



## Osiris Therapeutics Reports Third Quarter 2008 Financial Results

**COLUMBIA, Maryland – November 4, 2008** - Osiris Therapeutics, Inc. (NASDAQ:OSIR), the 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 third quarter of 2008.

### Highlights and Recent Developments

- Formed a major strategic alliance with Genzyme Corporation for Prochymal and Chondrogen in countries outside the United States and Canada in a transaction worth up to \$1.4 billion in up front and milestone payments.
- Completed enrollment of a 62 patient Phase II clinical trial evaluating Prochymal in patients with chronic obstructive pulmonary disease.
- Received \$35 million up-front payment for the initial close of the Osteocel transaction
- Achieved \$5.3 million in net income for the quarter.

"We are committed to making Prochymal the world's first approved stem cell therapy and we have made excellent progress in 2008," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "As the commercial launch of Prochymal draws near, our new partnership with Genzyme enables us to enter more markets, faster, and with greater certainty. This partnership provides us with a substantial amount of non-dilutive capital, a steady stream of near-term milestone opportunities, cost sharing, and significant royalties. Moving forward, we will continue to work relentlessly to better position Osiris to bring this remarkable technology to patients in need."

### Third Quarter Financial Results

Osiris reported net income of \$5.3 million for the third quarter of 2008 compared to a net loss of \$10.4 million in the third quarter of the prior year. Osiris reported a loss from continuing operations of \$19.9 million for the third quarter of 2008 compared to a loss from continuing operations of \$12.2 million for the same period of the prior year. The increase in the 2008 third quarter loss was largely the result of the continued advancement of clinical trials, costs associated with the production of increased amounts of Prochymal for use in clinical trials, and work on the Company's biologic license application with the FDA as commercialization of Prochymal is approached.

Research and development (R&D) expenses were \$18.6 million for the third quarter of 2009 compared to \$10.8 million for the same period of the prior year. General and administrative (G&A) expenses were \$1.9 million for the third quarter of 2008 compared to \$1.3 million for the same period of the prior year. R&D and G&A expenses incurred during the third quarter of 2008 approximate the costs incurred during the second quarter of 2008.

On July 24, 2008, Osiris completed the technology assets closing under the asset purchase agreement with NuVasive, Inc. and received the initial payment of \$35 million. Osiris recognized a gain on the sale of discontinued operations of \$25.5 million, after transaction costs of \$1.4 million and non-cash reserves established to give effect to the concessionary pricing specified in the Manufacturing Agreement as Amended.

On October 31, Osiris entered into a collaboration agreement with Genzyme Corp. whereby Genzyme will commercialize Prochymal and Chondrogen outside the United States and Canada. The companies have agreed to collaborate on the development of future indications to be commercialized. As a result of this transaction Osiris will receive \$75 million now and \$55 million on July 1, 2008 in upfront non-contingent, non-refundable payments. Osiris has rights to receive additional milestone payments of \$1.25 billion plus royalties based on revenues recognized by Genzyme.

### Webcast and Conference Call

The Company has scheduled a webcast and conference call to discuss its financial results today, November 4, 2008, 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) 874-1569 (U.S. participants) or (719) 325-4780 (international participants).



A replay of the conference call will be available approximately two hours after the completion of the call through November 18, 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 2745823. 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 products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Prochymal 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 also has partnered with Genzyme Corporation to develop Prochymal as a medical countermeasure to nuclear terrorism and other radiological emergencies. Furthermore, Prochymal is being developed for the repair of heart tissue following a heart attack, the protection of pancreatic islet cells in patients with type 1 diabetes, and the repair of lung tissue in patients with chronic obstructive pulmonary disease. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen for arthritis in the knee. Osiris is a fully integrated company, having developed 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. 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](http://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. 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 Collaboration Agreement with Genzyme 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 the ability of the parties to successfully perform under the collaborative arrangement and for Osiris to 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 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**  
**(Unaudited)**  
**Amounts in thousands**

	<u>September 30,</u> <u>2008</u>	<u>December 31,</u> <u>2007</u>
<b>ASSETS</b>		
Current assets:		
Cash	\$ 5,300	\$ 704
Investments available for sale	5,294	17,460
Accounts receivable	726	549
Prepaid expenses and other current assets	1,752	1,583
Current assets of discontinued operations	<u>5,801</u>	<u>8,445</u>
Total current assets	18,873	28,741
Property and equipment, net	306	2,020
Restricted cash	130	280
Other assets	540	1,404
Long-term assets of discontinued operations	<u>8,696</u>	<u>4,596</u>
Total assets	<u>\$ 28,545</u>	<u>\$ 37,041</u>
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 12,883	\$ 11,535
Notes payable, current portion	13,630	6,521
Capital lease obligations, current portion	6	886
Current liabilities of discontinued operations	<u>6,808</u>	<u>2,552</u>
Total current liabilities	33,327	21,494
Note payable, net of current portion	2,500	1,200
Other long-term liabilities	39	11
Long-term liabilities of discontinued operations	<u>873</u>	<u>—</u>
Total liabilities	<u>36,739</u>	<u>22,705</u>
Stockholders' (deficit) equity:		
Common stock, \$.001 par value, 90,000 shares authorized 31,808 and 31,648 shares outstanding in 2008 and 2007	32	32
Additional paid-in-capital	258,914	255,728
Accumulated deficit	<u>(267,140)</u>	<u>(241,424)</u>
Total stockholders' (deficit) equity	<u>(8,194)</u>	<u>14,336</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 28,545</u>	<u>\$ 37,041</u>



