



Osiris Therapeutics Reports Second Quarter 2009 Financial Results

COLUMBIA, Md., Aug 06, 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 second quarter of 2009.

Highlights and Recent Developments

- Treated first patient in a Prochymal Phase II trial for patients experiencing a heart attack.
- Submitted first portions of the Prochymal Biological License Application (BLA) to the Food and Drug Administration (FDA) for review.
- Received \$55.0 million from Genzyme, the balance of the initial license fee.
- Received a \$12.5 million installment payment from NuVasive related to the sale of Osteocel
- Achieved a \$750,000 milestone from the Juvenile Diabetes Research Foundation.
- Working with the FDA, expanded the Phase II type 1 diabetes trial to include pediatric patients.
- Created a new Biosurgery Division focused on developing high end biologic products for use in surgical procedures.

"We are pleased with the progress we have made over the past year solidifying our balance sheet," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "Our clinical, regulatory and operations teams have done an outstanding job preparing and submitting portions of the Prochymal BLA to the FDA. We anxiously await the results of our two Phase III trials in GvHD."

Second Quarter Financial Results

For the second quarter of 2009 Osiris reported revenues of \$10.5 million, compared to \$2.5 million for the same period of the prior year. Current year revenue primarily reflects the recognition of \$10.0 million in amortized license fees from Genzyme. The company reported net loss of \$9.7 million or \$0.30 per share for the quarter, compared to a loss of \$15.4 million and \$0.48 per share for the same period last year. The net loss number is comprised of loss from continuing operations of \$8.6 million and loss from discontinued operations of \$1.1 million. The loss on discontinued operations incurred in the second quarter of 2009 was primarily the impact of the increase in our estimated effective income tax rate to 12.7% for the year. Osiris expects to be subject to the Alternative Minimum Tax in 2009.

Research and development expenses for the second quarter of 2009 were \$18.5 million, slightly less than the \$19.0 million incurred in the second quarter of 2008. General and administrative expenses were \$2.3 million for the second quarter of 2009 compared to \$1.8 million for the same period of the prior year, primarily due to an increase in non-cash share-based compensation during the second quarter of 2009. Net cash used in continuing operations for the quarter was \$16.9 million.

As of June 30, 2009, Osiris had \$120.8 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, August 6, 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) 419-6598 (U.S. participants) or (719) 325-4883 (international participants).

A replay of the conference call will be available approximately two hours after the completion of the call through August 20, 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 4079419. 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

	June 30, 2009	December 31, 2008
	Unaudited	
ASSETS		
Current assets:		
Cash	\$ 1,162	\$ 940
Investments available for sale	50,800	61,298
Accounts receivable	68,815	61,287
Prepaid expenses and other current assets	4,144	2,060
Current assets of discontinued operations	64	3,223
Total current assets	124,984	128,808
Property and equipment, net	3,975	394

