



Osiris Therapeutics Reports Second Quarter 2010 Financial Results

COLUMBIA, Md. – August 6, 2010 - [Osiris Therapeutics, Inc.](#) (NASDAQ: OSIR), the leading stem cell company focused on developing and marketing products to treat medical conditions in the inflammatory, autoimmune, cardiovascular and orthopedic areas, announced today its results for the second quarter of fiscal 2010.

Highlights and Recent Developments

- [Prochymal New Drug Submission \(NDS\)](#) accepted for review for full marketing approval by the Biologics and Genetic Therapies Directorate of Health Canada for graft vs. host disease (GvHD).
- Granted Priority Review for Prochymal by Health Canada reducing the NDS evaluation period for approval from 300 to 180 days.
- Notified by Health Canada that upon approval, Prochymal will be added to its Register of Innovative Drugs, which confers eight years of market exclusivity.
- Announced the positive interim analysis of the first 207 patients in a clinical trial evaluating Prochymal for treatment-resistant [Crohn's disease](#).
- Granted [Orphan Drug](#) designation from the Food and Drug Administration (FDA) for Prochymal as a treatment for type 1 diabetes.
- Recorded net income of \$1.7 million for the quarter; \$0.05 per diluted common share.
- Reported cash, short-term investments and receivables of \$84.4 million at June 30, 2010.

"Today, Osiris is in a very strong position," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris Therapeutics. "With our excellent partners, solid balance sheet and first-in-class technology, Osiris is confidently executing its mission to gain approval for the world's first stem cell therapy."

First Quarter Financial Results

Net income for the second quarter of 2010 was \$1.7 million compared to a loss from continuing operations of \$8.6 million in the second quarter of 2009. Revenues were \$10.3 million in the second quarter of 2010, consisting primarily of the amortization of license fees from our collaboration agreements. Revenues in the second quarter of 2009 were \$10.5 million. As of June 30, 2010, Osiris had \$84.4 million of cash, receivables and short-term investments.

Research and development expenses for the second quarter of 2010 were \$6.5 million, compared to \$18.5 million incurred in the second quarter of 2009. The \$12.0 million decrease in R&D expenses reflects the completion of clinical work associated with our Phase 3 clinical trials. General and administrative expenses were \$1.6 million for the second quarter of 2010 compared to \$2.3 million for the same period of the prior year. Net cash used in continuing operations for the three months ended June 30, 2010 was \$5.6 million.

Webcast and Conference Call

A webcast and conference call to discuss the financial results is scheduled for today, August 6, 2010 at 9:00 a.m. 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) 303-6133 (U.S. participants) or (970) 315-0493 (international participants).

A replay of the conference call will be available approximately two hours after the completion of the call through August 19, 2010. Callers can access the replay by dialing (800) 642-1687 (U.S. participants) or (706) 645-9291



(international participants). The audio replay confirmation code is 89024964. 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 company focused on developing products to treat serious medical conditions in the inflammatory, autoimmune, 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)

Osiris and Genzyme formed 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. Genzyme holds these rights in all other countries except Japan, where JCR Pharmaceuticals holds rights to Prochymal for the treatment of patients with hematological malignancies.

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 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.

For additional information, please contact:

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

Media Contacts:
Andrew Law/Rachel Gross
Schwartz Communications
(781) 684-0770
Osiris@schwartz-pr.com



OSIRIS THERAPEUTICS, INC.
Balance Sheets
Amounts in thousands

	<u>June 30, 2010</u> <u>(unaudited)</u>	<u>December 31, 2009</u>
Assets		
Current assets:		
Cash	\$ 1,484	\$ 1,306
Investments available for sale	82,589	99,409
Accounts receivable	323	1,138
Inventory	126	-
Prepaid expenses and other current assets	786	948
Total current assets	85,308	102,801
Property and equipment, net	3,445	3,734
Restricted cash	666	666
Other assets	284	395
Total assets	\$ 89,703	\$ 107,596
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,894	\$ 9,013
Deferred revenue, current portion	40,898	41,011
Capital lease obligations, current portion	-	3
Current liabilities of discontinued operations	-	412
Total current liabilities	47,792	50,439
Deferred revenue, net of current portion	23,753	44,173
Other long-term liabilities	474	424
Total liabilities	72,019	95,036
Stockholders' equity		
Common stock, \$.001 par value, 90,000 shares authorized, 32,789 shares outstanding - 2010, 32,773 outstanding - 2009	33	33
Additional paid-in-capital	273,816	272,959
Accumulated other comprehensive income (loss)	16	(88)
Accumulated deficit	(256,181)	(260,344)
Total stockholders' equity	17,684	12,560
Total liabilities and stockholders' equity	\$ 89,703	\$ 107,596



