



Osiris Therapeutics Reports Third Quarter 2009 Financial Results

COLUMBIA, Md., Nov 04, 2009 (BUSINESS WIRE) -- [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 third quarter of 2009.

Highlights and Recent Developments

Prochymal for Graft vs. Host Disease (GvHD)

- Phase III data for Prochymal in steroid-refractory GvHD (Protocol 280) showed significant improvement in response rates for both liver and gastrointestinal GvHD - the two most deadly forms of the disease.
- In pediatric patients with steroid-refractory GvHD, Prochymal more than doubled complete response rates compared to placebo.
- Strong enrollment continues in the pediatric expanded access program (Protocol 275) with more than 60 children now having received treatment with Prochymal.
- Survival in Protocol 275 exceeds 60% despite Prochymal's use as a rescue agent for children who have failed an average of 3.2 lines of treatment prior to enrollment.

Other Corporate Developments

- Earned a \$15 million milestone payment from NuVasive after they reached \$35 million in cumulative Osteocel sales.
- Received the second \$12.5 million installment payment from NuVasive related to the sale of Osteocel.
- Created a new Biosurgery Division focused on developing high-end biologic products for use in surgical procedures.
- Achieved a \$750,000 milestone from the Juvenile Diabetes Research Foundation and expanded the Phase II type 1 diabetes trial to include pediatric patients.

"Having now treated more than 550 patients with GvHD, we are gaining a clear understanding of Prochymal's impact in the context of this very deadly and very complex disease," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "It appears that Prochymal's effects are particularly profound in those patients with forms of the disease that do not respond to current standard of care. We believe that Prochymal will play an important role in the treatment of GvHD, and along with our partners at Genzyme, remain confident and committed to bringing this first-in-class stem cell therapy to the patients who desperately need effective treatments."

Third Quarter Financial Results

For the third quarter of 2009, Osiris reported revenues of \$10.6 million, compared to \$1.0 million for the same period of the prior year. Current year third quarter revenue primarily reflects the recognition of \$10.0 million in amortized license fees from Genzyme. For the third quarter of 2009, Osiris reported a net loss of \$6.2 million or \$0.19 per share, compared to a net gain, driven by the recognition of income from the sale of Osteocel, of \$5.3 million or \$0.17 per share for the same period of the prior year.

Research and development expenses for the third quarter of 2009 were \$16.2 million, compared to \$18.6 million incurred in the third quarter of 2008. General and administrative expenses were \$1.5 million for the third quarter of 2009 compared to \$1.9 million for the same period of the prior year. Net cash provided by continuing operations for the quarter was \$40.7 million.

As of September 30, 2009, Osiris had \$102.9 million of cash and short-term investments. This figure does not include the final \$15 million milestone payment from NuVasive.

Webcast and Conference Call

The Company has scheduled a webcast and conference call to discuss its financial results today, November 4, 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 (866) 431-2027 (U.S. participants) or (719) 325-2274 (international participants).

A replay of the conference call will be available approximately two hours after the completion of the call through November 18, 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 6412442. 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 having 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 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. 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

September 30, 2009	December 31, 2008
Unaudited	

ASSETS

Current assets:		
Cash	\$ 1,572	\$ 940
Investments available for sale	101,321	61,298
Accounts receivable	218	61,287
Prepaid expenses and other current assets	2,770	2,060
Current assets of discontinued operations	--	3,223
Total current assets	105,881	128,808
Property and equipment, net	3,797	394
Restricted cash	666	130
Other assets	453	615
Long-term assets of discontinued operations	--	7,520
Total assets	\$ 110,797	\$ 137,467
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	\$ 16,192	\$ 10,513
Deferred revenue, current portion	40,660	40,471
Capital lease obligations, current portion	5	6
Current liabilities of discontinued operations	493	7,219
Total current liabilities	57,350	58,209
Deferred revenue, net of current portion	54,158	84,275
Other long-term liabilities	2,575	3
Total liabilities	114,083	142,487
Stockholders' deficit:		
Common stock, \$.001 par value, 90,000 shares authorized 32,772 and 32,676 shares outstanding in 2009 and 2008	33	33
Additional paid-in-capital	272,355	269,830
Accumulated other comprehensive income	358	33
Accumulated deficit	(276,032)	(274,916)
Total stockholders' deficit	(3,286)	(5,020)
Total liabilities and stockholders' deficit	\$ 110,797	\$ 137,467