Restricted cash	666	130
Other assets	337	615
Long-term assets of discontinued operations	--	7,520
Total assets	<u>\$ 129,962</u>	<u>\$ 137,467</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 15,475	\$ 10,513
Deferred revenue, current portion	40,480	40,471
Capital lease obligations, current portion	7	6
Current liabilities of discontinued operations	4,270	7,219
Total current liabilities	<u>60,232</u>	<u>58,209</u>
Deferred revenue, net of current portion	64,053	84,275
Other long-term liabilities	2,754	3
Total liabilities	<u>127,039</u>	<u>142,487</u>
Stockholders' equity (deficit):		
Common stock, \$.001 par value, 90,000 shares authorized 32,759 and 32,676 shares outstanding in 2009 and 2008	33	33
Additional paid-in-capital	272,129	269,830
Accumulated other comprehensive income	599	33
Accumulated deficit	(269,838)	(274,916)
Total stockholders' equity (deficit)	<u>2,923</u>	<u>(5,020)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 129,962</u>	<u>\$ 137,467</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenue from collaborative research agreements, government contract and royalties	\$ 10,469	\$ 2,530	\$ 23,195	\$ 2,892
Operating expenses:				
Research and development	18,540	19,048	37,107	35,742
General and administrative	2,321	1,782	5,234	4,390
	<u>20,861</u>	<u>20,830</u>	<u>42,341</u>	<u>40,132</u>
Loss from operations	(10,392)	(18,300)	(19,146)	(37,240)
Interest income (expense), net	155	(172)	253	(381)
Loss from continuing operations, before income taxes	(10,237)	(18,472)	(18,893)	(37,621)
Income tax benefit	1,650	--	2,398	--
Loss from continuing operations	<u>(8,587)</u>	<u>(18,472)</u>	<u>(16,495)</u>	<u>(37,621)</u>
Discontinued operations:				
Income (loss) from operations of discontinued operations, net of income taxes	(142)	3,104	1,097	6,653
Gain (loss) from sale of discontinued operations, net of income taxes	(952)	--	20,476	--
Income (loss) from discontinued operations	<u>(1,094)</u>	<u>3,104</u>	<u>21,573</u>	<u>6,653</u>
Net income (loss)	<u>\$ (9,681)</u>	<u>\$ (15,368)</u>	<u>\$ 5,078</u>	<u>\$ (30,968)</u>
Basic and diluted income (loss) per share				
Loss from continuing operations	\$ (0.26)	\$ (0.58)	\$ (0.50)	\$ (1.19)
Income (loss) from discontinued operations	(0.03)	0.10	0.66	0.21
Basic and diluted earnings (loss) per share	<u>\$ (0.30)</u>	<u>\$ (0.48)</u>	<u>\$ 0.16</u>	<u>\$ (0.98)</u>
Weighted Average Common Shares (basic)	<u>32,737</u>	<u>31,769</u>	<u>32,715</u>	<u>31,754</u>

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

	Six Months Ended June	
	30,	
	2009	2008
Cash flows from operating activities:		
Continuing Operations:		
Loss from continuing operations	\$ (16,495)	\$ (37,621)
Adjustments to reconcile loss from continuing operations to net cash used in continuing operations:		
Depreciation and amortization	305	940
Non cash share-based payments	1,771	887
Non cash interest expense	--	130
Changes in operating assets and liabilities:		
Accounts receivable	892	(995)
Prepaid expenses and other current assets	(2,083)	(513)
Other assets	278	560
Accounts payable and accrued expenses	4,220	9,736
Deferred revenue	(20,213)	--
Long-term interest payable and other liabilities	--	9
Net cash used in continuing operations	<u>(31,325)</u>	<u>(26,867)</u>
Discontinued Operations:		
Income from discontinued operations	21,573	6,653
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	(26,623)	--
Depreciation and amortization	210	149
Provision for bad debts	45	--
Non cash share-based payments	98	78
Changes in operating assets and liabilities:		
Accounts receivable	519	(1,684)
Inventory and other current assets	1,707	(546)
Accounts payable and accrued expenses	669	1,422
Net cash (used in) provided by discontinued operations	<u>(1,802)</u>	<u>6,072</u>
Net cash used in operating activities	<u>(33,127)</u>	<u>(20,795)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(181)	(3,676)
Proceeds from the sale of property and equipment	17	--
Proceeds from sale of discontinued operations, net of transaction costs	9,853	--
Proceeds from sale of investments available for sale	23,770	12,353
Net cash provided by investing activities	<u>33,459</u>	<u>8,677</u>
Cash flows from financing activities:		
Principal payments on capital lease obligations and notes payable	(4)	(2,238)
Restricted cash	(536)	--
Proceeds from convertible and short-term notes payable	--	16,000
Proceeds from issuance of common stock	430	5
Net cash (used in) provided by financing activities	<u>(110)</u>	<u>13,767</u>
Net increase in cash	222	1,649
Cash at beginning of period	940	704
Cash at end of period:	<u>\$ 1,162</u>	<u>\$ 2,353</u>

SOURCE: Osiris Therapeutics, Inc.

Osiris Therapeutics, Inc.
Erica Elchin, 443-545-1834
OsirisPR@Osiris.com

or

Media:

Schwartz Communications

Stacey Holifield/Andrew Law
781-684-0770
Osiris@schwartz-pr.com

Copyright Business Wire 2009