



Osiris Therapeutics Reports Fourth Quarter and Full Year 2009 Financial Results

COLUMBIA, Md. – February 24, 2010 - [Osiris Therapeutics, Inc.](http://www.Osiris.com) (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 fourth quarter and year ended December 31, 2009.

Recent and Full Year Highlights

- Reported data showing Prochymal achieved a 63% response rate when used as a rescue agent in children with end-stage GvHD.
- Achieved significant improvement in response rates over standard of care for both liver and gastrointestinal steroid-refractory GvHD – the two most deadly and difficult-to-treat forms of the disease.
- Submitted additional sections of the Biological License Application (BLA) for Prochymal to the Food and Drug Administration (FDA).
- Received \$1.5 million in milestone payments from the Juvenile Diabetes Research Foundation (JDRF) and completed enrollment of the 63 patient Phase II type 1 diabetes trial.
- Expanded the Phase II trial evaluating Prochymal in type 1 diabetes to include pediatric patients.
- Created a new Biosurgery division focused on developing high-end biologic products for use in surgical procedures.
- Published positive data in the *Journal of the American College of Cardiology* demonstrating the safety and effectiveness of Prochymal in treating heart attack patients.
- Earned and received the full \$85.0 million proceeds on the sale of Osteocel.
- Reported cash and short-term investments of \$100.7 million at year-end.

"At Osiris, the medical problems we are tackling are some of the most challenging and complex facing healthcare today," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "While there will be obstacles along the way, we must move forward with courage, determination and urgency. Our partners, our investors, and most importantly our patients deserve nothing less."

Fourth Quarter Financial Results

Net income for the fourth quarter of 2009 was \$15.7 million compared to a net loss of \$7.8 million in the fourth quarter of 2008. Revenues were \$10.8 million in the fourth quarter of 2009, consisting primarily of upfront license fees from the Genzyme agreement and our research, development and commercialization agreement with JDRF. Revenues during the fourth quarter of 2008 were \$6.2 million. As of December 31, 2009, Osiris had \$100.7 million of cash and short-term investments.

Loss from continuing operations during the fourth quarter of 2009 was \$0.3 million compared to \$11.9 million for the fourth quarter of 2008. Income from discontinued operations for the fourth quarter of 2009 was \$16.0 million. This includes the \$15.0 million final milestone payment received from NuVasive, Inc. after their cumulative sales of Osteocel reached the \$35.0 million threshold. The creation of the Biosurgery Division in the fourth quarter of 2009 allowed the company to effectively utilize the manufacturing facilities previously used to produce Osteocel, resulting in the reduction of a lease impairment charge recorded in the first quarter of this year. Net income from discontinued operations in the fourth quarter of 2008 was \$4.1 million, which reflected the recognition of a \$5.0 million milestone payment from NuVasive.

Research and development expenses for the fourth quarter of 2009 were \$9.9 million, compared to \$15.6 million incurred in the fourth quarter of 2008. The 37% decline in R&D expenses reflects the completion of substantially all clinical work associated with our Phase III clinical trials. General and administrative expenses were \$2.1 million for the fourth quarter of 2009 compared to \$2.3 million for the same period of the prior year. Net cash used in continuing operations for the quarter was \$14.8 million.



Full Year 2009 Financial Highlights

Net income was \$14.6 million for the year ended December 31, 2009 compared to a net loss of \$33.5 million in 2008. Loss from continuing operations was \$23.6 million in 2009 compared to a loss from continuing operations in 2008 of \$69.4 million. Income from discontinued operations in 2009 was \$38.1 million compared to \$35.9 million in the prior year.

Revenues of \$44.5 million were recognized in 2009, including \$40.0 million from the Genzyme collaboration agreement, \$3.0 million from the U.S. Department of Defense (DoD) contract and \$1.2 million from the research development and commercialization agreement with the JDRF. Revenues in 2008 were \$10.0 million, which included \$6.7 million from the Genzyme agreement, \$2.5 million from the DoD contract and \$0.6 million from the JDRF agreement.

R&D expenses for the 2009 fiscal year were \$63.3 million compared to \$69.9 million in the prior year. R&D expenses began to decrease in the second half of 2009 as work on Phase III clinical trials was being completed. G&A expenses in fiscal 2009 were \$8.8 million compared to \$8.6 million in the prior year.

Webcast and Conference Call

A webcast and conference call to discuss the financial results is scheduled for today, February 24, 2010, 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 March 10, 2010. Callers can access the replay by dialing (800) 642-1687 (U.S. participants) or (706) 645-9291 (international participants). The audio replay passcode is 56969647. 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, 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)

In November 2008, Osiris and Genzyme announced 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, with Genzyme holding these rights in all other countries.

