



Osiris Therapeutics Reports First Quarter 2008 Financial Results

COLUMBIA, Md., May 09, 2008 (BUSINESS WIRE) -- Osiris Therapeutics, Inc. (NASDAQ:OSIR), a leading stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas, announced today its results for the first quarter of 2008.

Highlights

- Entered into a definitive agreement with NuVasive, Inc. to sell the Osteocel product line for up to \$85 million in upfront and milestone payments, as well as a separate process and supply agreement for up to \$52 million in revenue for Osiris.
- Received approval for treatment use of Prochymal in pediatric patients under FDA's Expanded Access Program.
- Awarded Department of Defense Contract for Prochymal fully valued at \$224.7 million.
- Regained worldwide rights to cardiovascular indications for Prochymal.
- Reported positive one year results for Prochymal trial in heart attack patients and secured clearance to start Phase II trial for this multi-billion dollar indication.
- Eliminated \$1.2 million of debt through conversion into common stock at a premium.

"These are very exciting times for Osiris as we continue to clearly demonstrate the value of our first-in-class cell therapy platform," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris Therapeutics. "In the first quarter, we not only made substantial progress with our pipeline, we also put the financial elements in place to provide resources necessary for further development, including the commercial launch of Prochymal. With more than 150 trial sites across the world, our clinical programs are operating with remarkable efficiency, and we are positioned well for what we expect to be considerable growth as we close in on our mission to launch the world's first stem cell drug."

First Quarter Financial Highlights

Upon entering into the definitive agreement to sell the Osteocel product line, Osiris eliminated the Osteocel business from its ongoing operations and has presented the results of the group, for all periods, as a discontinued operation, in accordance with generally accepted accounting principles. For the first quarter of 2008, Osteocel sales were \$7.5 million, compared to \$2.0 million for the same period of the prior year.

In January 2008, Osiris was awarded a contract from the U.S. Department of Defense, fully valued at \$224.7 million, for the development and stockpiling of Prochymal to treat acute radiation syndrome (ARS), and commenced preclinical studies in this indication. The Company recognized revenue of \$0.3 million on this contract during the first quarter of 2008 from these initial efforts. Osiris also recognized revenue of \$0.1 million in royalties. During the first quarter of 2007, the Company recognized revenue of \$0.3 million, principally from a research, development and commercialization agreement which has since been terminated, enabling Osiris to regain worldwide rights to Prochymal for cardiac indications.

Osiris reported a net loss of \$15.6 million for the first quarter of 2008 compared to a net loss of \$11.5 million for the same period of the prior year. The increase in the 2008 first quarter loss was largely the result of the continued advancement of clinical trials and costs associated with the production of increased amounts of Prochymal for use in clinical trials. During the quarter, net cash used in operations was \$11.3 million.

Research and development expenses were \$16.7 million for the first quarter of 2008 compared to \$8.5 million for the same period of the prior year. During the first quarter of 2008, research and development expenses represented 86.5% of total operating expenses. General and administrative (G&A) expenses were \$2.6 million for the first quarter of 2008 compared to \$1.5 million for the same period of the prior year. The increase in G&A expenses in the first quarter of 2008 as compared to the same period of the prior year was largely driven by the costs associated with operating two facilities as well as other professional services. The lease on the Company's Baltimore, Maryland facility expires in September 2008, and at that time Osiris will consolidate all operations in its Columbia, Maryland location.

As of March 31, 2008, Osiris had \$42.0 million in available cash, including \$12.0 million in cash and short-term investments, and \$30.0 million available under its credit line with Friedli Corporate Finance.

Webcast and Conference Call

The Company has scheduled a webcast and conference call to discuss its financial results today, May 9, 2008, at 9:00 AM EDT. 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) 397-0291 (U.S. participants) or (719) 325-4920 (international participants).

A replay of the conference call will be available approximately two hours after the completion of the call through May 23, 2008. Callers can access the replay by dialing (888) 203-1112 (U.S. participants) or (719) 457-0820 (international participants). The audio replay passcode is 4062144. 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 a leading stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Osiris currently markets and sells Osteocel(R) for regenerating bone in orthopedic indications. Prochymal(TM) is being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease and also Crohn's disease, and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. Osiris has also partnered with Genzyme Corporation to develop Prochymal(TM) as a medical countermeasure to nuclear terrorism and other radiological emergencies. Prochymal is also being developed for the repair of heart tissue following a heart attack and for the protection of pancreatic islet cells in patients with type 1 diabetes. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen(TM) for arthritis in the knee. Osiris is a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. Osiris has developed an extensive intellectual property portfolio to protect the company's technology in the United States and a number of foreign countries including 47 U.S. and 253 foreign patents owned or licensed. More information can be found on the company's website, www.Osiris.com. (OSIR-G)

