OSIRIS THERAPEUTICS, INC.
Form 10-Q
May 14, 2007

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**

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

For The Quarterly Period Ended **March 31, 2007**

Commission file number **001-32966**

OSIRIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**71-0881115**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

7015 Albert Einstein Drive, Columbia, Maryland 21046

(Address of principal executive offices) (Zip code)

443-545-1800

(Registrant s telephone number, including area code)

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 x No o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer x

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

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

Class	**Outstanding at May 10, 2007**
Common Stock, par value $0.001 per share	27,470,132

OSIRIS THERAPEUTICS, INC.

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PART I FINANCIAL INFORMATION

Item 1. **Financial Statements - Unaudited**

OSIRIS THERAPEUTICS, INC.
Condensed Balance Sheets
Amounts in thousands

	March 31, 2007 (unaudited)	December 31, 2006
ASSETS		
Current assets:		
Cash	$ 1,892	$ 714
Short-term investments	27,629	38,467
Accounts receivable	188	1,596
Inventory and other current assets	1,623	2,858
Total current assets	31,332	43,635
Property and equipment, net	4,384	3,942
Restricted cash	291	297
Deferred financing costs, net	507	567
Other assets	563	727
Total assets	$ 37,077	$ 49,168
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 7,593	$ 8,339
Note payable, current portion	33	49
Capital lease obligations, current portion	1,155	1,129
Deferred revenue, current portion	952	952
Total current liabilities	9,733	10,469
Note payable, net of current portion	25,000	25,000
Capital lease obligations, net of current portion	595	895
Deferred revenue, net of current portion	159	397
Long-term interest payable and other liabilities	1,221	1,120
Total liabilities	36,708	37, 881
Stockholders equity:		
Common stock, $.001 par value, 90,000 shares authorized 27,468 and 27,321 shares outstanding in 2007 and 2006	27	27
Additional paid-in-capital	199,346	198,763
Accumulated deficit	(199,004)	(187,503)
Total stockholders equity	369	11,287
Total liabilities and stockholders equity	$ 37,077	$ 49,168

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 March 31,	
	2007	**2006**
Revenues:		
Product Sales	$ 2,000	$ 1,105
Cost of goods sold	901	489
Gross profit	1,099	616
Revenue from collaborative research licenses and royalties	279	295
Operating expenses:		
Research and development	11,030	4,368
General and administrative	1,506	1,138
Total operating expenses	12,536	5,506
Loss from operations	(11,158)	(4,595)
Interest expense, net	(343)	(526)
Net loss	$ (11,501)	$ (5,121)
Basic and diluted net loss per share	$ (0.42)	$ (0.56)
Weighted Average Common Shares (basic and diluted)	27,372	9,134

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

OSIRIS THERAPEUTICS, INC.
Condensed Statement of Stockholders Equity
For the three months ended March 31, 2007
(Unaudited)
Amounts in thousands, except for share and per share data

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Equity
Balance at January 1, 2007	27,321,319	$ 27	$ 198,763	$ (187,503)	$ 11,287
Exercise of options to purchase common stock ($0.40 - $0.80 per share)	133,813		54		54
Issuance of common stock for services rendered by directors ($23.62 per share)	12,500		295		295
Share-based payment employee compensation			234		234
Net loss				(11,501)	(11,501)
Balance at March 31, 2007	27,467,632	$ 27	$ 199,346	$ (199,004)	$ 369

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

OSIRIS THERAPEUTICS, INC.
Condensed Statements of Cash Flows
(Unaudited)
Amounts in thousands

	Three Months Ending March 31, 2007	2006
Cash flows from operations:		
Net loss	$ (11,501)	$ (5,121)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation and amortization	428	326
Non cash share-based payments	529	87
Non cash interest expense	60	623
Changes in operating assets and liabilities:		
Accounts receivable	1,408	(397)
Inventory and other current assets	1,235	(512)
Other assets	164	1
Accounts payable and accrued expenses	(746)	1,325
Deferred revenue	(238)	(238)
Long-term interest payable and other liabilities	100	(30)
Net cash used in operations:	(8,561)	(3,936)
Cash flows from investing activities:		
Purchases of property and equipment	(870)	(171)
Proceeds from sale of short-term investments	10,839	4,700
Net cash provided by investing activities	9,969	4,529
Cash flows from financing activities:		
Principal payments on capital lease obligations and notes payable	(290)	(264)
Restricted cash	6	6
Proceeds from the issuance of common stock	54	102
Net cash used in financing activities	(230)	(156)
Net increase in cash	1,178	437
Cash at beginning of period	714	597
Cash at end of period	$ 1,892	$ 1,034

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

OSIRIS THERAPEUTICS, INC.
NOTES TO 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 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 year ended December 31, 2006. 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 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 revenue recognition, deferred tax assets, and share-based compensation.