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,	
	2010	2009	2010	2009
Revenue from collaborative research agreements, government contract and royalties	\$ 10,304	\$ 10,469	\$ 21,681	\$ 23,195
Operating expenses:				
Research and development	6,456	18,540	13,016	37,107
General and administrative	1,602	2,321	3,409	5,234
	<u>8,058</u>	<u>20,861</u>	<u>16,425</u>	<u>42,341</u>
Income (loss) from operations	2,246	(10,392)	5,256	(19,146)
Other income, net	36	155	124	253
Income (loss) from continuing operations, before income taxes	2,282	(10,237)	5,380	(18,893)
Income tax (expense) benefit	(535)	1,650	(1,217)	2,398
Income (loss) from continuing operations	<u>1,747</u>	<u>(8,587)</u>	<u>4,163</u>	<u>(16,495)</u>
Discontinued operations:				
Income (loss) from operations of discontinued operations, net of income taxes	-	(142)	-	1,097
Gain (loss) from sale of discontinued operations, net of income taxes	-	(952)	-	20,476
Income (loss) from discontinued operations	<u>-</u>	<u>(1,094)</u>	<u>-</u>	<u>21,573</u>
Net income (loss)	<u>\$ 1,747</u>	<u>\$ (9,681)</u>	<u>\$ 4,163</u>	<u>\$ 5,078</u>
Basic income (loss) per share				
Income (loss) from continuing operations	\$ 0.05	\$ (0.26)	\$ 0.13	\$ (0.50)
Income (loss) from discontinued operations	-	(0.03)	-	0.66
Basic earnings (loss) per share	<u>\$ 0.05</u>	<u>\$ (0.30)</u>	<u>\$ 0.13</u>	<u>\$ 0.16</u>
Diluted income (loss) per share				
Income (loss) from continuing operations	\$ 0.05	\$ (0.26)	\$ 0.13	\$ (0.50)
Income (loss) from discontinued operations	-	(0.03)	-	0.66
Diluted earnings (loss) per share	<u>\$ 0.05</u>	<u>\$ (0.30)</u>	<u>\$ 0.13</u>	<u>\$ 0.16</u>
Weighted Average Common Shares (basic)	<u>32,780</u>	<u>32,737</u>	<u>32,777</u>	<u>32,715</u>
Weighted Average Common Shares (diluted)	<u>33,084</u>	<u>32,737</u>	<u>33,086</u>	<u>32,715</u>



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

	<u>Six Months Ended</u>	
	June 30,	
	<u>2010</u>	<u>2009</u>
Cash flows from operating activities:		
Continuing operations		
Income (loss) from continuing operations	\$ 4,163	\$ (16,495)
Adjustments to reconcile income (loss) from continuing operations to net cash used in operations:		
Depreciation and amortization	378	305
Non cash share-based payments	856	1,771
Changes in operating assets and liabilities:		
Accounts receivable	815	892
Prepaid expenses and other current assets	36	(2,083)
Other assets	111	278
Accounts payable and accrued expenses	(2,034)	4,220
Deferred revenue	(20,533)	(20,213)
Net cash used in continuing operations	<u>(16,208)</u>	<u>(31,325)</u>
Discontinued operations		
Income from discontinued operations	-	21,573
Adjustments to reconcile income from discontinued operations to net cash used in discontinued operations:		
Non cash impact of the sale of discontinued operations	-	(26,623)
Depreciation and amortization	-	210
Provision for bad debts	-	45
Non cash share-based payments	-	98
Changes in operating assets and liabilities:		
Accounts receivable	-	519
Inventory and other current assets	-	1,707
Accounts payable and accrued expenses	(412)	669
Net cash used in discontinued operations	<u>(412)</u>	<u>(1,802)</u>
Net cash used in operating activities	<u>(16,620)</u>	<u>(33,127)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(89)	(181)
Proceeds from the sale of property and equipment	-	17
Proceeds from sale of discontinued operations, net	-	9,853
Proceeds from sale of investments available for sale	17,098	23,770
Purchases of investments available for sale	(209)	-
Net cash provided by investing activities	<u>16,800</u>	<u>33,459</u>
Cash flows from financing activities:		
Principal payments on capital lease obligations and notes payable	(3)	(4)
Restricted cash	-	(536)
Proceeds from the exercise of stock options	1	430
Net cash used in financing activities	<u>(2)</u>	<u>(110)</u>
Net increase in cash	178	222
Cash at beginning of period	<u>1,306</u>	<u>940</u>
Cash at end of period	<u>\$ 1,484</u>	<u>\$ 1,162</u>