



Osiris Therapeutics Reports First Quarter 2009 Financial Results

COLUMBIA, Maryland – May 7, 2009 - 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 financial results for the first quarter of 2009.

Highlights and Recent Developments

- Achieved positive initial uptake and survival results from the pediatric expanded access program
- Completed enrollment in second Prochymal Phase III clinical trial for the treatment of acute graft versus host disease (GvHD).
- Reported positive two-year data from the Phase I clinical trial evaluating Prochymal in heart attack patients and treated the first patients in the Phase II program.
- Reached agreement with the FDA regarding the timing and content of the submission of the first marketing application for a stem cell product.
- Received approval to broaden Prochymal expanded access program in the US, making the stem cell drug candidate available to adults suffering from life-threatening GvHD.
- Discontinued enrollment in Phase III Crohn's disease study.
- Received \$5 million milestone payment and accelerated transfer of the Osteocel product line, including the removal of contingencies associated with the majority of the remaining milestone payments.

"We are very pleased with the progress being made across all of our development programs, particularly our lead program for GvHD," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "While the events of the Crohn's disease trial remind us of the significant challenges and risks associated with commercializing the world's first stem cell therapy, our resolve is strengthened by our initial positive experience treating children under our expanded access program. We have built a quality company with a strong financial position, and with data expected from several diverse clinical programs this year, we look forward to an exciting 2009."

First Quarter Financial Results

For the first quarter of 2009 Osiris reported revenues of \$12.7 million, compared to \$0.4 million for the same period of the prior year. The revenue number includes the recognition of \$10.0 million in amortized license fees from Genzyme and \$2.6 million related to our contract with the United States Department of Defense. The company reported net income of \$14.8 million or \$0.45 per share for the quarter, compared to a loss of \$0.49 per share for the same period last year. The net income number is comprised of loss from continuing operations of \$7.9 million and income from discontinued operations of \$22.7 million.

Research and development expenses for the first quarter of 2009 were \$18.6 million, an increase of \$1.9 million when compared to the first quarter of 2008. General and administrative expenses were \$2.9 million for the first quarter of 2009 compared to \$2.6 million for the same period of the prior year.

A gain on the sale of discontinued operations of \$21.4 million was recorded in the first quarter of 2009. This is comprised of the \$30.0 million in milestone payments, minus one-time termination costs of \$1.4 million, lease impairment charges of \$3.2 million and the write-down of leasehold improvements and other charges of \$4.0 million.

In March 2009, Osiris entered into amendments to the existing Asset Purchase and Manufacturing Agreements with NuVasive, Inc. to accelerate the transfer of the Osteocel product line and remove contingencies applicable to \$30.0 million of the \$45.0 million in remaining milestone payments. Osiris received \$5.0 million upon signing these amendments and is scheduled to receive \$12.5 million on June 30, 2009 and \$12.5 million on September 30, 2009. The remaining \$15.0 million milestone payment is scheduled to be paid if and when NuVasive achieves cumulative sales of Osteocel of \$35.0 million.

As of March 31, 2009, Osiris had \$134.7 million of cash, short-term investments and accounts receivable. This number does not include the \$15.0 million milestone payment the company expects to receive upon NuVasive reaching \$35.0 million in cumulative sales of Osteocel.



Webcast and Conference Call

The Company has scheduled a webcast and conference call to discuss its financial results today, May 7, 2009, 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) 718-5104 (U.S. participants) or (719) 325-4811 (international participants).