Revenue recognition

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

In July 2005, we launched Osteocel, our first commercial product. We recognize revenue on Osteocel sales when legal title to the product has passed to the customer, which is generally when the product is shipped from our Baltimore, MD facilities. We have agreements with our customers that specify the terms of sale, including price.

Cost of Goods Sold

Costs of goods sold consist primarily of the costs to obtain the tissue and other chemicals and supplies, plus labor and allocated overhead costs and the costs of operating the clean-room facilities related to the production of Osteocel.

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 shares issuable under our stock option plan, using the treasury stock method. Common equivalent shares from the conversion of convertible debt and the exercise of stock options and warrants are excluded from the computation of diluted loss per share as their effect is antidilutive.

Stock-Based Compensation Plans

In 1994, the Company 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 reserved 850,000 shares of common stock for issuance upon the exercise of stock options or other equity grants. 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 March 31, 2007 and changes during the three months then ended is presented below.

	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2006	695,915	$ 2.05	7.7	$ 10,400
Granted	284,000	22.69		
Exercised	(133,813)	0.40		2,086
Forfeited or expired	(8,064)	0.40		
Outstanding at March 31, 2007	838,038	9.30	8.6	7,847
Exercisable at March 31, 2007	287,271	0.40	7.8	5,259

The weighted average grant date fair value of options granted during the three months ended March 31, 2007 was $13.32 per share. We received a total of $54 in cash from the exercise of options during the three months ended March 31, 2007. Also during the three months ended March 31, 2007, we granted 12,500 unrestricted shares of common stock to members of our Board of Directors under our 2006 Omnibus Plan and recognized $295 in share-based expense. At March 31, 2007, 488,510 shares of common stock remain available for future grants under our 2006 Omnibus Plan.

Share-based employee compensation included in the statements of operations for the three months ended March 31, 2007 and 2006 was approximately $234 and $87, respectively. As of March 31, 2007, there was approximately $4.8 million of total unrecognized share-based compensation cost related to options granted under our plans that will be recognized over a weighted-average period of approximately 3-years.

Supplemental Cash Flow Information

Supplemental disclosure of cash flows information:		
Cash paid for interest	$ 101	$ 339
Cash paid for taxes		
Supplemental schedule of non-cash investing and financing activities:		
Common stock issued to directors for services rendered	295	86

Significant New Accounting Pronouncement

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, Fair Value Measurements (SFAS No.157). This statement provides a single definition of fair value, a framework for measuring fair value, and expanded disclosures concerning fair value. Previously, different definitions of fair value were contained in various accounting pronouncements creating inconsistencies in measurement and disclosures. SFAS No. 157 applies under those previously issued pronouncements that prescribe fair value as the relevant measure of value, except SFAS No. 123(R) and related interpretations and pronouncements that require or permit measurement similar to fair value but are not intended to measure fair value. This pronouncement is effective for fiscal years beginning after November 15, 2007. The Company is evaluating the impact of this new standard, but currently believes that adoption will not have a material impact on its financial position, results of operations, or cash flows.

3. Segment Reporting

Beginning in 2007, we started to manage our business in two reportable operating segments. Our reportable operating segments that are managed separately consist of our Biologic Drug Candidate segment and our Biologic Tissue Product segment. Our Biologic Drug Candidate segment focuses on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Its operations have focused on clinical trials. Our Biologic Drug Candidate segment does not presently have any products approved for sale and its revenues consist of license fees and royalties from collaborative research agreements.

Our Biologic Tissue Product segment includes the manufacture and sale of Osteocel, which we launched in July 2005. Osteocel is our biologic tissue product which is currently being used by orthopedic surgeons for focal bone repair.

