OSIRIS THERAPEUTICS, INC.
Form 10-Q
September 15, 2006

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 **June 30, 2006**

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.)

2001 Aliceanna St. Baltimore, Maryland 21231

(Address of principal executive offices) (Zip code)

410-522-5005

(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 o No x

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 acceleratef iler 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 September 1, 2006**
Common Stock, par value $0.001 per share	27,198,307

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

	June 30, 2006 (unaudited)	December 31, 2005
Assets		
Current assets:		
Cash	$ 814	$ 597
Short-term investments	27,765	42,774
Accounts receivable	804	974
Inventory and other current assets	1,840	367
Total current assets	31,223	44,712
Property and equipment, net	3,746	3,792
Restricted cash	309	190
Deferred financing costs, net	1,669	2,050
Other assets	268	270
Total assets	$ 37,215	$ 51,014
Liabilities and Stockholders Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,835	$ 4,565
Note payable, current portion	65	65
Capital lease obligations, current portion	1,077	1,027
Deferred revenue, current portion	952	952
Total current liabilities	7,929	6,609
Note payable, net of current portion	47,379	47,411
Capital lease obligations, net of current portion	1,472	2,024
Deferred revenue, net of current portion	873	1,349
Long-term interest payable and other liabilities	5,251	3,016
Mandatorily redeemable convertible preferred stock Series D 3,750 shares designated, 3,213 shares issued and outstanding in 2006 and 2005	64,267	64,267
Total liabilities	127,171	124, 676
Stockholders deficit:		
Convertible Preferred Stock, issuable in series, $0.001 par value, 16,250 shares authorized, 12,250 shares designated and 10,651 shares outstanding in 2006 and 2005	32,746	32,746
Common stock, $.001 par value, 90,000 shares authorized 9,176 and 9,098 shares outstanding In 2006 and 2005	9	9
Additional paid-in-capital	36,559	36,404
Deferred compensation		(277)
Accumulated deficit	(159,270)	(142,544)
Total stockholders deficit	(89,956)	(73,662)
Total liabilities and stockholders deficit	$ 37,215	$ 51,014

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

OSIRIS THERAPEUTICS, INC.
Condensed Statements of Operations
(Unaudited)
Amounts in thousands, except per share data

	Three Months Ended June 30, 2006	2005
Revenues:		
Product Sales	$ 1,689	$
Cost of goods sold	762	
Gross profit	927	
Revenue from collaborative research licenses and grants	298	1,339
Operating expenses:		
Research and development	10,922	3,592
General and administrative	1,209	487
Total operating expenses	12,131	4,079
Loss from operations	(10,906)	(2,740)
Interest expense, net	(699)	(654)
Net loss	$ (11,605)	$ (3,394)
Basic and diluted net loss per share	$ (1.27)	$ (0.38)
Weighted Average Common Shares (basic and diluted)	9,158	8,964

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

OSIRIS THERAPEUTICS, INC.
Condensed Statements of Operations
(Unaudited)
Amounts in thousands, except per share data

	Six Months Ended June 30, 2006	2005
Revenues:		
Product Sales	$ 2,794	$
Cost of goods sold	1,251	
Gross profit	1,543	
Revenue from collaborative research licenses and grants	593	1,724
Operating expenses:		
Research and development	15,290	6,249
General and administrative	2,347	1,239
Total operating expenses	17,637	7,488
Loss from operations	(15,501)	(5,764)
Interest expense, net	(1,225)	(1,498)
Net loss	$ (16,726)	$ (7,262)
Basic and diluted net loss per share	$ (1.83)	$ (0.81)
Weighted Average Common Shares (basic and diluted)	9,146	8,948

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

OSIRIS THERAPEUTICS, INC.
Statement of Stockholders Deficit
For the six months ended June 30, 2006
(Unaudited)
Amounts in thousands, except for share data

