



## Osiris Therapeutics Reports Third Quarter 2011 Financial Results

**COLUMBIA, Md. – November 4, 2011** - [Osiris Therapeutics, Inc.](http://www.osiris.com) (NASDAQ: OSIR), the leading stem cell company focused on developing and marketing products to treat medical conditions in inflammatory and cardiovascular disease areas and wound healing, announced today its results for the third quarter ended September 30, 2011.

### Highlights and Recent Developments

- Filed a complete response to inquiries from the Biologics and Genetic Therapies Directorate of Health Canada about Prochymal New Drug Submission (NDS) and post marketing commitments.
- Third quarter Biosurgery revenue increased more than 150% over the previous quarter.
- Reported net income of \$4.0 million for the quarter; \$0.12 per diluted common share.
- Reported cash, receivables and short-term investments of \$53.3 million as of September 30, 2011.

“We are pleased with the continued revenue growth of our Biosurgery products,” said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris Therapeutics. “Sales and marketing efforts are currently underway to drive widespread adoption of these remarkable products in a number of therapeutic areas. As always, our commitment to patients with serious unmet medical needs is a top priority and we remain focused on making life-altering therapies available to the patients that need them most.”

### Third Quarter Financial Results

Net income for the third quarter of 2011 was \$4.0 million compared to \$4.5 million in the third quarter of 2010. Revenues were \$10.6 million in the third quarter of 2011, consisting primarily of the amortization of license fees from our collaboration agreements. Revenues in the third quarter of 2010 were \$10.8 million. As of September 30, 2011, Osiris had \$53.3 million of cash, receivables and short-term investments.

Research and development expenses for the third quarter of 2011 were \$5.0 million, compared to \$5.5 million incurred in the third quarter of 2010. General and administrative expenses were \$1.4 million for the third quarter of 2011 compared to \$1.3 million for the same period of the prior year. Net cash used in operations for the three months ended September 30, 2011 was \$4.4 million.

### Webcast and Conference Call

A webcast and conference call to discuss the financial results is scheduled for today, November 4, 2011 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 November 11, 2011. Callers can access the replay by dialing (855) 859-2056 (U.S. participants) or (404) 537-3406 (international participants). The audio replay confirmation code is 21423019. 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 and marketing products to treat medical conditions in inflammatory and cardiovascular disease areas and wound healing. Osiris currently



markets and sells Grafix and Ovation for tissue repair. 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 46 U.S. and 144 foreign patents.

Osiris and Genzyme formed a strategic alliance for the development and commercialization of Prochymal and Chondrogen. Under the terms of the agreement, Osiris has 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.

Osiris, Prochymal, Grafix and Ovation 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 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:**

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OSIRIS THERAPEUTICS, INC.  
Condensed Balance Sheets  
Amounts in thousands

|  | <u>September 30, 2011</u> | <u>December 31, 2010</u> |
|--|---------------------------|--------------------------|
|  | <u>(Unaudited)</u>        |                          |
| <b>Assets</b>  |                           |                          |
| Current assets:  |                           |                          |
| Cash   | \$ 1,403                  | \$ 1,442                 |
| Investments available for sale   | 50,454                    | 66,166                   |
| Accounts and other receivables   | 1,460                     | 1,928                    |
| Inventory  | 729                       | 510                      |
| Deferred tax asset   | 2,192                     | 3,170                    |
| Prepaid expenses and other current assets  | 762                       | 736                      |
| Total current assets   | <u>57,000</u>             | <u>73,952</u>            |
| Property and equipment, net  | 2,646                     | 3,127                    |
| Restricted cash  | 392                       | 521                      |
| Other assets   | 19                        | 184                      |
| Total assets   | <u>\$ 60,057</u>          | <u>\$ 77,784</u>         |
| <b>Liabilities and Stockholders' Equity</b>  |                           |                          |
| Current liabilities:   |                           |                          |
| Accounts payable and accrued expenses  | \$ 5,613                  | \$ 5,569                 |
| Deferred revenue, current portion  | 13,573                    | 40,960                   |
| Total current liabilities  | <u>19,186</u>             | <u>46,529</u>            |
| Deferred revenue, net of current portion   | -                         | 3,333                    |
| Other long-term liabilities  | 442                       | 465                      |
| Total liabilities  | <u>19,628</u>             | <u>50,327</u>            |
| Stockholders' equity:  |                           |                          |
| Common stock, \$.001 par value, 90,000 shares<br>authorized, 32,827 shares outstanding - 2011,<br>32,794 shares outstanding - 2010 | 33                        | 33                       |
| Additional paid-in-capital   | 277,749                   | 274,646                  |
| Accumulated other comprehensive income (loss)  | 22                        | (3)                      |
| Accumulated deficit  | (237,375)                 | (247,219)                |
| Total stockholders' equity   | <u>40,429</u>             | <u>27,457</u>            |
| Total liabilities and stockholders' equity   | <u>\$ 60,057</u>          | <u>\$ 77,784</u>         |