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
(Unaudited)
Amounts in thousands

	December 31,	
	2009	2008
	<u>Unaudited</u>	
ASSETS		
Current assets:		
Cash	\$ 1,306	\$ 940
Investments available for sale	99,409	61,298
Accounts receivable	1,138	61,287
Prepaid expenses and other current assets	948	2,060
Current assets of discontinued operations	—	3,223
Total current assets	<u>102,801</u>	<u>128,808</u>
Property and equipment, net	3,734	394
Restricted cash	666	130
Other assets	395	615
Long-term assets of discontinued operations	—	7,520
Total assets	<u>\$ 107,596</u>	<u>\$ 137,467</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,013	\$ 10,513
Deferred revenue, current portion	41,011	40,471
Capital lease obligations, current portion	3	6
Current liabilities of discontinued operations	412	7,219
Total current liabilities	<u>50,439</u>	<u>58,209</u>
Deferred revenue, net of current portion	44,173	84,275
Other long-term liabilities	424	3
Total liabilities	<u>95,036</u>	<u>142,487</u>
Stockholders' equity (deficit):		
Common stock, \$.001 par value, 90,000 shares authorized 32,773 and 32,676 shares outstanding in 2009 and 2008	33	33
Additional paid-in-capital	272,959	269,830
Accumulated other comprehensive income (loss)	(88)	33
Accumulated deficit	(260,344)	(274,916)
Total stockholders' equity (deficit)	<u>12,560</u>	<u>(5,020)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 107,596</u>	<u>\$ 137,467</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2009	2008	2009	2008
Revenue from collaborative research agreements, government contract and royalties	\$ 10,754	\$ 6,157	\$ 44,533	\$ 10,044
Operating expenses:				
Research and development	9,912	15,563	63,266	69,897
General and administrative	2,062	2,309	8,807	8,586
	<u>11,974</u>	<u>17,872</u>	<u>72,073</u>	<u>78,483</u>
Loss from operations	(1,220)	(11,715)	(27,540)	(68,439)
Other income (expense), net	890	(178)	1,277	(978)
Loss from continuing operations, before income taxes	(330)	(11,893)	(26,263)	(69,417)
Income tax benefit	63	—	2,699	—
Loss from continuing operations	<u>(267)</u>	<u>(11,893)</u>	<u>(23,564)</u>	<u>(69,417)</u>
Discontinued operations:				
Income (loss) from operations of discontinued operations, net of income taxes	15	(744)	1,084	5,525
Gain from sale of discontinued operations, net of income taxes	15,940	4,861	37,052	30,400
Income from discontinued operations	<u>15,955</u>	<u>4,117</u>	<u>38,136</u>	<u>35,925</u>
Net income (loss)	<u>\$ 15,688</u>	<u>\$ (7,776)</u>	<u>\$ 14,572</u>	<u>\$ (33,492)</u>
Basic and diluted income (loss) per share				
Loss from continuing operations	\$ (0.01)	\$ (0.37)	\$ (0.72)	\$ (2.18)
Income (loss) from discontinued operations	0.49	0.13	1.16	1.12
Basic and diluted earnings (loss) per share	<u>\$ 0.48</u>	<u>\$ (0.24)</u>	<u>\$ 0.45</u>	<u>\$ (1.05)</u>
Weighted Average Common Shares (basic)	<u>32,773</u>	<u>32,259</u>	<u>32,742</u>	<u>31,895</u>



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

	Year Ended December 31,	
	2009	2008
Cash flows from operating activities:		
Continuing Operations:		
Loss from continuing operations	\$ (23,564)	\$ (69,417)
Adjustments to reconcile loss from continuing operations to net cash provided by (used in) continuing operations:		
Depreciation and amortization	665	1,633
Non cash share-based payments	2,456	1,627
Non cash interest expense	—	130
Changes in operating assets and liabilities:		
Accounts receivable	55,149	(60,738)
Prepaid expenses and other current assets	1,112	(477)
Other assets	220	784
Accounts payable and accrued expenses	(1,950)	(1,022)
Deferred revenue	(39,562)	124,746
Net cash provided by (used in) continuing operations	<u>(5,474)</u>	<u>(2,734)</u>
Discontinued Operations:		
Income from discontinued operations	38,136	35,925
Adjustments to reconcile income from discontinued operations to net cash (used in) provided by discontinued operations:		
Non cash impact of the sale of discontinued operations	(44,788)	(30,400)
Depreciation and amortization	210	562
Provision for bad debts	45	29
Non cash share-based payments	98	187
Changes in operating assets and liabilities:		
Accounts receivable	1,516	2,779
Inventory and other current assets	1,707	1,821
Accounts payable and accrued expenses	(3,563)	2,053
Net cash (used in) provided by discontinued operations	<u>(6,639)</u>	<u>12,956</u>
Net cash provided by (used in) operating activities	<u>(12,113)</u>	<u>10,222</u>
Cash flows from investing activities:		
Purchases of property and equipment	(304)	(2,974)
Proceeds from the sale of property and equipment	17	104
Proceeds from sale of discontinued operations, net of transaction costs	9,736	33,607
Proceeds from sale of investments available for sale	54,185	16,195
Purchases of investments available for sale	(51,187)	(60,000)
Net cash provided by (used in) investing activities	<u>12,447</u>	<u>(13,068)</u>
Cash flows from financing activities:		
Principal payments on capital lease obligations and notes payable	(7)	(14,357)
Restricted cash	(536)	150
Proceeds from convertible and short-term notes payable	—	17,000
Proceeds from issuance of common stock	575	289
Net cash provided by financing activities	<u>32</u>	<u>3,082</u>
Net increase in cash	366	236
Cash at beginning of period	940	704
Cash at end of period:	<u>\$ 1,306</u>	<u>\$ 940</u>