	Convertible Preferred Stock Shares	Amount	Common Stock Shares	Amount	Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Total Stockholders Deficit
Balance at January 1, 2006	10,650,544	$ 32,746	9,097,506	$ 9	$ 36,404	$ (277)	$ (142,544)	$ (73,662)
Exercise of options to purchase Common Stock ($0.40 per share)			49,789		20			20
Issuance of common stock for services rendered by directors ($11.00 per share)			22,807		198			198
Issuance of common stock for services rendered by consultant ($6.84 per share)			6,250		43			43
Reclassification due to adoption of new accounting standard					(277)	277		
Stock-based compensation					171			171
Net loss							(16,726)	(16,726)
Balance at June 30, 2006	10,650,544	$ 32,746	9,176,352	$ 9	$ 36,559	$	$ (159,270)	$ (89,956)

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

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

	Six Months Ending June 30, 2006	2005
Cash flows from operations:		
Net loss	$ (16,726)	$ (7,262)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation and amortization	743	720
Non cash compensation expense	412	44
Non cash interest expense	381	900
Increase (decrease) in cash resulting from changes in assets and liabilities:		
Accounts receivable	170	(624)
Inventory and other current assets	(1,473)	(42)
Other assets	2	(294)
Accounts payable and accrued expenses	1,270	796
Deferred revenue	(476)	(476)
Other long-term liabilities	2,235	(231)
Net cash used in operations:	(13,462)	(6,469)
Cash flows from investing activities:		
Purchases of property and equipment	(697)	(138)
Proceeds from sale of short-term investments	15,009	
Net cash provided by (used in) investing activities	14,312	(138)
Cash flows from financing activities:		
Principal payments on capital lease obligations and notes payable	(534)	(429)
Restricted cash	(119)	11
Proceeds from notes payable		6,919
Proceeds from the issuance of preferred and common stock, net of offering costs	20	8,088
Net cash (used in) provided by financing activities	(633)	14,589
Net increase in cash	217	7,982
Cash at beginning of period	597	488
Cash at end of period	$ 814	$ 8,470

The accompanying notes are an integral part of these 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 financial statements of Osiris Therapeutics, Inc. 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 Registration Statement on Form S-1, as amended (Registration No. 333-134037), which was declared effective by the SEC on August 3, 2006. The financial information as of June 30, 2006 and 2005 and for the three and six months then ended is 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. Initial Public Offering and Reverse Stock Split

On August 9, 2006, the Company consummated its initial public offering, consisting of 3,500,000 shares of common stock at a public offering price of $11.00, resulting in net proceeds to the Company of approximately $34.2 million (after deducting payment of underwriters discounts and commissions, as well as offering expenses).

In connection with the initial public offering, the Company effected a 1-for-4 reverse stock split of the issued and outstanding common stock. Information relating to common stock and common stock-equivalents set forth in this report (including the share numbers in the preceding paragraph) have been restated to reflect this split for all periods presented. Upon consummation of the initial public offering, all shares of the Company s Class I, Series 2003, Series B, Series C, Series E and the Mandatorily Redeemable Series D convertible preferred stock were converted into an aggregate of 10,867,284 shares of our common stock. In addition, approximately $21.8 million of our convertible notes payable, together with accrued interest, were converted into an aggregate of 2,774,076 shares of our common stock.

Immediately following the initial public offering, we had 27,198,307 shares of common stock outstanding.

3. 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 stock-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 consists primarily of the costs to obtain the tissue, direct labor and other chemicals and supplies for Osteocel, which we launched in July 2005. Beginning in 2006, we estimate the portion of our facilities and general and administrative expenses that are directly attributable to our manufacturing activities, and include these costs in cost of goods sold.

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, and the conversion of our preferred stock and convertible debt, using the treasury stock method. Common equivalent shares from the conversion of preferred stock and 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

On January 1, 2006, we adopted the provisions of Financial Accounting Standards Board Statement No. 123R, *Share-Based Payment* (Statement 123R). Statement 123R sets accounting requirements for share-based compensation to employees, and requires companies to recognize in the statement of operations the grant-date fair value of stock options and other equity-based compensation.

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 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. As of June 30, 2006, we have not granted any options under the 2006 Omnibus Plan.

