



## Osiris Therapeutics Reports Fourth Quarter and Full Year 2010 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 and orthopedic areas, announced today its results for the fourth quarter and full year ended December 31, 2010.

### Recent and Full Year Highlights

- Completed enrollment in a 220-patient Phase 2 trial for patients experiencing their first heart attack.
- Submitted [Prochymal New Drug Submission \(NDS\)](#) to the Biologics and Genetic Therapies Directorate of Health Canada.
- Received Orphan Drug designation from Swissmedic, the Swiss Agency for Therapeutic Products, and the Therapeutic Goods Administration, Australia's regulatory agency for medical drugs and devices, for Prochymal as a treatment for GvHD, making the drug eligible for expedited review.
- Granted Priority Review for Prochymal by Health Canada.
- Announced a positive interim analysis of the first 207 patients in a clinical trial evaluating Prochymal for treatment-resistant [Crohn's disease](#) and continued patient enrollment.
- 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.
- Completed enrollment in a 63-patient trial evaluating Prochymal in patients with type 1 diabetes and recognized \$1.2 million in funding from the Juvenile Diabetes Research Foundation (JDRF).
- Strengthened the senior management team with the addition of Stephen W. Potter as Senior Vice President of Operations and Corporate Development.
- Reported cash and short-term investments of \$67.6 million at year-end.

"With quiet determination, Osiris made tremendous progress on all fronts in 2010," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "We now move into 2011 with the most advanced cell therapy pipeline, featuring late stage programs in major indications such as Crohn's and cardiac disease. Above all, our efforts remain keenly focused on our groundbreaking GvHD program that seeks to achieve our overriding goal of making Prochymal the world's first approved stem cell therapy."

### Fourth Quarter Financial Results

Net income from continuing operations for the fourth quarter of 2010 was \$4.4 million compared to a loss from continuing operations in the fourth quarter of 2009 of \$0.3 million. Revenues were \$10.8 million in the fourth quarter of 2010, 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 2009 were \$10.8 million. As of December 31, 2010, Osiris had \$67.6 million of cash and short-term investments.

Research and development expenses for the fourth quarter of 2010 were \$5.0 million, compared to \$9.9 million incurred in the fourth quarter of 2009. The 49% decline in R&D expenses reflects the completion of substantially all clinical work associated with our Phase 3 clinical trials. General and administrative expenses were \$1.8 million for the fourth quarter of 2010 compared to \$2.1 million for the same period of the prior year. Net cash used in continuing operations for the quarter was \$8.6 million, which included \$2.6 million of income taxes.

### Full Year 2010 Financial Highlights

Net income was \$13.1 million for the year ended December 31, 2010 compared to \$14.6 million in 2009. Income from continuing operations was \$13.1 million in 2010 compared to a loss from continuing operations of \$23.6 million in 2009. There was no income from discontinued operations in 2010 compared to a \$38.1 million gain the prior year.

Revenues of \$43.2 million were recognized in 2010, including \$40.0 million from the Genzyme collaboration agreement, \$0.5 million from the U.S. Department of Defense (DoD) contract, \$1.2 million from the research, development and commercialization agreement with the JDRF and a \$1.0 million milestone earned on our license agreement with JCR Pharmaceuticals. Revenues in 2009 were \$44.5 million, which included \$40.0 million from the Genzyme collaboration agreement, \$3.0 million from the U.S. Department of Defense contract and \$1.2 million from the JDRF agreement.

R&D expenses for the 2010 fiscal year were \$23.5 million compared to \$63.3 million in the prior year. R&D expenses decreased significantly in 2010 due to the completion of several Phase 3 clinical trials. G&A expenses in fiscal 2010 were \$6.5 million compared to \$8.8 million in the prior year.

### **Webcast and Conference Call**

A webcast and conference call to discuss the financial results is scheduled for today, March 7, 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 March 14, 2011. Callers can access the replay by dialing (800) 642-1687 (U.S. participants) or (706) 645-9291 (international participants). The audio replay passcode is 46155828. 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 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 Prochymal are registered trademarks of Osiris Therapeutics, Inc. More information can be found on the company's website, [www.Osiris.com](http://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.

**OSIRIS THERAPEUTICS, INC.**  
**Condensed Balance Sheets**  
**Amounts in thousands**

	<b>December 31,</b>	
	<b>2010</b>	
	<b>Unaudited</b>	<b>2009</b>
<b>Assets</b>		
Current assets:		
Cash	\$ 1,442	\$ 1,306
Investments available for sale	66,166	99,409
Accounts receivable	1,928	1,138
Inventory	510	-
Deferred tax asset	3,170	-
Prepaid expenses and other current assets	736	948
Total current assets	73,952	102,801
Property and equipment, net	3,127	3,734
Restricted cash	521	666
Other assets	184	395
Total assets	\$ 77,784	\$ 107,596
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,569	\$ 9,013
Deferred revenue, current portion	40,960	41,011
Capital lease obligations, current portion	-	3
Current liabilities of discontinued operations	-	412
Total current liabilities	46,529	50,439
Deferred revenue, net of current portion	3,333	44,173
Other long-term liabilities	465	424
Total liabilities	50,327	95,036
Stockholders' equity		
Common stock, \$.001 par value, 90,000 shares authorized, 32,794 shares outstanding - 2010, 32,773 outstanding - 2009	33	33
Additional paid-in-capital	274,646	272,959
Accumulated other comprehensive loss	(3)	(88)
Accumulated deficit	(247,219)	(260,344)
Total stockholders' equity	27,457	12,560
Total liabilities and stockholders' equity	\$ 77,784	\$ 107,596