We evaluate the performance of our Biologic Tissue Product segment based upon gross profit and operating income before net interest expense, depreciation, and corporate general and administrative expenses, which we refer to as segment profit or loss. We have presented estimated 2006 segment results through the gross profit result to compare to our 2007 presentation in the table below. However, because our Biologic Tissue Product segment was not managed as a separate segment during 2006 we are unable to determine the other operating expenses that may have been attributable to this practice in 2006.

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 segment. Accordingly, capital expenditures and total asset information by reportable segment is not presented. The reportable segments use the same accounting policies as those used by the company. There are no significant inter-segment sales or transfers.

Substantially all of our revenues and assets are attributed to and are received from entities located in the United States. During the three months ended March 31, 2007 and 2006, we sold product produced in our Biologic Tissue Product segment to two customers, both of which represent greater than ten percent of our revenues.

	Biologic Drug Candidates	Biologic Tissue Product	Corporate	Total
Three Months Ended March 31, 2007				
Revenues	$ 279	$ 2,000	$	$ 2,279
Gross profit		1,099		1,099
Segment profit (loss)	(8,215)	(1,437)	(1,506)	(11,158)
Three Months Ended March 31, 2006				
Revenues	$ 295	$ 1,105	$	$ 1,400
Gross profit		616		616

The loss in our Biologic Tissue Product segment for the quarter ending March 31, 2007 was primarily attributable to costs associated with the expansion of our Osteocel manufacturing facility, as we experienced failed production qualification runs while expanding our capacity. The production issues were subsequently resolved in late March, and the expanded facility is currently producing product at previously projected output.

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 Securities and Exchange Commission, or SEC, including, among others, our quarterly reports on Form 10-Q and 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 MSCs 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; and results of our scientific research. 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 and projections will result or be achieved.

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, 2006, and our unaudited Condensed Financial Statements for the three months ended March 31, 2007 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 this report or in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006, including in this report under Part II Item 1A Risk Factors, and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 under Part I Item 1A Risk Factors. There may be other factors that may cause our actual results to differ materially from the forward-looking statements.

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

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

Introduction and Overview

The following is a discussion and analysis of our financial condition and results of operations for the three month periods ended March 31, 2007 and 2006, and significant factors that could affect our prospective financial condition and results of operations. 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, 2006. 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 focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Beginning in the first quarter of 2007, we began to manage our business in two operating segments. Our reportable operating segments that are managed separately consist of our Biologic Drug Candidate segment and our Biologic Tissue Product segment.

In our Biologic Drug Candidate segment, we currently have five clinical trials ongoing. We are currently enrolling patients in a Phase III clinical trial for Prochymal, our lead biologic drug candidate, for the treatment of steroid refractory Graft versus Host Disease, or GvHD. We were recently given clearance to conduct a Phase III trial using Prochymal to treat Crohn s Disease. In addition, we have two other clinical stage

biologic drug candidates, Chondrogen for regenerating cartilage in the knee, and Provacel for repairing heart tissue following a heart attack. We have developed stem cell capabilities in research and development, manufacturing, marketing and distribution. We manufacture clinical batches of our biologic drug candidates.

Our Biologic Tissue Product segment produces and markets Osteocel, which was launched in July 2005 for regenerating bone in orthopedic indications. During the first quarter of 2007, we expanded our Osteocel manufacturing facility and experienced failed production qualification runs. The production issues were subsequently resolved in late March, and the expanded facility is currently producing product at previously projected output. We manufacture Osteocel. We, together with AlloSource, distribute Osteocel in orthopedic indications and jointly distribute Osteocel with Blackstone Medical, Inc., a division of Orthofix International, N.V., for spinal procedures and orthopedic indications.

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 March 31, 2007, we had an accumulated deficit of $199.0 million.

Financial Operations Overview

Revenue

Osteocel is our only commercial product. Sales of Osteocel generated revenue of approximately $2.0 million for the quarter ended March 31, 2007.

Other than Osteocel, we have no commercial products for sale. A substantial portion of our revenue in the future will be dependent on the approval and sale of our biologic drug candidates. Our revenue may vary substantially from quarter to quarter and from year to year. We believe that period-to-period comparisons of our results of operations are not meaningful and should not be relied upon as indicative of our future performance.