A summary of option activity as of June 30, 2006 and changes during the six 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, 2005	556,480	$ 0.40		
Granted	226,000	3.98		
Exercised	(49,789)	0.40		
Forfeited or expired	(3,813)	0.40		
Outstanding at June 30, 2006	738,878	$ 1.11	8.55	$ 7,307
Exercisable at June 30, 2006	173,400	$ 0.41	7.22	$ 1,837

The weighted average grant date fair value of options granted during the six months ended June 30, 2006 was $7.36 per share. The total intrinsic value of options exercised during the six months ended June 30, 2006 was $351. We received a total of $20 in cash from the exercises of options during the six months ended June 30, 2006.

Share-based compensation included in the statements of operations for the three and six months ended June 30, 2006 was approximately $144 and $171, respectively. As of June 30, 2006, there was approximately $1.8 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.

Pro Forma Information under SFAS 123 for Periods Prior to January 1, 2006

Through fiscal year 2005, the Company accounted for stock-based awards to employees using the intrinsic value method in accordance with APB 25 and related interpretations and provided the required pro forma disclosures of SFAS 123. Under APB 25 the compensation expense is calculated as the difference between the fair value of the common stock on the date such options were granted and their exercise price.

The following table summarizes the pro forma effect on the net loss and per share data if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation for the six-month period ended June 30, 2005.

	Six Months Ended June 30, 2005
Net loss	$ (7,262)
Add: Stock-based employee compensation expense included in net loss	44
Less: Stock-based employee compensation expense determined under SFAS 123	(67)
Pro forma net loss	$ (7,285)
Net loss per share:	
Basic and diluted, net loss as reported	$ (0.81)
Pro forma basic and diluted, net loss	$ (0.81)

The weighted average fair value of options granted during the six months ended June 30, 2005 was $2.95 per share.

Significant New Accounting Pronouncement

On July 13, 2006, the FASB issued Interpretation, or FIN, No. 48, Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109. FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in our financial statements. It also prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, among other things. The provisions of FIN No. 48 are effective for us beginning January 1, 2007. We do not believe the adoption of this accounting pronouncement will have a material effect on our financial position, results of operations or cash flows.

5. Long-Term Debt and Capital Lease Obligations

	June 30, 2006	December 31, 2005
Bank Loan, payable in quarterly installments and bearing interest at LIBOR plus applicable margins, 6.64% - 7.14% in 2006	$ 82	$ 114
Line of Credit, 8%, to be repaid from future product sales	5,000	5,000
Term Note, 6% redeemable at the option of the holder after the IPO, due in 2008	20,600	20,600
Long-term debt that did not convert at the initial public offering	**25,682**	**25,714**
Term Note, 5% convertible into Common stock at $6.00/share	2,000	2,000
Term Notes, 6% convertible into common stock at initial public offering at specified prices	19,762	19,762
Long-term debt that converted upon the initial public offering	**21,762**	**21,762**
Total long-term debt	47,444	47,476
Less current portion	(65)	(65)
Long-term debt	$ 47,379	$ 47,411
Total capital lease obligations	2,549	3,051
Less current portion	(1,077)	(1,027)
Capital lease obligations, long-term	$ 1,472	$ 2,024

During June 1995, we borrowed $750 thousand from a commercial bank in connection with the acquisition and renovation of our Baltimore, Maryland facilities. This loan is partially guaranteed by an agency of the State of Maryland and matures in September 2007. This loan bears interest at LIBOR plus 2.0% to 2.5% (6.64% to 7.14% at June 30, 2006). Compensating balance arrangements with Wachovia Bank require us to maintain a cash balance of 105% of the non-guaranteed portion of this loan, which is shown as a component of restricted cash in the accompanying balance sheet. At June 30, 2006, this compensating balance requirement was $27.2.

At June 30, 2006, we had issued convertible promissory notes outstanding to twenty-six shareholders for a total of $19.8 million. These notes accrue interest at 6% per annum, and provide for redemption premiums starting at 9% of the principal amount and escalating up to 27% of the principal amount, depending upon the date of redemption or conversion to Common Stock. At June 30, 2006, we accrued the redemption premium that we were presently liable for as long-term interest payable. All twenty-six convertible promissory notes, together with accrued interest were subsequently converted into 2,376,223 shares of our common stock upon the completion of our initial public offering on August 9, 2006.

