and a corresponding charge to earnings is recognized. Our investments available for sale at June 30, 2008 consist of investment grade student loan auction rate certificates that are presently illiquid at par value. The collateral for these securities is guaranteed by agencies of the United States; however, because of the current turmoil in the credit markets, these securities cannot presently be sold at par value.

Stock-Based Compensation Plans

In 1994, we adopted the Amended and Restated 1994 Stock Incentive Plan (the 1994 Plan) under which 875,000 shares of common stock have been reserved for issuance upon the exercise of options or other equity grants that we issue from time to time. In 2006, we adopted the 2006 Omnibus Plan, under which we initially reserved 850,000 shares of common stock for issuance upon the exercise of stock options or other equity grants. At our annual meeting of stockholders held on June 4, 2008, our stockholders approved our Amended and Restated 2006 Omnibus Plan, pursuant to which our 2006 Omnibus Plan was amended and restated to, among other things, increase the number of shares available for grant at any time thereunder by 600,000 shares from 850,000 to 1,450,000. We stopped granting options under the 1994 Plan upon the completion of our initial public offering in August 2006.

A summary of the combined activity under both of our stock-based compensation plans as of June 30, 2008 and changes during the six 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
Outstanding at December 31, 2007	880,410	\$ 8.64	7.2	\$ 5,091
Granted	336,000	12.08		
Exercised	(13,069)	0.41		150
Forfeited or expired	(88,375)	12.35		
Outstanding at June 30, 2008	1,114,966	9.48	8.0	5,401
Exercisable at June 30, 2008	415,641	3.87	7.0	4,142

The weighted average grant date fair value of options granted during the six months ended June 30, 2008 was \$7.91 per share. We received a total of \$5 in cash from the exercise of options during the six months ended June 30, 2008.

Also during the six months ended June 30, 2008, we granted 21,500 unrestricted shares of common stock to members of our Board of Directors under our 2006 Omnibus Plan and recognized \$258 in share-based expense. As of June 30, 2008, 717,760 shares of common stock remain

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available for future grants under our 2006 Omnibus Plan, as recently amended and restated.

Share-based compensation (including director compensation) included in our statements of operations for the three and six months ended June 30, 2008 and 2007 is allocable to our biologic drug candidate business, discontinued operations and general administrative activities, as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Biologic drug candidates	\$ 101	\$ 186	\$ 330	\$ 330
Discontinued operations	38	13	79	22
General and administrative	151	121	555	497
Total	\$ 290	\$ 320	\$ 964	\$ 849

As of June 30, 2008, there was approximately \$5.2 million of total unrecognized share-based compensation cost related to options granted under our plans which will be recognized over a weighted-average period of approximately 3.5 years.

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	Six Months Ended June 30,	
	2008	2007
Supplemental disclosure of cash flows information:		
Cash paid for interest	\$ 305	\$ 1,190
Cash paid for income taxes		
Supplemental schedule of non-cash investing and financing activities:		
Common stock issued to directors for services rendered	258	295

Significant New Accounting Pronouncements

On December 12, 2007, the Financial Accounting Standards Board, or FASB, ratified the consensus reached by the Emerging Issues Task Force, or EITF, on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008. We are currently evaluating the impact of adopting EITF 07-1 on our financial statements and cannot estimate the impact of adoption at this time.

On June 27, 2007, the FASB ratified the consensus reached by the EITF on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties, and amortize them over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We adopted EITF 07-3 in the first quarter of 2008. There was no material impact on our financial statements upon adoption.

In September 2006, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 157, *Fair Value Measurements*. This standard defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, except that under FASB Staff Position 157-2, *Effective Date of FASB Statement No. 157*, companies are allowed to delay the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities that are not recognized or disclosed at fair value on a recurring basis until fiscal years beginning after November 15, 2008. We adopted SFAS No. 157 with regard to all financial assets and liabilities in our financial statements in the first quarter of 2008 and have elected to delay the adoption of SFAS No. 157 for non-financial assets and non-financial liabilities not recognized or disclosed at fair value on a recurring basis until the first quarter of 2009. For further discussion of

SFAS No. 157, see Note 5 to the Condensed Financial Statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115*. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Entities that elect the fair value option will report unrealized gains and losses in earnings at each subsequent reporting date. The fair value option may be elected on an instrument-by-instrument basis, with few exceptions. SFAS No. 159 also establishes presentation and disclosure requirements to facilitate comparisons between companies that choose different measurement attributes for similar assets and liabilities. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We elected not to adopt the fair value option of SFAS No. 159 at this time.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133*. SFAS No. 161 will require entities to provide qualitative disclosures about the objectives and strategies for using derivatives, quantitative disclosures about the fair value of gains and losses on derivative contracts, and disclosures about credit-risk related to contingent features in their hedged positions. The statement also asks entities to disclose more information about (i) the location and amounts of derivative instruments in financial statements; (ii) how derivatives and related hedges are accounted for under SFAS No. 133; and (iii) how the hedges affect the entity's financial position, financial performance and cash flows. The statement is effective for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged, but not required. As of March 31, 2008 we have not adopted SFAS No. 161. We do not expect the adoption of SFAS No. 161 to have a material impact on our financial statements.