**OSIRIS THERAPEUTICS, INC.**  
**Condensed Statements of Operations**  
**(Unaudited)**

Amounts in thousands, except per share data

<b>Three Months Ended</b>		<b>Years Ended</b>	
<b>December 31,</b>		<b>December 31,</b>	
<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>

<b>Product sales</b>	\$ 84	\$ -	\$ 183	\$ -
Cost of goods sold	<u>28</u>	<u>-</u>	<u>62</u>	<u>-</u>
Gross profit	<u>56</u>	<u>-</u>	<u>121</u>	<u>-</u>
<b>Revenue from collaborative research agreements, government contract and royalties</b>	10,681	10,754	43,021	44,533
Operating expenses:				
Research and development	5,025	9,912	23,501	63,266
General and administrative	<u>1,773</u>	<u>2,062</u>	<u>6,450</u>	<u>8,807</u>
	<u>6,798</u>	<u>11,974</u>	<u>29,951</u>	<u>72,073</u>
Income (loss) from operations	3,939	(1,220)	13,191	(27,540)
Other income, net	<u>24</u>	<u>890</u>	<u>175</u>	<u>1,277</u>
Income (loss) from continuing operations, before income taxes	3,963	(330)	13,366	(26,263)
Income tax benefit (expense)	<u>451</u>	<u>63</u>	<u>(241)</u>	<u>2,699</u>
<b>Income (loss) from continuing operations</b>	<u>4,414</u>	<u>(267)</u>	<u>13,125</u>	<u>(23,564)</u>
<b>Discontinued operations:</b>				
Income from operations of discontinued operations, net of income taxes	-	15	-	1,084
Gain from sale of discontinued operations, net of income taxes	-	15,940	-	37,052
<b>Income from discontinued operations</b>	<u>-</u>	<u>15,955</u>	<u>-</u>	<u>38,136</u>
<b>Net income</b>	<u>\$ 4,414</u>	<u>\$ 15,688</u>	<u>\$ 13,125</u>	<u>\$ 14,572</u>
<b>Basic income (loss) per share</b>				
Income (loss) from continuing operations	\$ 0.13	\$ (0.01)	\$ 0.40	\$ (0.72)
Income from discontinued operations	-	0.49	-	-
Basic earnings (loss) per share	<u>\$ 0.13</u>	<u>\$ 0.48</u>	<u>\$ 0.40</u>	<u>\$ (0.72)</u>
<b>Diluted income (loss) per share</b>				
Income (loss) from continuing operations	\$ 0.13	\$ (0.01)	\$ 0.40	\$ (0.72)
Income from discontinued operations	-	0.49	-	1.16
Diluted earnings (loss) per share	<u>\$ 0.13</u>	<u>\$ 0.48</u>	<u>\$ 0.40</u>	<u>\$ 0.45</u>
Weighted Average Common Shares (basic)	<u>32,792</u>	<u>32,773</u>	<u>32,784</u>	<u>32,742</u>
Weighted Average Common Shares (diluted)	<u>33,113</u>	<u>32,773</u>	<u>33,097</u>	<u>32,742</u>

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

	<b>Year ended December 31,</b>	
	<b>2010</b>	
	<b>Unaudited</b>	<b>2009</b>
<b>Cash flows from operating activities:</b>		
<b>Continuing operations</b>		
Income (loss) from continuing operations	\$ 13,125	\$ (23,563)
<b>Adjustments to reconcile loss from continuing operations to net cash used in operations:</b>		
Depreciation and amortization	755	664

Non cash share-based payments	1,684	2,456
Non cash interest expense	-	-
Deferred tax benefit	(3,170)	-
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(790)	55,149
Inventory, prepaid expenses, and other current assets	(298)	1,112
Other assets	211	220
Accounts payable and accrued expenses	(3,403)	(1,950)
Deferred revenue	(40,891)	(39,562)
Net cash used in continuing operations	<u>(32,777)</u>	<u>(5,474)</u>
<b>Discontinued operations</b>		
Income from discontinued operations	-	38,136
<b>Adjustments to reconcile loss from discontinued operations to net cash provided by discontinued operations:</b>		
Non cash impact of the sale of discontinued operations	-	(44,788)
Depreciation and amortization	-	210
Provision for bad debts	-	45
Non cash share-based payments	-	98
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	-	1,516
Inventory and other current assets	-	1,707
Accounts payable and accrued expenses	(412)	(3,563)
Net cash (used in) provided by discontinued operations	<u>(412)</u>	<u>(6,639)</u>
Net cash (used in) provided by operating activities	<u>(33,189)</u>	<u>(12,113)</u>
<b>Cash flows from investing activities:</b>		
<b>Investing activities of continuing operations:</b>		
Purchases of property and equipment	(148)	(304)
Proceeds from the sale of property and equipment	-	17
Proceeds from sale of discontinued operations, net	-	9,736
Proceeds from sale of investments available for sale	33,598	54,185
Purchases of investments available for sale	(270)	(51,187)
Net cash provided by (used in) investing activities of continuing operations	<u>33,180</u>	<u>12,447</u>
<b>Investing activities of discontinued operations</b>		
Purchases of property and equipment of disc ops	-	-
Net cash used by discontinued operations	<u>-</u>	<u>-</u>
Net cash provided by (used in) investing activities	<u>33,180</u>	<u>12,447</u>
<b>Cash flows from financing activities:</b>		
Principal payments on capital lease obligations and notes payable	(3)	(7)
Restricted cash	145	(536)
Proceeds from convertible and short-term notes payable	-	-
Proceeds from the issuance of preferred and common stock, net	3	575
Net cash provided by financing activities	<u>145</u>	<u>32</u>
Net increase in cash	136	366
Cash at beginning of period	<u>1,306</u>	<u>940</u>
Cash at end of period	<u>\$ 1,442</u>	<u>\$ 1,306</u>

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