In December 2004, we issued a convertible promissory note to a foreign investor for $2.0 million. This note bore interest at 5% and the principal and accrued interest was converted into 397,853 shares of our common stock upon the completion of our initial public offering on August 9, 2006.

In November 2005, we issued a $20.6 million promissory note to a foreign investor. This Note bears interest at 6% and has redemption premiums that start at 9% and increase over time up to 27%. Interest payments are due in November 2006, 2007 and upon maturity in November 2008. This note was convertible into our common stock only if the initial public offering took place after December 2006. The note also contains demand features whereby the holder can request redemption and early repayment at any time after the completion of an initial public offering.

6. Preferred Stock Rights and Preferences

Our Convertible Preferred Stock consisted of the following designated shares at June 30, 2006 and December 31, 2005:

	December 31, 2005 and June 30, 2006	No. Shares of Common Stock Issued Upon Conversion at IPO (Aggregate Liquidation Preference / Conversion Price Per Share
Convertible preferred stock, Class I,Series 2003, $0,001 par value, 2,000,000 shares designated, issued and outstanding	$ 10,000	500,000
Convertible preferred stock, Series B, $0.001 par value, 750,000 shares designated, 545,454 shares issued and outstanding	3,000	136,364
Convertible preferred stock, Series C, $0.001 par value, 3,500,000 shares designated, 548,090 shares issued and outstanding	2,243	308,300
Convertible preferred stock, Series E, $0.001 par value, 8,000,000 shares designated, 7,557,000 shares issued and outstanding	17,503	1,889,250
	$ 32,746	2,833,914

We issued 2,000,000 shares of our Class I, Series 2003 convertible preferred stock to a collaborative partner as part of an agreement related to product development, clinical trials and FDA approval. These shares were converted into 500,000 shares of our common stock at the conversion price of $20.00 per share (after adjustment for the 1-for 4 reverse stock split) upon the completion of our initial public offering.

We issued 545,454 shares of our Series B convertible preferred stock in 2003, as part of a collaborative agreement. These shares were converted into 136,364 shares of our common stock at the conversion price of $22.00 per share (after adjustment for the 1-for 4 reverse stock split) upon the completion of our initial public offering.

We issued 548,090 shares of our Series C convertible preferred stock in 2004 at the price of $4.50 per share. These shares were converted into 308,300 shares of our common stock at the conversion price of $8.00 per share (after adjustment for the 1-for 4 reverse stock split) upon the completion of our initial public offering.

We issued 7,557,000 shares of our Series E convertible preferred stock in 2005 at a price of $2.50 per share. These shares were converted into 1,889,250 shares of our common stock at the conversion price of $10.00 per common share (after adjustment for the 1-for 4 reverse stock split) upon the completion of our initial public offering.

Also in 2005, we issued 3,213,335 shares of Series D Mandatorily Redeemable Convertible Preferred Stock at a price of $2.00 per share. These shares were converted into 8,033,370 shares of our common stock at the conversion price of $0.80 per share (after adjustment for the 1-for 4 reverse stock split) upon the completion of our initial public offering.

These Series D shares included a mandatory redemption feature whereby if the Company did not complete an initial public offering prior to June 1, 2007 and the shares are not previously converted into common stock, the Company must then redeem the shares at a price of $20.00 per share. The Series D Mandatorily Redeemable Convertible Preferred Stock is recorded as a liability in the balance sheet at June 30, 2006 and December 31, 2005, in accordance with SFAS No. 150 Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. In addition to the initial net proceeds of $5,962 from the Series D offering, a redemption premium of $58,305 was recorded as a liability.

7. Warrants

At June 30, 2006, the Company had warrants to purchase its common stock outstanding as shown in the following table.