3. Discontinued Operations & Subsequent Event

In April 2008, we committed to a plan to sell our biologic tissue product business, including 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. 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. On May 8, 2008, we entered into an Asset Purchase Agreement to sell the Osteocel asset disposal group to NuVasive, Inc., a Delaware corporation. The agreement provides for the sale to be effected at two closings

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a technology assets closing, at which technology and certain other business assets are transferred, and a manufacturing assets closing, at which manufacturing assets and facilities are transferred. On July 24, 2008, we held a Special Meeting of Stockholders at which our stockholders overwhelmingly approved the sale of the Osteocel business. The technology assets closing also occurred on that date, at which time we received an initial payment of \$35.0 million. The manufacturing assets closing is expected to occur approximately 18 months after the date of the technology assets closing.

The Asset Purchase Agreement provides for up to \$50.0 million of contingent additional payments to us upon our achievement of milestone events, in addition to the \$35.0 million initial payment, as follows:

Milestone	Amount	Cut-Off Date
Initial payment	\$ 35,000	Received in July 2008
Cumulative sales to NuVasive of 125,000 units(1)	5,000	April 2009
Cumulative sales to NuVasive of 250,000 units	5,000	January 2010
Net end-user sales of \$35 million	15,000	none
Cumulative sales to NuVasive of 275,000 units	5,000	January 2010
Cumulative sales to NuVasive of 308,300 units	2,500	January 2010
Cumulative sales to NuVasive of 366,600 units	2,500	January 2010
Cumulative sales to NuVasive of 424,900 units	2,500	January 2010
Transfer of Manufacturing Assets	12,500	January 2010
Total possible purchase price	\$ 85,000	

(1)Each unit represents 1.0 cubic centimeter of Osteocel product.

If and when the requisite milestone events occur, we will recognize the milestone proceeds as a component of gain (loss) from the sale of discontinued operations. We expect to recognize a gain on the initial payment during the third quarter of 2008.

Concurrent with the technology assets closing, we entered into a Manufacturing Agreement with NuVasive, Inc., under which we will continue to manufacture Osteocel for up to 18-months and sell 100% of the product to NuVasive at specified prices. NuVasive has certain minimum purchase order obligations under the Manufacturing Agreement. We could recognize up to approximately \$52.0 million in revenue from discontinued operations under the Manufacturing Agreement, but do not expect to report significant, if any, profits from manufacturing the product under this Agreement.

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The net assets allocable to the Osteocel asset disposal group at June 30, 2008 and December 31, 2007 were as follows:

	2008		2007
Accounts receivable	\$ 6,009	\$	4,324
Inventory	4,471		3,983
Other current assets	195		138
Current assets of discontinued operations	10,675		8,445
Property and equipment, net	8,172		4,596
Current liabilities of discontinued operations	(3,974)		(2,552)
Net assets of discontinued operations	\$ 14,873	\$	10,489

We eliminated the Osteocel asset disposal group from our ongoing operations as a result of the disposal transaction and have presented the results of the group's operations as a discontinued operation for all periods. Summarized operating results of the Osteocel asset disposal group are as follows:

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Product Sales	\$ 8,955	\$ 3,252	\$ 16,466	\$ 5,252
Cost of goods sold	4,786	1,503	8,567	2,404
Gross Profit	4,169	1,749	7,899	2,848
Failed production runs				2,433
Selling, general & administrative expenses	1,065	143	1,246	246
	1,065	143	1,246	2,679
Income from operations of discontinued operations	\$ 3,104	\$ 1,606	\$ 6,653	\$ 169

4. Notes Payable

In December 2007, we issued a short-term promissory note to an international pharmaceutical company in the principal amount of \$6,521. This note bears interest at 8% and is due in installment payments during 2008. We paid \$1,630, plus accrued interest during the three months ended March 31, 2008, and then paid \$3,260, plus accrued interest in July 2008. This note will be paid in full prior to December 31, 2008.

In March and May 2008, we issued an aggregate of \$10.5 million in convertible promissory notes to several non-U.S. investors pursuant to a private placement intended to qualify under Regulation S and Section 4(2) of the Securities Act of 1933, as amended. Three of these notes with an aggregate principal amount of \$8.0 million bear interest at 2% and become due and payable on November 30, 2008. The fourth note with a principal amount of \$2.5 million bears interest at 4% and becomes due and payable on November 30, 2009. The notes are convertible at the option of the respective holders at any time, into shares of our common stock at conversion prices ranging from \$12.04 to \$13.18 per share (the respective closing prices on the NASDAQ Global Exchange on the dates of the definitive agreements). The notes provide for redemption at any time at our option, with 30-days prior written notice. The note holders are afforded certain registration rights in respect of any shares issued upon conversion.

