



Osiris Therapeutics Reports First Quarter 2010 Financial Results

COLUMBIA, Md. – May 7, 2010 - [Osiris Therapeutics, Inc.](#) (NASDAQ: OSIR), the leading stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, cardiovascular and orthopedic areas, announced today its results for the first quarter of fiscal 2010.

Highlights and Recent Developments

- Announced the positive interim analysis of the first 207 patients in a clinical trial evaluating Prochymal for treatment-resistant Crohn's disease.
- Granted Orphan Drug designation from the Food and Drug Administration (FDA) for Prochymal as a treatment for type 1 diabetes.
- Achieved \$1.0 million milestone from JCR Pharmaceuticals for development progress with Prochymal in Japan.
- Reported data showing Prochymal achieved a 63% response rate when used as a rescue agent in children with end-stage graft versus host disease (GvHD).
- Presented data showing Prochymal significantly improves response rates over standard of care for both liver and gastrointestinal steroid-refractory GvHD.
- Recorded net income of \$2.4 million for the quarter; \$0.07 per diluted common share.
- Reported cash, short-term investments and receivables of \$91.2 million at March 31, 2010.

"We're pleased with the progress we've made across many of our programs including Crohn's disease, type 1 diabetes and GvHD," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris Therapeutics. "Given our strong balance sheet, financial discipline and practical approach to drug development, we are well-positioned to bring this first-in-class technology to the patients who need it most."

First Quarter Financial Results

Net income for the first quarter of 2010 was \$2.4 million compared to a loss from continuing operations of \$7.9 million in the first quarter of 2009. Net income for the first quarter of 2009 of \$14.8 million included \$22.7 million of income from discontinued operations. Revenues were \$11.4 million in the first quarter of 2010, consisting primarily of upfront license fees from the Genzyme agreement and a \$1.0 million milestone payment achieved from our collaboration with JCR Pharmaceuticals for development progress of Prochymal in Japan. Revenues in the first quarter of 2009 were \$12.7 million. As of March 31, 2010, Osiris had \$91.2 million of cash, receivables and short-term investments.

Research and development expenses for the first quarter of 2010 were \$6.6 million, compared to \$18.6 million incurred in the first quarter of 2009. The \$12.0 million decrease in R&D expenses reflects the completion of clinical work associated with our Phase III clinical trials. General and administrative expenses were \$1.8 million for the first quarter of 2010 compared to \$2.9 million for the same period of the prior year. Net cash used in continuing operations for the quarter was \$10.6 million.

Webcast and Conference Call

A webcast and conference call to discuss the financial results is scheduled for today, May 7, 2010 at 9:00 am 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 20, 2010. 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 72589651. 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 therapeutic company focused on developing products to treat serious medical conditions in the inflammatory, autoimmune, orthopedic 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 49 U.S. patents each having one or more foreign counterparts. Osiris, Prochymal and Chondrogen are registered trademarks of Osiris Therapeutics, Inc. More information can be found on the company's website, www.Osiris.com. (OSIR-G)

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.

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.

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OSIRIS THERAPEUTICS, INC.
Condensed Balance Sheets
Amounts in thousands

	<u>March 31, 2010</u> <u>(unaudited)</u>	<u>December 31, 2009</u>
Assets		
Current assets:		
Cash	\$ 1,215	\$ 1,306
Short-term investments	88,588	99,409
Accounts receivable	1,389	1,138
Inventory	117	-
Prepaid expenses and other current assets	715	948
Total current assets	92,024	102,801
Property and equipment, net	3,582	3,734
Restricted cash	666	666
Other assets	340	395
Total assets	<u>\$ 96,612</u>	<u>\$ 107,596</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,794	\$ 9,013
Deferred revenue, current portion	40,925	41,011
Capital lease obligations, current portion	1	3
Current liabilities of discontinued operations	-	412
Total current liabilities	46,720	50,439
Deferred revenue, net of current portion	33,963	44,173
Other long-term liabilities	475	424
Total liabilities	81,158	95,036
Stockholders' equity		
Common stock, \$.001 par value, 90,000 shares authorized, 32,775 shares outstanding - 2010, 32,773 outstanding - 2009	33	33
Additional paid-in-capital	273,334	272,959
Accumulated other comprehensive income (loss)	15	(88)
Accumulated deficit	(257,928)	(260,344)
Total stockholders' equity	15,454	12,560
Total liabilities and stockholders' equity	<u>\$ 96,612</u>	<u>\$ 107,596</u>