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. 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 proposed sale of Osiris' Osteocel product line include the risk that the conditions relating to the closing of the sale transaction may not be satisfied, or may be delayed, or that the terms may be altered for any reason; changing relationships with customers, suppliers or employees; the risk that Osiris may not be able to fully perform or to manufacture sufficient quantities of product for any reason, including raw material availability, to generate milestone payments and manufacturing revenue. Examples of forward-looking statements include, but are not limited to, statements regarding the following: Osiris' product development efforts; clinical trials and anticipated regulatory requirements; the success of its product candidates in development; status of the regulatory process for its biologic drug candidates; implementation of its corporate strategy; its financial performance; its product research and development activities and projected expenditures, including its anticipated timeline and clinical strategy for mesenchymal stem cells and biologic drug candidates; its cash needs; patents and proprietary rights; ability of its potential products to treat disease; its plans for sales and marketing; its plans regarding its facilities; manufacturing capabilities; types of regulatory frameworks Osiris expects will be applicable to its potential products; and results of the Company's 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. Additional factors that could cause actual results could differ materially from those anticipated in forward-looking statements include the factors described in the section entitled "Risk Factors" in Osiris' Annual Report on Form 10-K filed with the United States Securities and Exchange Commission. Accordingly, you should not unduly rely on these forward-looking statements. Osiris undertakes 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.

	March 31, 2008	December 31, 2007
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ASSETS		
Current assets:		
Cash	\$ 4,719	\$ 704
Short-term investments	7,280	17,460
Accounts receivable	360	549
Prepaid expenses and other current assets	1,334	1,583
Current assets of discontinued operations	8,649	8,445
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Total current assets	22,342	28,741
Property and equipment, net	1,629	2,020
Restricted cash	280	280
Other assets	1,106	1,404
Long-term assets of discontinued operations	5,539	4,596
	-----	-----
Total assets	\$30,896	\$37,041
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$13,430	\$11,535
Notes payable, current portion	12,891	6,521
Capital lease obligations, current portion	587	886
Current liabilities of discontinued operations	3,068	2,552
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Total current liabilities	29,976	21,494
Note payable, net of current portion	--	1,200
Capital lease obligations, net of current portion	8	11
	-----	-----
Total liabilities	29,984	22,705
	-----	-----
Stockholders' equity:		
Common stock, \$.001 par value, 90,000 shares authorized 31,766 and 31,648 shares outstanding in 2008 and 2007	32	32
Additional paid-in-capital	257,904	255,728
Accumulated deficit	(257,024)	(241,424)
	-----	-----
Total stockholders' equity	912	14,336
	-----	-----
Total liabilities and stockholders' equity	\$30,896	\$37,041
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OSIRIS THERAPEUTICS, INC.
Condensed Statements of Operations
(Unaudited)
Amounts in thousands, except per share data

Three Months Ended March 31,	
-----	-----
2008	2007
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Revenue from government contracts,

collaborative research licenses and royalties	\$	362	\$	279
Operating expenses:				
Research and development		16,694		8,494
General and administrative		2,608		1,506
		-----		-----
Total operating expenses		19,302		10,000
		-----		-----
Loss from operations		(18,940)		(9,721)
Interest expense, net		(209)		(343)
		-----		-----
Loss from continuing operations		(19,149)		(10,064)
		-----		-----
Income (loss) from operations of discontinued operations		3,549		(1,437)
		-----		-----
Net loss	\$	(15,600)	\$	(11,501)
		=====		=====
Basic and diluted net loss per share:				
(Loss) from continuing operations	\$	(0.60)	\$	(0.37)
Income (loss) from discontinued operations		0.11		(0.05)
		-----		-----
Net loss	\$	(0.49)	\$	(0.42)
		=====		=====
Weighted Average Common Shares (basic and diluted)		31,741		27,372
		=====		=====

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

	Three Months Ended	
	March 31,	
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	2008	2007
	-----	-----
Cash flows from operating activities:		
Net loss	\$(15,600)	\$(11,501)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation and amortization	523	428
Non cash share-based payments	675	529
Non cash interest expense	146	60
Changes in operating assets and liabilities:		
Accounts receivable	558	1,408
Inventory and other current assets	(324)	1,235
Other assets	279	164
Accounts payable and accrued expenses	2,411	(746)
Deferred revenue	--	(238)

Long-term interest payable and other liabilities	--	100
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Net cash used in operations	(11,332)	(8,561)
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Cash flows from investing activities:		
Purchases of property and equipment	(1,077)	(870)
Proceeds from sale of short-term investments	10,353	10,839
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Net cash provided by investing activities	9,276	9,969
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Cash flows from financing activities:		
Principal payments on capital lease obligations and note payable	(1,932)	(290)
Restricted cash	--	6
Proceeds from convertible notes payable	8,000	--
Proceeds from the exercise of stock options	3	54
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Net cash provided by (used in) financing activities	6,071	(230)
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Net increase in cash	4,015	1,178
Cash at beginning of period	704	714
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Cash at end of period:	\$ 4,719	\$ 1,892
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SOURCE: Osiris Therapeutics, Inc.

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