In June 2008, we issued an aggregate of \$5.5 million in short-term notes to several non-U.S. investors pursuant to a private placement intended to qualify under Regulation S and Section 4(2) of the Securities Act of 1933, as amended. These notes bear interest at 10% semi-annually and become due and payable in December 2008. The notes are not convertible but are redeemable at our option with ten days prior written notice, upon any monthly anniversary of the date of issuance. We expect to repay these short-term notes from the proceeds of the initial closing price of the sale of our Osteocel business.

5.

Fair Value

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 establishes a standard framework for measuring fair value in generally accepted accounting principles, clarifies the definition of fair value within that framework, and expands disclosures about the use of fair value measurements. We adopted SFAS 157 in the first quarter of 2008 with regard to all financial assets and liabilities in our financial statements going forward, and, consistent with FASB Staff Position 157-2, *Effective Date of FASB Statement No. 157*, we have elected to delay the adoption of SFAS 157 for non-financial assets and liabilities not recognized or disclosed at fair value on a recurring basis until the first quarter of 2009. See below for a further discussion. The adoption of SFAS 157 had no material impact on our financial statements.

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

Financial assets recorded at fair value in the Condensed Financial Statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels, defined by SFAS 157 and directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities, are as follows:

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Amounts in thousands, except for share and per share data

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 auction rate certificates and commercial paper where fair value is based on valuation methodologies such as models using observable market inputs, such as benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data.

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

We carry no investments classified as Level 3.

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

Fair value measurements at June 30, 2008 using		
Quoted prices in active markets for identical assets	Significant other observable inputs	Significant unobservable inputs

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	June 30, 2008	(Level 1)	(Level 2)	(Level 3)
Assets:				
Overnight Securities included in Cash	\$ 1,900	\$ 1,900	\$	\$
Investments available for sale	4,662		4,662	

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

Forward-Looking Information

This report includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Forward-looking statements include statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, compensation arrangements, financing needs, plans or intentions relating to acquisitions, business trends and other information that is not historical information and, in particular, may appear under the headings Risk Factors in our Annual Report 10-K under Part I Item 1A, Part II Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and the other documents we file with the United States Securities and Exchange Commission, or SEC, including, among others, our quarterly reports on Form 10-Q and any amendments thereto. When used in this Quarterly Report, the words *estimates*, *expects*, *anticipates*, *projects*, *plans*, *intends*, *believes*, *forecasts* and variations of such words or similar expressions are intended to identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements regarding the following: our product development efforts; our clinical trials and anticipated regulatory requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for mesenchymal stem cells and biologic drug candidates; our cash needs; patents and proprietary rights; ability of our potential products to treat disease; our plans for sales and marketing; our plans regarding facilities; types of regulatory frameworks we expect will be applicable to our potential products; results of our scientific research; and our ability to benefit from the sale of our Osteocel business and to earn milestone payments and perform under and derive revenue from the related manufacturing agreement. All forward-looking statements, including, without limitation, management's examination of historical operating trends, are based upon our current expectations and various assumptions. Our expectations, beliefs and projections are expressed in good faith and we believe there is a reasonable basis for them. However, there can be no assurance that management's expectations, beliefs or projections will result or be achieved and you should not unduly rely on forward-looking statements.

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our audited Financial Statements and related notes thereto and other disclosures included as part of our Annual Report on Form 10-K for the year ended December 31, 2007, and our unaudited Condensed Financial Statements for the three and six months ended June 30, 2008 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, 2007 under Part I Item 1A Risk Factors, and in our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2008 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.

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

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

Introduction and Overview

The following is a discussion and analysis of our financial condition and results of operations for the three and six month periods ended June 30, 2008 and 2007. 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, 2007. Historical results and any discussion of prospective results may not indicate our future performance. See Forward Looking Information.

We are a leading stem cell therapeutic company headquartered in Columbia, Maryland, focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic, and cardiovascular areas. We were incorporated in Delaware in April 2002. Our predecessor company was organized in 1992. Our lead biologic drug candidate, Prochymal®, is being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease (GvHD) and Crohn's disease, and is the only stem cell therapeutic currently granted both Orphan Drug and Fast Track status by the Food and Drug Administration (FDA). Prochymal is also being developed for the repair of heart tissue following a heart attack, the protection of pancreatic islet cells in patients with type 1 diabetes, and the treatment of patients with chronic obstructive pulmonary disease. Our pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen® for osteoarthritis in the knee. We have partnered with Genzyme Corporation to develop Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies. We have also partnered with the Juvenile Diabetes Research Foundation for the development of Prochymal as a treatment for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus.