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

	Three Months Ended March 31,	
	2010	2009
Revenue from collaborative research agreements, government contract and royalties	\$ 11,377	\$ 12,726
Operating expenses:		
Research and development	6,560	18,567
General and administrative	1,807	2,913
	<u>8,367</u>	<u>21,480</u>
Income (loss) from operations	3,010	(8,754)
Other income, net	88	98
Income (loss) from continuing operations, before income taxes	3,098	(8,656)
Income tax (expense) benefit	(682)	748
Income (loss) from continuing operations	<u>2,416</u>	<u>(7,908)</u>
Discontinued operations:		
Income from operations of discontinued operations, net of income taxes of \$117 in 2009	-	1,239
Gain from sale of discontinued operations, net of income taxes of \$2,026 in 2009	-	21,428
Income from discontinued operations	<u>-</u>	<u>22,667</u>
Net income	<u>\$ 2,416</u>	<u>\$ 14,759</u>
Basic income per share		
Income (loss) from continuing operations	\$ 0.07	\$ (0.24)
Income from discontinued operations	-	0.69
Basic earnings per share	<u>\$ 0.07</u>	<u>\$ 0.45</u>
Diluted income per share		
Income (loss) from continuing operations	\$ 0.07	\$ (0.24)
Income from discontinued operations	-	0.69
Diluted earnings per share	<u>\$ 0.07</u>	<u>\$ 0.45</u>
Weighted Average Common Shares (basic)	<u>32,774</u>	<u>32,692</u>
Weighted Average Common Shares (diluted)	<u>33,088</u>	<u>32,692</u>



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

	<u>Three Months Ended</u>	
	March 31,	
	<u>2010</u>	<u>2009</u>
Cash flows from operating activities:		
Continuing operations		
Income (loss) from continuing operations	\$ 2,416	\$ (7,908)
Adjustments to reconcile income (loss) from continuing operations to net cash used in operations:		
Depreciation and amortization	190	127
Non cash share-based payments	374	1,018
Changes in operating assets and liabilities:		
Accounts receivable	(251)	246
Prepaid expenses and other current assets	116	254
Other assets	55	156
Accounts payable and accrued expenses	(3,168)	1,796
Deferred revenue	(10,296)	(10,092)
Net cash used in continuing operations	<u>(10,564)</u>	<u>(14,403)</u>
Discontinued operations		
Income from discontinued operations	-	22,667
Adjustments to reconcile income from discontinued operations to net cash used in discontinued operations:		
Non cash impact of the sale of discontinued operations	-	(14,121)
Depreciation and amortization	-	210
Non cash share-based payments	-	125
Changes in operating assets and liabilities:		
Accounts receivable	-	(17,214)
Inventory and other current assets	-	1,707
Accounts payable and accrued expenses	(412)	4,261
Net cash used in discontinued operations	<u>(412)</u>	<u>(2,365)</u>
Net cash used in operating activities	<u>(10,976)</u>	<u>(16,768)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(38)	(35)
Proceeds from the sale of property and equipment	-	17
Proceeds from sale of discontinued operations, net	-	9,870
Proceeds from sale of investments available for sale	11,097	11,806
Purchases of investments available for sale	(173)	-
Net cash provided by investing activities	<u>10,886</u>	<u>21,658</u>
Cash flows from financing activities:		
Principal payments on capital lease obligations and notes payable	(2)	(2)
Restricted cash	-	(536)
Proceeds from the issuance of common stock, net	1	134
Net cash used in financing activities	<u>(1)</u>	<u>(404)</u>
Net (decrease) increase in cash	(91)	4,486
Cash at beginning of period	1,306	940
Cash at end of period	<u>\$ 1,215</u>	<u>\$ 5,426</u>