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Revenue from collaborative research agreements, government contract and royalties	\$ 10,584	\$ 995	\$ 33,779	\$ 3,887
Operating expenses:				
Research and development	16,247	18,592	53,354	54,334
General and administrative	1,511	1,887	6,745	6,277
	17,758	20,479	60,099	60,611
Loss from operations	(7,174)	(19,484)	(26,320)	(56,724)
Interest income (expense), net	134	(419)	387	(800)
Loss from continuing operations, before income taxes	(7,040)	(19,903)	(25,933)	(57,524)
Income tax benefit	238	--	2,636	--
Loss from continuing operations	(6,802)	(19,903)	(23,297)	(57,524)
Discontinued operations:				
Income (loss) from operations of discontinued operations, net of income taxes	(28)	(384)	1,069	6,269
Gain from sale of discontinued operations, net of income taxes	636	25,539	21,112	25,539

Income from discontinued operations	608	25,155	22,181	31,808
Net income (loss)	<u>\$ (6,194)</u>	<u>\$ 5,252</u>	<u>\$ (1,116)</u>	<u>\$ (25,716)</u>
Basic and diluted income (loss) per share				
Loss from continuing operations	\$ (0.21)	\$ (0.63)	\$ (0.71)	\$ (1.81)
Income (loss) from discontinued operations	0.02	0.80	0.68	1.00
Basic and diluted earnings (loss) per share	<u>\$ (0.19)</u>	<u>\$ 0.17</u>	<u>\$ (0.03)</u>	<u>\$ (0.81)</u>
Weighted Average Common Shares (basic)	<u>32,764</u>	<u>31,808</u>	<u>32,731</u>	<u>31,799</u>

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

	Nine Months Ended September 30,	
	2009	2008
Cash flows from operating activities:		
Continuing Operations:		
Loss from continuing operations	\$ (23,297)	\$ (57,524)
Adjustments to reconcile loss from continuing operations to net cash provided by (used in) continuing operations:		
Depreciation and amortization	483	1,453
Non cash share-based payments	1,852	1,290
Non cash interest expense	--	130
Changes in operating assets and liabilities:		
Accounts receivable	56,101	(177)
Prepaid expenses and other current assets	(710)	(169)
Other assets	162	864
Accounts payable and accrued expenses	4,670	(2,950)
Deferred revenue	(29,928)	--
Long-term interest payable and other liabilities	--	(839)
Net cash provided by (used in) continuing operations	<u>9,333</u>	<u>(57,922)</u>
Discontinued Operations:		
Income from discontinued operations	22,181	31,808
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	(26,595)	(27,986)
Depreciation and amortization	210	295
Provision for bad debts	45	29
Non cash share-based payments	98	134
Changes in operating assets and liabilities:		
Accounts receivable	1,516	844
Inventory and other current assets	1,707	1,066
Accounts payable and accrued expenses	(3,108)	4,256
Long-term liabilities	--	873
Net cash (used in) provided by discontinued operations	<u>(3,946)</u>	<u>11,319</u>
Net cash provided by (used in) operating activities	<u>5,387</u>	<u>(46,603)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(181)	(4,029)
Proceeds from the sale of property and equipment	17	104
Proceeds from sale of discontinued operations, net of transaction costs	9,797	33,636
Proceeds from sale of investments available for sale	35,578	12,353
Purchases of investments available for sale	(50,000)	--
Net cash provided by (used in) investing activities	<u>(4,789)</u>	<u>42,064</u>
Cash flows from financing activities:		

Principal payments on capital lease obligations and notes payable	(5)	(8,277)
Restricted cash	(536)	150
Proceeds from convertible and short-term notes payable	--	17,000
Proceeds from issuance of common stock	575	262
Net cash provided by financing activities	34	9,135
Net increase in cash	632	4,596
Cash at beginning of period	940	704
Cash at end of period:	\$ 1,572	\$ 5,300

SOURCE: Osiris Therapeutics, Inc.

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