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We are a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. We have developed an extensive intellectual property portfolio to protect our technology in the United States and a number of foreign countries, including 47 U.S. and 255 foreign patents owned or licensed. 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 mesenchymal stem cells (MSC) in a controlled fashion to produce up to 10,000 treatments of our biologic drug candidates from a single bone marrow donation. Our ability to produce a large quantity of treatments from one donation provides us with manufacturing efficiencies and product consistency that are essential to commercialization.
- Universal Compatibility.** Many stem cell therapies under development can elicit a rejection response in the recipient and therefore require donor-to-recipient matching or potentially harmful immunosuppression. This greatly reduces manufacturing efficiencies and creates a risk of mismatch which can result in an acute inflammatory response and, potentially, in death. Based on our clinical experience, we believe that our biologic drug candidates are not rejected by the patient's immune system and so, like type O negative blood, do not require donor-to-recipient matching. This universal compatibility allows us to produce a standardized product available to all patients in almost any medical setting.
- Treatment on Demand.** Our biologic drug candidates can be stored frozen at end-user medical facilities until they are needed. We anticipate that medical facilities will be able to prescribe and dispense these products in much the same way as conventional drugs. In contrast, other stem cell technologies under development require weeks to prepare after a patient's need is identified. This is a key feature of our technology, as many patients in the critical care setting require prompt treatment.

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

Product/Candidate	Indication	Status
Prochymal	Steroid Refractory Acute GvHD	Phase III
	First Line Treatment of Acute GvHD	Phase III
	Biologics Refractory Crohn's Disease	Phase III
	Type I Diabetes	Phase II
	Acute Myocardial Infarction	Phase II

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	Chronic Obstructive Pulmonary Disease	Phase II
	Acute Radiation Syndrome	Phase III (Animal Rule)
Chondrogen	Osteoarthritis & Cartilage Protection	Phase II/III

Financial Operations Overview

Revenue

We recognize revenue on collaborative and royalty agreements and a contract with the United States Department of Defense for the development and stockpiling of Prochymal for the treatment of acute radiation syndrome. Our collaborative agreement with the Juvenile Diabetes Research Foundation provides for funding of up to \$4.0 million in support of developing Prochymal as a treatment for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus. We recognize revenue on this collaborative agreement when we achieve the specified milestone events. During the three months ended June 30, 2008, we recognized \$2.0 million in revenue upon the achievement of certain milestones under this collaborative 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 project. 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. As a result, we cannot state

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precisely the total costs incurred for each of our clinical and preclinical projects on a project-by-project basis. From inception in December 1992 through June 30, 2008, we incurred aggregate research and development costs of approximately \$270 million.

We expect our research and development expenses to increase substantially in the future, as we expand our clinical trial activity, as our biologic drug candidates 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 design of the trial and trial endpoints;
- 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.

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As a result of the uncertainties discussed above, 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.

We have incurred annual operating losses since inception and expect to incur substantial operating losses in the future in connection with the development of our core products. As of June 30, 2008, we had an accumulated deficit of \$272.5 million.

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. In anticipation of commercialization and bringing our biologic drug candidates to market, we are incurring increases in our general and administrative expense in the areas of business development and intellectual property. We have also incurred increased general and administrative costs for legal and accounting compliance costs, investor relations and other activities associated with operating as a publicly traded company. Continued increases will also likely result from the additional hiring of operational, financial, accounting, facilities engineering and information systems personnel.

Interest Expense, Net

Interest income consists of interest earned on our cash and short-term investments. Interest expense consists of interest incurred on convertible debt, capital leases and other debt financings. We pay interest on our short-term loans, capital leases and our convertible long-term debt.

Income Taxes

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 of approximately \$80 million that may be utilized prior to us having to recognize any income tax expense or make payments to the taxing authorities. Utilization of our net operating loss carry-forwards in any one year may be limited under Internal Revenue Code Section 382, and we could be subject to the alternative minimum tax.

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Critical Accounting Policies

There have been no material changes in our critical accounting policies, estimates and judgments during the six months ended June 30, 2008 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2007, other than as disclosed herein.