	Common Stock # of Shares	**Weighted Average Price Per Share**
Warrants outstanding, January 1, 2006	2,125,000	$ 0.40
Warrants granted	1,000,000	11.00
Warrants exercised		
Warrants cancelled	(1,250,000)	0.40
Warrants outstanding, June 30, 2006	1,875,000	$ 6.05
Warrants outstanding after the IPO	1,000,000	$ 11.00

In connection with a 2004 financing arrangement, we issued warrants to purchase 1,250,000 shares of our common stock at $0.40 per share. In the first half of 2006, these warrants were cancelled. In May 2006, we issued warrants to Peter Friedli, the chairman of our board of directors, to purchase 1,000,000 shares of our common stock at the price our stock was offered to the public in the initial public offering. These warrants have a five-year life and entitle Mr. Friedli to purchase up to 1,000,000 shares of our common stock for $11.00 per share at any time prior to expiration.

The 875,000 warrants that were exercisable at $0.40 per share as of June 30, 2006 were all exercised concurrent with the closing of our initial public offering in August 2006.

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Introduction and Overview.

Forward-looking Statements

This report contains forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. Forward-looking statements include statements about our expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as anticipate, believe, continue, ongoing, estimate, expect, intend, may, plan, predict, project or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. 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; 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 our facilities; types of regulatory frameworks we expect will be applicable to our potential products; and results of our scientific research. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including the factors described in the section entitled Risk Factors in our Registration Statement on Form S-1, File No: 333-134037, as filed with the United States Securities and Exchange Commission and declared effective on August 3, 2006. Accordingly, you should not unduly rely on these forward-looking statements. We undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this report or to reflect the occurrence of unanticipated events.

Overview

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. Our marketed product, Osteocel, and our biologic drug candidates utilize mesenchymal stem cells, or MSCs. In July 2005, we launched Osteocel for regenerating bone in orthopedic indications. 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. Prochymal is also in Phase II clinical trials for acute GvHD and 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 Osteocel and clinical batches of our biologic drug candidates. We distribute Osteocel in orthopedic indications and jointly distribute Osteocel with Blackstone Medical, Inc. for spinal procedures.

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, 2006, we had an accumulated deficit of $159.3 million.

Financial Operations Overview

Revenue

Osteocel is our only commercial product. Sales of Osteocel generated revenue of approximately $2.8 million for the six months ended June 30, 2006. In prior years, we have entered into strategic agreements with other companies for the development and commercialization of select stem cell biologic drug candidates for specific indications and geographic markets. In 2003, we entered into an agreement with a major pharmaceutical company relating to the development of our cardiac biologic drug candidate, and we received a $5.0 million fee for licensing the use of our technology. This fee is being recognized as revenue over a 63-month period, $476 of which was recognized in the first six months of 2006 and 2005. Also in 2003, we entered into an agreement with a foreign pharmaceutical company granting it exclusive rights to Prochymal for the

treatment of GvHD in Japan. We recognized $0.5 million of revenue in the first half of 2005 related to this agreement. We do not expect to enter into collaborations in the future.

Historically, we have also recognized revenue from governmental grants for research and in the first six months of 2005, we recorded $644 in grant revenues from two separate grants. Revenue from research grants is recognized as the related research expenditures are incurred. During 2006, we did not have any active government grants and, we do not expect to solicit governmental grants in the future.

Other than Osteocel, we have no commercial products for sale and do not anticipate that we will have any other commercial products for sale for at least the next several years. 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. 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 June 30, 2006, we incurred aggregate research and development costs of approximately $159 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. Following the initial public offering, we anticipate 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. These increases will also likely include the hiring of additional 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 capital leases and other debt financings. We pay interest on our bank loan and capital leases and accrue non-cash interest on some of 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 carryforwards. In the event that we become profitable within the next several years, we have net deferred tax assets of approximately $60 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 carryforwards in any one year may be limited however, and we could be subject to the alternative minimum tax.

Critical Accounting Policies

The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of our financial statements as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in the notes to our audited financial statements for the year ended December 31, 2005 included in the final prospectus relating to our initial public offering.

Results Of Operations

Comparison of Quarters ended June 30, 2006 and 2005

Revenue

Total revenues increased 48% to $2.0 million for the quarter ended June 30, 2006, compared to $1.3 million in the second quarter of 2005. Our revenues in 2006 resulted primarily from $1.7 million generated from the sale of Osteocel and the recognition of $0.3 million in licensing fees and royalties. In the quarter ended June 30, 2005, we recognized $1.3 million in license fees and grants. We did not have any revenue from our Osteocel product in the second quarter of 2005, as the product had not been launched.