Cost of Goods Sold

Our cost of goods sold relate to direct costs of producing Osteocel, which we launched in July 2005. Cost of goods sold consist primarily of the costs of obtaining tissue and other chemicals and supplies, direct labor and allocated costs of our facilities and overhead.

Research and Development Costs

Our research and development costs consist of expenses incurred in identifying, developing and testing biologic drug candidates and our biologic tissue product. 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. As a result, we cannot state precisely the total costs incurred for each of our clinical and preclinical projects on a project-by-project basis. From inception through March 31, 2007, we incurred aggregate research and development costs of approximately $194 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 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 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.

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 and since the closing of our initial public offering in August 2006, we began to incur increases in our general and administrative expense 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 and Other Income (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 bank loan, 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 $70 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 IRC Section 382, and we could be subject to the alternative minimum tax.

Critical Accounting Policies

There have been no material changes in our critical accounting policies, estimates and judgments during the three months ended March 31, 2007 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2006, other than as disclosed herein.

Results of Operations

Comparison of Quarters ended March 31, 2007 and 2006

Revenue

Total revenues increased 63% to $2.3 million for the three months ended March 31, 2007, compared to $1.4 million in the corresponding period in 2006. Our revenues in 2007 resulted primarily from $2.0 million generated from the sale of Osteocel and the recognition of $0.3 million in licensing fees and royalties. In the three months ended March 31, 2006, we recognized $1.1 million from the sale of Osteocel and $0.3 million in license fees and royalties.

Cost of Goods Sold

Cost of goods sold were $0.9 million for the three months ended March 31, 2007 compared to $0.5 million in the prior year. The cost of goods sold associated with sales of Osteocel was comprised of payments to tissue banks, direct labor costs and the costs of processing, testing and preserving Osteocel, plus allocated costs of our facilities and overhead. The gross profit on Osteocel sales for the three months ended March 31, 2007 was 55%, compared with 56% for the comparable period in 2006.

Research and Development Expenses

Research and development expenses were approximately $11 million for the three months ended March 31, 2007 compared to $4.4 million in the prior year. The increase in research and development expenses in 2007 reflects the increased number of clinical trials in process versus the prior year and, to a lesser degree, costs associated with the expansion of our Osteocel manufacturing facility, as we experienced failed production qualification runs while expanding our capacity. The production issues were subsequently resolved in late March, and the expanded facility is currently producing product at previously projected output.

General and Administrative Expenses

General and administrative expenses were $1.5 million for the three months ended March 31, 2007 compared to $1.1 million in the prior year. The increase in 2007 over the prior year was attributable to additional personnel and related costs to support the company s growth and costs incurred in connection with becoming a public company.

Interest Expense, Net

Interest expense, net was $0.3 million for the three months ended March 31, 2007 compared to $0.5 million in the prior year.

Liquidity and Capital Resources

Liquidity

At March 31, 2007, we had $1.9 million in cash and $27.6 million in short-term investments. In addition to the cash and short-term investments, at March 31, 2007 we had drawn only $5.0 million of the $50.0 million line of credit available for the development of Provacel under a loan agreement with a large pharmaceutical company. This $5.0 million draw occurred in March 2004. In connection with this line of credit, we have granted the pharmaceutical company a security interest in the intellectual property, equipment and books and records involved in the development, manufacture and distribution of Provacel. The pharmaceutical company is also obligated to make additional investments in our Company and pay licensing fees up to $45.0 million to us upon completion of certain milestones.

In addition to the $5.0 million balance on the line of credit, at March 31, 2007, our debt included approximately $20.0 million of convertible promissory notes due in 2009.

Cash Flows

Net cash used in operating activities was $8.6 million for the three months ended March 31, 2007 primarily reflecting our net loss of $11.5 million, which was partially offset by $1.9 million in favorable changes in working capital, $0.5 million in non-cash stock-based compensation expense, and $0.4 million in depreciation and amortization. Net cash used in operating activities for the first quarter of 2006 was $3.9 million, primarily reflecting a net loss of $5.1 million, which was partially offset by $0.6 million in non-cash interest expense and $0.3

million in depreciation and amortization.