A replay of the conference call will be available approximately two hours after the completion of the call through May 21, 2009. Callers can access the replay by dialing (888) 203-1112 (U.S. participants) or (719) 457-0820 (international participants). The audio replay passcode is 2394197. 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 48 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 having rights to 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 the sale of our Osteocel assets and related transactions include typical business transactional risks, the risk of changing relationships with customers, suppliers or employees; and the risk that we may not be able to fully perform or generate or receive milestone payments. 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 Quarterly 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,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
	<u>Unaudited</u>	
ASSETS		
Current assets:		
Cash	\$ 5,426	\$ 940
Investments available for sale	49,584	61,298
Accounts receivable	79,727	61,287
Prepaid expenses and other current assets	1,805	2,060
Current assets of discontinued operations	<u>7,336</u>	<u>3,223</u>
Total current assets	143,878	128,808
Property and equipment, net	4,005	394
Restricted cash	666	130
Other assets	459	615
Long-term assets of discontinued operations	<u>—</u>	<u>7,520</u>
Total assets	<u>\$ 149,008</u>	<u>\$ 137,467</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 12,973	\$ 10,513
Deferred revenue, current portion	40,480	40,471
Capital lease obligations, current portion	7	6
Current liabilities of discontinued operations	<u>7,862</u>	<u>7,219</u>
Total current liabilities	61,322	58,209
Deferred revenue, net of current portion	74,173	84,275
Other long-term liabilities	<u>2,466</u>	<u>3</u>
Total liabilities	<u>137,961</u>	<u>142,487</u>
Stockholders' equity (deficit):		
Common stock, \$.001 par value, 90,000 shares authorized 32,712 and 32,676 shares outstanding in 2009 and 2008	33	33
Additional paid-in-capital	271,107	269,830
Accumulated other comprehensive income	64	33
Accumulated deficit	<u>(260,157)</u>	<u>(274,916)</u>
Total stockholders' equity (deficit)	11,047	(5,020)
Total liabilities and stockholders' equity (deficit)	<u>\$ 149,008</u>	<u>\$ 137,467</u>

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

	<u>Three Months Ended March 31,</u>	
	<u>2009</u>	<u>2008</u>
Revenue from collaborative research agreements, government contract and royalties	\$ 12,726	\$ 362
Operating expenses:		
Research and development	18,567	16,694
General and administrative	2,913	2,608
	<u>21,480</u>	<u>19,302</u>
Loss from operations	(8,754)	(18,940)
Interest income (expense), net	98	(209)
Loss from continuing operations, before income taxes	(8,656)	(19,149)
Income tax benefit	748	—
Loss from continuing operations	<u>(7,908)</u>	<u>(19,149)</u>
Discontinued operations:		
Income from operations of discontinued operations, net of income taxes	1,239	3,549
Gain from sale of discontinued operations, net of income taxes	21,428	—
Income from discontinued operations	<u>22,667</u>	<u>3,549</u>
Net income (loss)	<u>\$ 14,759</u>	<u>\$ (15,600)</u>
Basic and diluted earnings (loss) per share:		
Loss from continuing operations	\$ (0.24)	\$ (0.60)
Income from discontinued operations	0.69	0.11
Basic and diluted earnings (loss) per share	<u>\$ 0.45</u>	<u>\$ (0.49)</u>
Weighted Average Common Shares, basic	<u>32,692</u>	<u>31,741</u>



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

	Three Months Ended March 31,	
	2009	2008
Cash flows from operating activities:		
Continuing Operations:		
Loss from continuing operations	\$ (7,908)	\$ (19,149)
Adjustments to reconcile loss from continuing operations to net cash used in continuing operations:		
Depreciation and amortization	127	481
Non cash share-based payments	1,018	650
Non cash interest expense	—	146
Changes in operating assets and liabilities:		
Accounts receivable	246	189
Prepaid expenses and other current assets	254	250
Other assets	156	279
Accounts payable and accrued expenses	1,796	1,895
Deferred revenue	(10,092)	—
Net cash used in continuing operations	(14,403)	(15,259)
Discontinued Operations:		
Income from discontinued operations	22,667	3,549
Adjustments to reconcile income to net cash provided by discontinued operations:		
Gain from sale of discontinued operations, net of non-cash charges	(14,121)	—
Depreciation and amortization	210	42
Non cash share-based payments	125	25
Changes in operating assets and liabilities:		
Accounts receivable	(17,214)	369
Inventory and other current assets	1,707	(574)
Accounts payable and accrued expenses	4,261	516
Net cash (used in) provided by discontinued operations	(2,365)	3,927
Net cash used in operating activities	(16,768)	(11,332)
Cash flows from investing activities:		
Purchases of property and equipment	(35)	(1,077)
Proceeds from the sale of property and equipment	17	—
Proceeds from sale of discontinued operations, net of transaction costs	9,870	—
Proceeds from sale of investments available for sale	11,806	10,353
Net cash provided by investing activities	21,658	9,276
Cash flows from financing activities:		
Principal payments on capital lease obligations and notes payable	(2)	(1,932)
Restricted cash	(536)	—
Proceeds from convertible and short-term notes payable	—	8,000
Proceeds from issuance of common stock	134	3
Net cash (used in) provided by financing activities	(404)	6,071
Net increase in cash	4,486	4,015
Cash at beginning of period	940	704
Cash at end of period:	\$ 5,426	\$ 4,719