Results of Operations

Comparison of Three Months Ended June 30, 2008 and 2007

Revenues from Continuing Operations

Revenues from continuing operations were \$2.5 million for the three months ended June 30, 2008 compared to \$0.3 million for the second quarter of fiscal 2007. Our revenues for the three month period include \$2.0 million of milestone revenue from the Juvenile Diabetes Research Foundation (JDRF), as provided for in our collaborative agreement for the development of Prochymal as a treatment for the preservation of insulin production in patients with newly diagnosed type 1 diabetes. Revenues for the three month period also include \$0.5 million in revenue recognized on our contract with the United States Department of Defense for the development of Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies, and \$0.1 million in royalty revenue. Revenues from continuing operations for the three months ended June 30, 2007 were \$0.3 million, and consisted primarily of the recognition of unearned revenue from a license agreement that was terminated in December 2007.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2008 were \$19.0 million, and were \$2.3 million higher than our research and development expenses for the first quarter of fiscal 2008. Research and development expenses for the three months ended June 30, 2007 were \$10.4 million. The increase in these expenses compared to the prior year and the first quarter of fiscal 2008 reflect the increase in our clinical trial activities. At June 30, 2008, we were conducting three Phase III clinical trials in several inflammatory disease indications, and Phase II clinical trials for acute myocardial infarction, type 1 diabetes and chronic obstructive pulmonary disease. In addition, we were conducting preclinical research on acute radiation syndrome. The increased clinical trial activities have increased the demand for clinical batches of our biologic drug candidates and we have experienced increased costs in our contract manufacturing activities. We are also incurring research and development expenses in connection with the preparation of our biologic license application as we prepare filings with the FDA towards the commercialization of Prochymal.

General and Administrative Expenses (excluding discontinued operations)

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General and administrative expenses were \$1.8 million for the three months ended June 30, 2008 compared to \$1.5 million for the comparable period in fiscal 2007. The increase in general and administrative expenses is primarily attributable to increases in our professional staff in the areas of intellectual property and business development.

Interest Expense, Net

Interest expense, net was \$0.2 million for the three months ended June 30, 2008 compared to \$0.4 million in the corresponding period in fiscal 2007. In June 2008, we issued \$5.5 million of short-term promissory notes, which accrue interest at 10% semi-annually and are due and payable in December 2008. Accordingly, we expect our interest expense, net to increase during the remainder of the current fiscal year.

Comparison of the Six Months ended June 30, 2008 and 2007

Revenue from Continuing Operations

Revenues from continuing operations for the six months ended June 30, 2008 were \$2.9 million compared to \$0.6 million in the comparable period of fiscal 2007. Our fiscal 2008 revenues include \$2.0 million in milestone revenue from the collaborative agreement with JDRF, \$0.8 million in contract revenue from contracts with the United States Department of Defense and \$0.1 million of royalty revenue. Our revenues in the comparable period of fiscal 2007 consisted of \$0.5 million in license fees from an agreement with an international pharmaceutical company which was terminated in December 2007, and \$0.1 million of royalty revenue.

Research and Development Expenses

Research and development expenses for the six months ended June 30, 2008 were \$35.7 million compared to \$18.9 million for the six months ended June 30, 2007. The approximately 89% increase in research and development expenses in 2008 as compared to 2007 is

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consistent with our business plan and reflect the substantial increase in our clinical trial activities and activities related to the pending filing of our biologic license application with the FDA, as we approach commercialization of Prochymal.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2008 were \$4.4 million compared to \$3.0 million in the comparable period of fiscal 2007. The increase in 2008 includes legal costs incurred to protect and defend our intellectual property portfolio and increases in our management staff in anticipation of qualifying and commercializing Prochymal.

Interest Expense, Net

Interest expense, net was \$0.4 million for the first six months of fiscal 2008 compared to \$0.8 million for the comparable period of fiscal 2007.

Income from Operations of Discontinued Operations

Income from operations of the Osteocel asset disposal group was \$3.1 million for the three months ended June 30, 2008 compared to earnings of \$1.6 million for the comparable period of fiscal 2007, and \$6.7 million for the six months ended June 30, 2008 compared to earnings of \$0.2 million for the comparable period of fiscal 2007, as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Product Sales	\$ 8,955	\$ 3,252	\$ 16,466	\$ 5,252
Cost of goods sold	4,786	1,503	8,567	2,404
Gross Profit	4,169	1,749	7,899	2,848
Failed production runs				2,433
Selling, general & administrative expenses	1,065	143	1,246	246
	1,065	143	1,246	2,679
Income from operations of discontinued operations	\$ 3,104	\$ 1,606	\$ 6,653	\$ 169

In April 2008, we committed to a plan to sell our biologic tissue product practice, consisting of the Osteocel asset disposal group. On May 8, 2008 we entered into an Asset Purchase Agreement for the sale of the Osteocel asset disposal group to NuVasive, Inc., and on July 24, 2008, the technology assets closing occurred and we received a \$35.0 million payment. As discussed in Note 3 to the Condensed Financial Statements included in this Quarterly Report on Form 10-Q, we have the opportunity to receive up to an additional \$50.0 million in milestone payments related to the sale of this business unit.

Concurrent with the technology assets closing, we entered into a Manufacturing Agreement with NuVasive under which we will continue to manufacture OsteoCel for up to 18-months and sell 100% of the product to NuVasive at specified prices. NuVasive has certain minimum purchase order obligations under the Manufacturing Agreement. We could recognize up to approximately \$52.0 million in additional revenue from discontinued operations under the Manufacturing Agreement, but we do not expect to report significant, if any, profits from manufacturing the product under this agreement.