Net cash provided by investing activities was $10.0 million for the three months ended March 31, 2007. Net cash provided in investing activity for the three months ended March 31, 2006 was $4.5 million. Net cash provided by investing activities in 2007 includes cash flows from the sale of $10.8 million of short-term investments, partially offset by the purchase of $0.9 million of property and equipment. In the first quarter of 2006, we sold $4.7 million of short-term investments and had purchases of property and equipment of $0.2 million.

Net cash used in financing activities was $0.2 million for the three months ended March 31, 2007. Net cash used in financing activities was $0.2 million for the three months ended March 31, 2006.

Capital Resources.

Our future capital requirements will depend on many factors, including:

- the level of cash flows from Osteocel sales;
- 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 building and operating our manufacturing facilities, both in the near term to support Osteocel sales and our clinical activities and also in anticipation of expanding our commercialization activities;
- 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 may 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. Although not our current focus, we might also seek funding through 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 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.

If we are unable to obtain adequate financing on a timely basis, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our business, financial condition and results of operations.

We expect that our available cash and interest income, including the availability under our line-of-credit, will be sufficient to finance currently planned activities through early 2008. These estimates are based on certain assumptions, which could be negatively impacted by the matters discussed under Risk Factors in our Annual Report on Form 10-K.

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 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. Therefore, we would not expect our operating results or cash flows to be affected to any significant 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.

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. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (a) are effective to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is timely recorded, processed, summarized and reported and (b) include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. There have not been any changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2007 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, filed with the Securities and Exchange Commission on March 26, 2007.

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

On August 4, 2006, we sold 3,500,000 shares of our common stock in our initial public offering at the price to the public of $11.00 per share. The offer and sale of all of the shares in the offering were registered under the Securities Act of 1933, as amended, pursuant to a registration statement on Form S-1 (File No. 333-13407), which was declared effective by the Securities and Exchange Commission on August 3, 2006. The underwriters of the offering were Jefferies & Company, Inc., Lazard Capital Markets, LLC and Leerink Swann & Co., Inc. There were no selling stockholders in the offering.

We registered 3,500,000 shares of our common stock in connection with the initial public offering and the aggregate offering amount was $38.5 million. We paid approximately $2.7 million in underwriting discounts and commissions to the underwriter. We also incurred other expenses in connection with the offering of approximately $1.4 million, including registration fees, accounting and legal, printing and engraving and other expenses.

None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates, to persons owning 10 percent or more of our common stock or to any affiliates or ours. After deducting the underwriting discounts and commissions and these other estimated offering expenses, our net proceeds from the offering were approximately $34.4 million. We deposited the net proceeds in two highly rated financial institutions in the United States.

There has been no material change in our planned use of proceeds from our initial public offering as described in our final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b). Between August 4, 2006 and March 31, 2007, we used approximately $15.0 million of the net proceeds to fund our operating activities, including activities relating to the development of our biologic drug candidates and for working capital, capital expenditures, repayment of debt and other general corporate purposes. During this period, our research and development expenses comprised approximately 91% of our operating expenses. The remaining approximately $19.4 million in net proceeds remains on deposit in two highly rated financial institutions in the United States. At March 31, 2007, we had $29.5 million in cash and short-term investments.

Item 3. Defaults Upon Senior Securities

None

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

None

Item 5. Other Information

Since August 2006, we have subleased approximately 61,000 square feet of additional space in Columbia, Maryland. We continue to lease 118,000 square feet of space in Baltimore, Maryland, but have been working to transition our principal executive offices from Baltimore to Columbia, Maryland. We have completed this transition, and as reflected on the cover page of this Quarterly Report on Form 10-Q, our principal executive offices are now located at 7015 Albert Einstein Drive, Columbia, Maryland 21046. Our biologic tissue product manufacturing facilities remain at the Baltimore location.

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Item 6. **Exhibits**

Exhibit Number	**Description of Exhibit**
31.1	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	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	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.

The certification attached as Exhibit 32 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Osiris Therapeutics, Inc. 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 this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURE

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

Osiris Therapeutics, Inc.

Date: May 14, 2007

/s/ Cary J. Claiborne
Cary J. Claiborne
Chief Financial Officer

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