



Osiris Therapeutics Reports First Quarter 2011 Financial Results

COLUMBIA, Md.--(BUSINESS WIRE)-- [Osiris Therapeutics, Inc.](#) (NASDAQ: OSIR), the leading stem cell company focused on developing and marketing products to treat medical conditions in the inflammatory, autoimmune, cardiovascular, wound care and orthopedic areas, announced today its results for the first quarter ended March 31, 2011.

Highlights and Recent Developments

- Won top score on one of three abstracts presented describing the science and initial clinical results of Grafix®, a living skin substitute, at the 24th Annual Symposium on Advanced Wound Care.
- Completed enrollment in a 220-patient Phase 2 trial for patients experiencing their first heart attack.
- Fully filed a complete response to inquiries from the Biologics and Genetic Therapies Directorate of Health Canada about [Prochymal New Drug Submission \(NDS\)](#).
- Received International Organization for Standardization (ISO) medical device certification, an internationally recognized quality standard.
- Strengthened the senior management team with the addition of Stephen W. Potter as Senior Vice President of Operations and Corporate Development.
- Reported net income of \$4.0 million for the quarter; \$0.12 per diluted common share.
- Reported cash, receivables and short-term investments of \$63.2 million as of March 31, 2011.

"Osiris is off to a strong start in 2011," stated C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris Therapeutics. "We continue to make good progress with Prochymal in GvHD and our other larger, late stage indications. We are particularly pleased with the clinical performance of our new, sophisticated Biosurgery products. Our expectations are that 2011 will be a transformative year for the company."

First Quarter Financial Results

Net income for the first quarter of 2011 was \$4.0 million compared to \$2.4 million in the first quarter of 2010. Revenues were \$10.4 million in the first quarter of 2011, consisting primarily of the amortization of license fees from our collaboration agreements. Revenues in the first quarter of 2010 were \$11.4 million. As of March 31, 2011, Osiris had \$63.2 million of cash, receivables and short-term investments.

Research and development expenses for the first quarter of 2011 were \$4.7 million, compared to \$6.6 million incurred in the first quarter of 2010. General and administrative expenses were \$1.7 million for the first quarter of 2011 compared to \$1.8 million for the same period of the prior year. Net cash used in continuing operations for the three months ended March 31, 2011 was \$6.0 million.

Webcast and Conference Call

A webcast and conference call to discuss the financial results is scheduled for today, May 9, 2011 at 9:00 a.m. ET. To access the webcast, visit the Investor Relations section of the company's website at <http://investor.osiris.com/events.cfm>. Alternatively, callers may participate in the conference call by dialing (877) 303-6133 (U.S. participants) or (970) 315-0493 (international participants).

A replay of the conference call will be available approximately two hours after the completion of the call through May 15, 2011. Callers can access the replay by dialing (800) 642-1687 (U.S. participants) or (706) 645-9291 (international participants). The audio replay confirmation code is 63039837. To access a replay of the webcast, visit the Investor Relations section of the company's website at <http://investor.osiris.com/events.cfm>.

About Osiris Therapeutics

Osiris Therapeutics, Inc. is the leading stem cell company focused on developing products to treat serious medical conditions

in the inflammatory, autoimmune, orthopedic, wound care and cardiovascular areas. The company's pipeline of internally developed biologic drug candidates under evaluation includes Prochymal for inflammatory, autoimmune and cardiovascular indications, as well as Chondrogen for arthritis in the knee. Osiris is a fully integrated company, with capabilities in research, development, manufacturing and distribution of stem cell products. Osiris has developed an extensive intellectual property portfolio to protect the company's technology, including 47 U.S. and over 300 foreign patents.

Osiris and Genzyme formed a strategic alliance for the development and commercialization of Prochymal and Chondrogen. Under the terms of the agreement, Osiris retains commercialization rights to Prochymal and Chondrogen in the United States and Canada. Genzyme holds these rights in all other countries except Japan, where JCR Pharmaceuticals holds rights to Prochymal for the treatment of patients with hematological malignancies.

Osiris and Prochymal are registered trademarks of Osiris Therapeutics, Inc. More information can be found on the company's website, www.Osiris.com. (OSIR-G)

Forward-Looking Statements

This press release contains forward-looking statements. 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," "potential," "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 and the ability to successfully navigate these requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for Prochymal, Chondrogen and our other MSC and biologic drug candidates; our cash needs; patents and proprietary rights; the safety and ability of our potential products to treat disease and the results of our scientific research; 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. Risks and uncertainties related to our Collaboration Agreement with Genzyme for the development and commercialization of Prochymal and Chondrogen include, among others: typical business transactional risks; risks related to product development and clinical trial design, performance and completion; uncertainty of the success of Prochymal and Chondrogen in clinical trials and their ability to treat disease; Genzyme's early termination and opt-out rights; the ability of Osiris and Genzyme to successfully navigate regulatory requirements and to manufacture and commercialize products; and the uncertainty as to our ability to successfully perform under the collaborative arrangement and earn milestone and royalty payments thereunder. 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 Annual Report on Form 10-K and other Periodic Reports filed on Form 10-Q, with the United States Securities and Exchange Commission. 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 press release or to reflect the occurrence of unanticipated events.