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Liquidity and Capital Resources

Liquidity

At June 30, 2008, we had \$7.0 million in cash and investments available for sale. Our investments available for sale consist of investment grade auction rate certificates which are presently illiquid at par value. As discussed more fully in Item 3 Quantitative and Qualitative Disclosures About Market Risk in this Quarterly Report on Form 10-Q, we recorded an unrealized loss on the fair value of these investments of \$0.6 million during the three months ended June 30, 2008, as other comprehensive loss. The fair value of our auction rate securities could change significantly based on market conditions and continued uncertainties in the credit markets. Our portfolio managers are presently unable to provide us with an estimate of how long the credit crisis in the auction rate certificate market will exist. Estimating the fair value of investments in auction rate certificates requires numerous assumptions and are inherently subjective. There can be no assurance as to when the market for auction rate securities will stabilize and the fair value of our auction rate securities could change significantly based on market conditions and continued uncertainties in the credit markets.

In October 2007, we obtained a \$30.0 million financing commitment from Friedli Corporate Finance, Inc., which is owned by Peter Friedli, the Chairman of our Board of Directors and largest shareholder. This financing commitment is for a twelve month term and provides for financing through the issuance by us of either common stock at a price determined as the basis of market value, or promissory notes. During the six months ended June 30, 2008, we have issued \$10.5 million in convertible promissory notes and an additional \$5.5 million of short-term promissory notes, separate from this financing commitment.

At June 30, 2008, our short-term debt consisted of \$4.9 million payable during 2008 to an international pharmaceutical company, \$5.5 million in short-term notes due December 2008, and \$8.0 million of convertible promissory notes which mature on November 30, 2008. The notes provide for redemption with prior notice at our option. The convertible notes may be converted into common stock at any time at the discretion of the note holders, and may be redeemed at our option at any time upon thirty days prior notice.

On July 24, 2008, at a Special Meeting of Stockholders, our Stockholders approved the Asset Purchase Agreement dated May 8, 2008, between us and NuVasive, Inc. for the sale of our Osteocel business unit. On that same date, the technology assets closing occurred and we received a payment of \$35.0 million in cash under the terms of the Asset Purchase Agreement. The Asset Purchase Agreement also provides for the opportunity for us to receive up to an additional \$50.0 million in milestone payments. These milestone payments become payable beginning in the first quarter of 2009, assuming that certain conditions to payment are satisfied. There can be no assurance that we will successfully complete any or all of the events which will trigger any of the milestone payments. Concurrent with the closing of the sale, we entered into a Manufacturing Agreement with NuVasive whereby we will continue to manufacture Osteocel for up to 18-months for the exclusive sale to NuVasive at specified prices. We understand that NuVasive intends to distribute Osteocel to Blackstone Medical and others in accordance with the terms of certain preexisting agreements.

Cash Flows

Net cash used in operating activities of continuing operations was \$11.6 million for the three months ended June 30, 2008, primarily reflecting our loss from continuing operations of \$18.5 million, partially offset by \$0.7 million of non-cash charges and \$6.2 million of favorable working

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capital changes, consisting primarily of increases in accounts payable and accrued expenses. During the second quarter of fiscal 2007, net cash used in operating activities of continuing operations was \$12.9 million, which was comprised of our loss from continuing operations of \$12.1 million, netted against \$0.8 million of non-cash charges and \$1.6 million of unfavorable changes in our working capital.

Net cash provided by operating activities of discontinued operations was \$2.1 million for the three months ended June 30, 2008, which reflects the income from discontinued operations of \$3.1 million, partially offset by unfavorable changes in working capital of \$1.1 million, which is a primarily increase in accounts receivable. Net cash used in operating activities of discontinued operations for the three months ended June 30, 2007 was \$1.4 million, which is made up of the income from continuing operations of \$1.6 million offset by \$3.0 million of unfavorable working capital changes as we increased both the inventory and accounts receivable of the Osteocel business unit.

Net cash used in investing activities was \$0.6 million for the three months ended June 30, 2008, consisting of \$2.6 million of fixed asset additions, netted against \$2.0 million of withdrawals from our investments available for sale accounts. The fixed asset additions are primarily related to the move of our Osteocel manufacturing operations from our Baltimore, Maryland facility to our Columbia, Maryland facility. Net cash used in investing activities during the second quarter of fiscal 2007 was \$6.2 million, including \$1.5 million of capital expenditures and the net increase in our investments available for sale. During the three months ended June 30, 2007, we invested the proceeds from a \$20.0 million private placement of our common stock in investments available for sale.

Net cash provided by financing activities was \$8.0 million for the three months ended June 30, 2008, representing the proceeds from the issuance of convertible and short-term notes payable. During the second quarter of fiscal 2007, net cash provided by financing activities was \$19.3 million, which primarily resulted from the \$20.0 million private placement of common stock.