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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2008</u>	<u>2007</u>	<u>2008</u>	<u>2007</u>
<b>Revenue from government contracts, collaborative research agreements and royalties</b>	\$ 995	\$ 294	\$ 3,887	\$ 868
<b>Operating expenses:</b>				
Research and development	18,592	10,842	54,334	29,776
General and administrative	1,887	1,294	6,277	4,301
	<u>20,479</u>	<u>12,136</u>	<u>60,611</u>	<u>34,077</u>
<b>Loss from operations</b>	(19,484)	(11,842)	(56,724)	(33,209)
<b>Interest expense, net</b>	(419)	(330)	(800)	(1,091)
<b>Loss from continuing operations</b>	(19,903)	(12,172)	(57,524)	(34,300)
<b>Discontinued operations:</b>				
Income (loss) from operations of discontinued operations	(384)	1,782	6,269	1,951
Gain from sale of discontinued operations	25,539	—	25,539	—
<b>Income from discontinued operations</b>	<u>25,155</u>	<u>1,782</u>	<u>31,808</u>	<u>1,951</u>
<b>Net income (loss)</b>	<u>\$ 5,252</u>	<u>\$ (10,390)</u>	<u>\$ (25,716)</u>	<u>\$ (32,349)</u>
<b>Basic and diluted net income (loss) per share</b>				
Loss from continuing operations	\$ (0.63)	\$ (0.42)	\$ (1.81)	\$ (1.22)
Income from discontinued operations	0.80	0.06	1.00	0.07
Net income (loss)	<u>\$ 0.17</u>	<u>\$ (0.36)</u>	<u>\$ (0.81)</u>	<u>\$ (1.15)</u>
Weighted Average Common Shares (basic and diluted)	<u>31,808</u>	<u>29,230</u>	<u>31,799</u>	<u>28,234</u>



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

	<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities:</b>		
<b>Continuing Operations:</b>		
Loss from continuing operations	\$ (57,524)	\$ (34,300)
<b>Adjustments to reconcile loss from continuing operations to net cash used in continuing operations:</b>		
Depreciation and amortization	1,453	1,261
Non cash share-based payments	1,290	1,164
Non cash interest expense	130	182
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(177)	73
Prepaid expenses and other current assets	(169)	(40)
Other assets	864	393
Accounts payable and accrued expenses	(2,950)	(1,389)
Deferred revenue	—	(714)
Long-term interest payable and other liabilities	(839)	299
Net cash provided by continuing operations	(52,922)	(33,071)
<b>Discontinued Operations:</b>		
Income from discontinued operations	31,808	1,951
<b>Adjustments to reconcile income to net cash provided by discontinued operations:</b>		
Gain from sale of discontinued operations, net of non-cash charges	(27,986)	—
Depreciation and amortization	295	80
Provision for bad debts	29	—
Non cash share-based payments	134	66
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	844	(236)
Inventory and other current assets	1,066	(546)
Accounts payable and accrued expenses	4,256	23
Long-term liabilities	873	—
Net cash provided by discontinued operations	11,319	1,338
Net cash used by operating activities	(46,603)	(31,733)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(4,029)	(4,184)
Proceeds from the sale of property and equipment	104	—
Proceeds from sale of discontinued operations, net of transaction costs	33,636	—
Proceeds from sale of investments available for sale	12,353	35,787
Purchases of investments available for sale	—	(18,730)
Net cash provided by investing activities	42,064	12,873
<b>Cash flows from financing activities:</b>		
Principal payments on capital lease obligations and notes payable	(8,277)	(896)
Restricted cash	150	17
Proceeds from convertible and short-term notes payable	17,000	—
Proceeds from issuance of common stock	262	20,009
Payment of debt financing fees	—	(400)
Net cash provided by financing activities	9,135	18,730
Net increase in cash	4,596	(130)
Cash at beginning of period	704	714
<b>Cash at end of period:</b>	<b>\$ 5,300</b>	<b>\$ 584</b>