OSIRIS THERAPEUTICS, INC. Balance Sheets Amounts in thousands

	March 31, 2011	December 31, 2010
	(unaudited)	
Assets		
Current assets:		
Cash	\$ 1,437	\$ 1,442
Investments available for sale	60,171	66,166
Accounts receivable	1,625	1,928
Inventory	639	510
Deferred tax asset	3,170	3,170
Prepaid expenses and other current assets	625	736
Total current assets	67,667	73,952
Property and equipment, net	2,963	3,127
Restricted cash	521	521

Other assets	167	184
Total assets	<u>\$ 71,318</u>	<u>\$ 77,784</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,693	\$ 5,569
Deferred revenue, current portion	<u>34,053</u>	<u>40,960</u>
Total current liabilities	38,746	46,529
Deferred revenue, net of current portion	-	3,333
Other long-term liabilities	<u>460</u>	<u>465</u>
Total liabilities	<u>39,206</u>	<u>50,327</u>
Stockholders' equity		
Common stock, \$.001 par value, 90,000 shares authorized, 32,819 shares outstanding - 2011, 32,794 shares outstanding - 2010	33	33
Additional paid-in-capital	275,250	274,646
Accumulated other comprehensive income (loss)	9	(3)
Accumulated deficit	<u>(243,180)</u>	<u>(247,219)</u>
Total stockholders' equity	<u>32,112</u>	<u>27,457</u>
Total liabilities and stockholders' equity	<u>\$ 71,318</u>	<u>\$ 77,784</u>

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

	Three Months Ended	
	March 31,	
	<u>2011</u>	<u>2010</u>
Product sales	\$ 37	\$ -
Cost of goods sold	<u>15</u>	<u>-</u>
Gross profit	<u>22</u>	<u>-</u>
Revenue from collaborative research agreements, government contract and royalties	10,395	11,377
Operating expenses:		
Research and development	4,711	6,560
General and administrative	<u>1,696</u>	<u>1,807</u>
	<u>6,407</u>	<u>8,367</u>
Income from operations	4,010	3,010
Other income, net	<u>29</u>	<u>88</u>
Income before income taxes	4,039	3,098
Income tax expense	<u>-</u>	<u>(682)</u>
Net income	<u>\$ 4,039</u>	<u>\$ 2,416</u>

Basic earnings per share	<u>\$ 0.12</u>	<u>\$ 0.07</u>
Diluted earnings per share	<u>\$ 0.12</u>	<u>\$ 0.07</u>
Weighted average common shares (basic)	<u>32,807</u>	<u>32,774</u>
Weighted average common shares (diluted)	<u>33,113</u>	<u>33,088</u>

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

	<u>Three Months Ended</u>	
	<u>March 31,</u>	
	<u>2011</u>	<u>2010</u>
Cash flows from operating activities:		
Continuing operations		
Net income	\$ 4,039	\$ 2,416
Adjustments to reconcile net income to net cash used in continuing operations:		
Depreciation and amortization	189	190
Non cash share-based payments	604	374
Changes in operating assets and liabilities:		
Accounts receivable	303	(251)
Prepaid expenses, inventory, and other current assets	(18)	116
Other assets	17	55
Accounts payable and accrued expenses	(869)	(3,168)
Deferred revenue	<u>(10,240)</u>	<u>(10,296)</u>
Net cash used in continuing operations	<u>(5,975)</u>	<u>(10,564)</u>
Discontinued operations		
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	-	(412)
Net cash used in discontinued operations	-	(412)
Net cash used in operating activities	<u>(5,975)</u>	<u>(10,976)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(25)	(38)
Proceeds from sale of investments available for sale	6,000	11,097
Purchases of investments available for sale	<u>(5)</u>	<u>(173)</u>
Net cash provided by investing activities	<u>5,970</u>	<u>10,886</u>
Cash flows from financing activities:		
Principal payments on capital lease obligations	-	(2)
Proceeds from the exercise of stock options	-	1
Net cash used in financing activities	<u>-</u>	<u>(1)</u>
Net decrease in cash	(5)	(91)
Cash at beginning of period	<u>1,442</u>	<u>1,306</u>
Cash at end of period	<u>\$ 1,437</u>	<u>\$ 1,215</u>

For additional information:

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