Cost of Goods Sold

Cost of goods sold were $0.8 million for the quarter ended June 30, 2006 compared to $0.0 in the second quarter of 2005. 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. We did not have any cost of goods sold from our Osteocel product in the second quarter of 2005, as the product had not been launched.

Research and Development Expenses

Research and development expenses were approximately $10.9 million for the quarter ended June 30, 2006 compared to $3.6 million in the prior year. The increase in research and development expenses in 2006 reflects the increased number of clinical trials in process verses the prior year. In 2006, we incurred costs associated with the enrollment of a Phase II trial for Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD, a Phase II trial for Prochymal for treatment of steroid refractory GvHD, a Phase II trial for Prochymal for treatment of Crohn s Disease, a Phase I/II clinical trial for Chondrogen, and a Phase I clinical trial for Provacel.

General and Administrative Expenses

General and administrative expenses including fees, were $1.2 million for the quarter ended June 30, 2006 compared to $0.5 million in the second quarter of 2005. The increase was attributable to additional personnel and related costs to support the company s growth and in preparation of our initial public offering.

Interest Expense, Net

Interest expense, net was $0.7 million for both quarters ended June 30, 2006 and 2005.

Comparison of Six Months ended June 30, 2006 and 2005

Revenue

Total revenues increased 96% to $3.4 million for the six months ended June 30, 2006, compared to $1.7 million in the corresponding period in 2005. Our revenues in 2006 resulted primarily from $2.8 million generated from the sale of Osteocel and the recognition of $0.6 million in licensing fees and royalties. In the six months ended June 30, 2005, we recognized $1.7 million in license fees and grants. We did not have any revenue from our Osteocel product in the six months ended June 30, 2005, as the product had not been launched.

Cost of Goods Sold

Cost of goods sold were $1.3 million for the six months ended June 30, 2006 compared to $0.0 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. We did not have any cost of goods sold from our Osteocel product in the prior year, as the product had not been launched.

Research and Development Expenses

Research and development expenses were approximately $15.3 million for the six months ended June 30, 2006 compared to $6.2 million in the prior year. The increase in research and development expenses in 2006 reflects the increased number of clinical trials in process verses the prior year. In 2006, we incurred costs associated with the enrollment of a Phase II trial for Prochymal as an add-on therapy to steroids for the first-line treatment of acute GvHD, a Phase II trial for Prochymal for treatment of steroid refractory GvHD, a Phase II trial for Prochymal for treatment of Crohn s Disease, a Phase I/II clinical trial for Chondrogen, and a Phase I clinical trial for Provacel.

General and Administrative Expenses

General and administrative expenses were $2.3 million for the six months ended June 30, 2006 compared to $1.2 million in the prior year. The increase was attributable to additional personnel and related costs to support the company s growth and in preparation of the initial public offering.

Interest Expense, Net

Interest expense, net was $1.2 million for the six months ended June 30, 2006 compared to $1.5 million in the prior year. The decrease was driven by higher interest income in 2006.

Liquidity and Capital Resources

Liquidity

At June 30, 2006, we had $0.8 million in cash and $27.8 million in short-term investments. In addition to the sources described above, at June 30, 2006, 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 Boston Scientific. In connection with this line of credit, we have granted Boston Scientific a security interest in the intellectual property, equipment and books and records involved in the development, manufacture and distribution of Provacel. Boston Scientific 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 balance on the line of credit, at June 30, 2006 our long term debt included approximately $42.3 million of convertible promissory notes due in 2008. Since June 30, 2006, upon closing of our initial public offering, approximately $21.8 million of the convertible promissory notes, together with accrued interest of approximately $2.0 million, converted into shares of our common stock. The remaining $20.6 million is evidenced by a convertible promissory note issued to a foreign investor in 2005, which bears interest at a 6% per annum and has redemption premiums that start at 9% and increase over time to 27%. Interest payments are due in November 2006, 2007 and upon maturity in November 2008. This note was convertible into common stock only if the initial public offering took place after December 2006. The note also contains demand features whereby the holder can request redemption and early repayment at any time after the completion of the initial public offering.