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Net cash used in operating activities of continuing operations was \$26.9 million for the six months ended June 30, 2008, reflecting our loss from operations of \$37.6 million, which was partially offset by \$2.0 million of non-cash charges and \$8.8 million of favorable working capital changes, consisting primarily of increases in our accounts payable and accrued expenses. Net cash used in operating activities of continuing operations for the three months ended June 30, 2007 was \$22.7 million, reflecting our loss from continuing operations of \$22.1 million, partially offset by non-cash charges of \$1.8 million and net unfavorable working capital changes of \$2.3 million.

Net cash provided by the operations of discontinued operations was \$6.1 million for the six months ended June 30, 2008, reflecting income from discontinued operations of \$6.6 million, partially offset by \$0.2 million of non-cash charges and \$0.8 million of unfavorable changes in working capital. Net cash used by discontinued operations for the six months ended June 30, 2007 was \$0.2 million, which is comprised of income from discontinued operations of \$0.2 million, offset by unfavorable changes in working capital.

Net cash provided by investing activities for the six months ended June 30, 2008 was \$8.7 million and consisted of proceeds from the sale of investments available for sale of \$12.4 million netted against capital expenditures of \$3.7 million. The capital expenditures are related primarily to the build-out of our Osteocel manufacturing facilities at our Columbia, Maryland location, and to related equipment purchases. Net cash provided by investing activities for the six months ended June 30, 2007 was \$3.7 million, which represented \$2.3 million of capital expenditures offset by net sale of our investments available for sale of \$6.1 million.

Net cash provided by financing activities for the six months ended June 30, 2008 was \$13.8 million, consisting of borrowings of \$10.5 million of convertible promissory notes and \$5.5 million of short-term promissory notes, netted against payments of \$2.2 million on a promissory note we issued in December 2007 and payments on our capital leases. Net cash provided by financing activities for the six months ended June 30, 2007 was \$19.1 million, primarily reflecting the proceeds of the \$20.0 million private placement of our common stock.

Capital Resources

Our future capital requirements will depend on many factors, including, but not limited to:

- the achievement of the milestone events related to the sale of the Osteocel business unit and performance under the related manufacturing agreement;
- the scope and results of our research and preclinical development programs;
- the scope and results of our clinical trials, particularly regarding the number of patients required for our Phase III trials for Prochymal;

- 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 costs of maintaining, expanding and protecting our intellectual property portfolio, including litigation costs and liabilities;
- the costs of repaying our debt; and
- the costs of enlarging our work force consistent with expanding our business and operations and status as a public company, and as necessary to enhance and train our sales network in anticipation of the approval of our biologic drug candidates for commercial sale.

As a result of these and other factors, we will likely need or choose to seek additional funding prior to our becoming cash flow positive on an operational basis. We would likely seek such funding through public or private financings or some combination of them. We might also seek funding through additional collaborative arrangements if determined to be necessary or appropriate.

Additional funding may not be available to us on acceptable terms, or at all. If we obtain capital funding through collaborative arrangements, these arrangements could require us to relinquish rights to our technologies or biologic drug candidates. If we raise capital through the sale of equity, or securities convertible into equity, dilution to our then existing stockholders would result. If we raise additional capital through the incurrence of debt, we would likely become subject to covenants restricting our business activities, and holders of debt instruments would have rights and privileges senior to those of our equity investors. In addition, servicing the interest and repayment obligations under these borrowings would divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

We expect that our available cash and interest income, including the availability under our line-of-credit and financing commitment, will be sufficient to finance currently planned activities through at least 2009. These estimates are based on certain assumptions, which could be negatively impacted by the matters discussed under "Risk Factors" in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K, among other things.

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If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, which may have a material adverse affect on our business, financial condition and results of operations. See **Risk Factors** in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K.

Off-Balance Sheet Arrangements.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Due to the short duration of our investment portfolio and the high quality of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. However, our investment portfolio consists of investment grade auction rate certificates which are presently illiquid at par value. Our portfolio managers are presently unable to provide us with an estimate of how long the credit crisis in the auction rate certificate market will exist. During the three months ended June 30, 2008, we recorded impairment in the fair market value of our investments available for sale of \$632, based upon estimates provided to us by the custodial investment banks. This charge is reflected in the accompanying condensed statement of stockholder's equity (deficit) as accumulated other comprehensive loss. Estimating the fair value of investments in auction rate securities requires numerous assumptions and are inherently subjective. There can be no assurance as to when the market for auction rate securities will stabilize. The fair value of our auction rate securities could change significantly based on market conditions and continued uncertainties in the credit markets. If conditions in the credit markets deteriorate further causing additional auctions to fail, the funds associated with these auction rate certificates may not be accessible for an undetermined period of time, and we may be required to record additional unrealized losses in other comprehensive income, or record an other than temporary loss as part of net loss.

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

We do not enter into hedging or derivative instrument arrangements.

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 June 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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, 2007, filed with the United States Securities and Exchange Commission on March 17, 2008, and "Risk Factors" in Part II - Item 1A of our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2008, filed with the United States Securities and Exchange Commission on May 12, 2008. If any of the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 or Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2008 actually occur, our business, financial condition or results of operations could be materially adversely affected.