Cash Flows

Net cash used in operating activities was $13.5 million for the six months ended June 30, 2006 primarily reflecting our net loss of $16.7 million, partially offset by $1.7 million in favorable working capital, $0.8 million in non-cash interest and stock-based compensation expense and $0.7 million in depreciation and amortization. Net cash used for operating activities was $6.5 million for the six months ended June 30, 2005. Net cash used in operating activities for 2005 primarily reflects our net loss of $7.3 million, partially offset by $0.9 million in non-cash interest expense.

Net cash provided by investing activities was $14.3 million for the six months ended June 30, 2006. Net cash used in investing activity for the six months ended June 30, 2005 was $0.1 million. Net cash provided by investing activities in 2006 includes cash flows from the sale of $15.0 million of short-term investments.

Net cash used by financing activities was $0.6 million for the six months ended June 30, 2006. Net cash provided by financing activities was $14.6 million for the six months ended June 30, 2005 and consisted principally of $6.9 million in net proceeds from the issuance of convertible notes and $8.1 million in net proceeds from the issuance of common and preferred stock.

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 trial 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 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 that raised in the initial public offering of our common stock, will be sufficient to finance currently planned activities through early 2008, although no assurance can be given that changes will not occur that would consume available capital resources before such time and we may need or want to raise additional financing within this period of time. These estimates are based on certain assumptions, which could be negatively impacted by the factors discussed above and under Risk Factors included in the Registration Statement on Form S-1, as amended (Registration No. 333-134037), which was declared effective by the SEC on August 3, 2006.

Off-Balance Sheet Arrangements.

We have no off-balance sheet financing arrangements other than operating leases 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-collect ability 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 June 30, 2006 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 from the risk factors previously disclosed in Risk Factors of our Registration Statement on Form S-1, as amended (Registration No. 333-134037), which was declared effective by the SEC on August 3, 2006.

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

Recent Sales of Unregistered Securities

This information was previously reported under the heading Recent Sales of Unregistered Securities in our Registration Statement on Form S-1, as amended (File No. 333-13407), declared effective by the SEC on August 3, 2006.

Initial Public Offering and Use of Proceeds from Sales of Registered Securities

On August 9, 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 $1.6 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 commons stock or to any affiliates of ours.

After deducting the underwriting discounts and commissions and these other estimated offering expenses, our net proceeds from the offering were approximately $34.2 million. We have 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).

Item 3. Defaults Upon Senior Securities

None

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

None

Item 5. Other Information

None

Item 6. Exhibits

Exhibit Number	Description of Exhibit
3.1	Form of Amended and Restated Certificate of Incorporation of the Registrant to be effective upon consummation of this offering.
3.2	Form of Amended and Restated Bylaws of the Registrant to be effective upon consummation of this offering.
4.1	Form of Common Stock Certificate.
10.1	Amended and Restated 1994 Stock Incentive Plan, as amended.
10.2	2006 Omnibus Plan
10.3	Director Compensation Policy.
10.7	Employment Agreement by and between the Registrant and Earl R. Fender, dated as of June 12, 2006.
10.26	Sublease Agreement by and between the Registrant and Broadwing Corporation, dated as of June 2, 2006.
10.27	Agreement of Lease by and between the Registrant and Columbia Gateway S-28, L.L.C., dated June 6, 2006.
10.29	Termination Letter from Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, to the Registrant, dated May 10, 2006.
10.30	Indemnification Letter from Friedli Corporate Finance, Inc., f/k/a Friedli Corporate Finance AG, and Peter Friedli to the Registrant, dated May 19, 2006.
10.31	Warrant to Purchase up to 4,000,000 shares of Common Stock granted by Registrant to Peter Friedli, dated May 24, 2006.
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 905 of the Sarbanes-Oxley Act of 2002.

Incorporated herein by reference to the exhibit of the same number in the Company s Registration Statement on Form S-1 (Commission File No. 333-134037).

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: September 15, 2006

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