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

On May 23 2008, we accepted a subscription agreement for the sale of a \$2.5 million convertible promissory note to a non-U.S. investor, in a private placement intended to qualify under Regulation S and Section 4(2), of the Securities Act of 1933, as amended. The note was funded on May 29, 2008 and bears interest at a rate of four percent (4%) per annum, payable upon maturity on November 30, 2008. The note is convertible at any time at the sole discretion of the holder into shares of our common stock at the conversion price of \$13.18 per share, and is redeemable by us with thirty days prior notice. The note holder is afforded registration rights in respect of any shares issued upon conversion. The net proceeds to us from the offering and sale of the notes have been used to further our clinical trial activities and for general corporate purposes.

Item 3. Defaults Upon Senior Securities.

None.

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

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Annual Meeting. We held our Annual Meeting of Stockholders on June 4, 2007. Of the 31,769,836 shares of common stock outstanding as of the record date of the Annual Meeting, 25,934,971 shares, or 81.6% of the total shares eligible to vote at the Annual Meeting, were represented in person or by proxy. Three proposals were submitted to our stockholders and approved at the Annual Meeting, as follows:

Election of Directors. C. Randal Mills and Felix Gutzwiller were elected to serve as members of the board of directors for a term expiring at our Annual Meeting of Stockholders to be held in 2011 and until their successors are duly elected and qualified. The number of votes cast for or withheld from each nominee, both in person and by proxy, was as follows:

C. Randal Mills	25,768,862 FOR	166,109 WITHHOLD
Felix Gutzwiller	25,883,060 FOR	51,911 WITHHOLD

The term of office of each Peter Friedli, Jay M. Moyes and Gregory H. Barnhill continued following the meeting.

Approval of Amended and Restated 2006 Omnibus Plan. The Amended and Restated Plan to increase the aggregate number of shares of common stock available for grants and awards by 600,000 shares, and approve other technical changes was approved by the stockholders as follows:

FOR	21,043,477
AGAINST	101,806
ABSTAIN	5,949
BROKER NON-VOTES	4,783,739

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Ratify Independent Registered Public Accountants. The appointment of Stegman & Company, independent registered public accountants, to act as our independent auditors for the fiscal year ending December 31, 2008 was ratified, as follows:

FOR	25,911,139
AGAINST	12,493
ABSTAIN	11,338

Special Meeting. We held a Special Meeting of Stockholders on July 24, 2008 to seek approval of the sale of our Osteocel business to NuVasive, Inc. under the terms and conditions of the Asset Purchase Agreement. Of the 31,770,555 shares of common stock outstanding as of the record date of the Special Meeting, 20,287,831, or 63.4% of the total shares eligible to vote, were represented in person or by proxy. One proposal was submitted to our stockholders and approved at the Special Meeting as follows:

Approval of the Asset Purchase Agreement and the Transactions Contemplated Thereby. The Asset Purchase Agreement and the transactions contemplated thereby were approved by our stockholders as follows:

FOR	20,242,224
AGAINST	11,389
ABSTAIN	34,218
BROKER NON-VOTES	0

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
10.1	Amended and Restated 2006 Omnibus Plan of the Registrant, dated June 4, 2008.
10.2	Asset Purchase Agreement, dated May 8, 2008, by and between the Registrant and NuVasive, Inc. (Incorporated herein by reference to Exhibit 10.01 to the Current Report on Form 8-K filed by the Registrant with the SEC on May 12, 2008.)
10.3	Form of Voting Agreement, dated May 8, 2008, by and among each of Peter Friedli, Venturetec, Inc., U.S. Venture 05, Inc., Joyce, Ltd. and C. Randal Mills, Ph.D., and NuVasive, Inc. (Incorporated herein by reference to Exhibit 10.02 to the Current

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Report on Form 8-K filed by the Registrant with the SEC on May 12, 2008.)

- 10.4 Form of Subscription Agreements, dated June 12, 2008 and June 30, 2008, respectively, by and between the Registrant and certain non-U.S. purchasers in connection with the issuance and sale of Promissory Notes in the aggregate principal amount of \$5.5 million.
- 10.5 Form of Promissory Notes of the Registrant, dated June 12, 2008 and June 30, 2008, issued to certain non-U.S. purchasers in the aggregate principal amount of \$5.5 million.
- 31.1.1 Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15D-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002).
- 31.2.1 Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15D-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002).
- 32.1 Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Osiris Therapeutics, Inc.

Date: August 11, 2008

/s/ RICHARD W. HUNT
Richard W. Hunt
Chief Financial Officer (Principal Financial Officer)

Date: August 11, 2008

/s/ PHILIP R. JACOBY, JR.
Philip R. Jacoby, Jr.
Vice President of Finance (Principal Accounting Officer)