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

|  | Three Months Ended<br>September 30, |                 | Nine Months Ended<br>September 30, |                 |
|--|-------------------------------------|-----------------|------------------------------------|-----------------|
|  | 2011                                | 2010            | 2011                               | 2010            |
| <b>Product sales</b>   | \$ 331                              | \$ 99           | \$ 498                             | \$ 99           |
| Cost of goods sold   | 139                                 | 34              | 209                                | 34              |
| Gross profit   | 192                                 | 65              | 289                                | 65              |
| <b>Revenue from collaborative research agreements,<br/>government contract and royalties</b> | 10,242                              | 10,659          | 30,861                             | 32,340          |
| Operating expenses:  |                                     |                 |                                    |                 |
| Research and development   | 5,018                               | 5,460           | 4,938                              | 8,476           |
| General and administrative   | 1,429                               | 1,268           | 6,405                              | 4,677           |
|  | 6,447                               | 6,728           | 21,343                             | 23,153          |
| Income from operations   | 3,987                               | 3,996           | 9,807                              | 9,252           |
| Other income, net  | 26                                  | 27              | 80                                 | 151             |
| Income before income taxes   | 4,013                               | 4,023           | 9,887                              | 9,403           |
| Income tax benefit (expense)   | -                                   | 525             | (43)                               | (692)           |
| <b>Net income</b>  | <b>\$ 4,013</b>                     | <b>\$ 4,548</b> | <b>\$ 9,844</b>                    | <b>\$ 8,711</b> |
| Basic earnings per share   | \$ 0.12                             | \$ 0.14         | \$ 0.30                            | \$ 0.27         |
| Diluted earnings per share   | \$ 0.12                             | \$ 0.14         | \$ 0.30                            | \$ 0.26         |
| Weighted average common shares (basic)   | 32,826                              | 32,789          | 32,818                             | 32,781          |
| Weighted average common shares (diluted)   | 33,121                              | 33,100          | 33,121                             | 33,095          |



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

|   | <b>Nine Months Ended</b> |                    |
|---|--------------------------|--------------------|
|   | <b>September 30,</b>     |                    |
|   | <b><u>2011</u></b>       | <b><u>2010</u></b> |
| <b>Cash flows from operating activities:</b>  |                          |                    |
| <b>Continuing operations:</b>   |                          |                    |
| Net income  | \$ 9,844                 | \$ 8,711           |
| <b>Adjustments to reconcile net income to net cash used in continuing operations:</b> |                          |                    |
| Depreciation and amortization   | 560                      | 566                |
| Non cash share-based payments   | 1,341                    | 1,281              |
| Non cash expense- extension of expiration date warrant to related party               | 1,740                    | -                  |
| <b>Changes in operating assets and liabilities:</b>                                   |                          |                    |
| Accounts and other receivables  | 468                      | 876                |
| Prepaid expenses, inventory, and other current assets                                 | 733                      | (162)              |
| Other assets  | 165                      | (2,747)            |
| Accounts payable and accrued expenses   | 21                       | (1,938)            |
| Deferred revenue  | (30,720)                 | (30,801)           |
| Net cash used in continuing operations  | <u>(15,848)</u>          | <u>(24,214)</u>    |
| <b>Discontinued operations:</b>   |                          |                    |
| <b>Changes in operating assets and liabilities:</b>                                   |                          |                    |
| Accounts payable and accrued expenses   | -                        | (412)              |
| Net cash used in discontinued operations  | <u>-</u>                 | <u>(412)</u>       |
| Net cash used in operating activities   | <u>(15,848)</u>          | <u>(24,626)</u>    |
| <b>Cash flows from investing activities:</b>  |                          |                    |
| Purchases of property and equipment   | (79)                     | (98)               |
| Proceeds from sale of investments available for sale                                  | 15,805                   | 24,598             |
| Purchases of investments available for sale   | (68)                     | (236)              |
| Net cash provided by investing activities   | <u>15,658</u>            | <u>24,264</u>      |
| <b>Cash flows from financing activities:</b>  |                          |                    |
| Principal payments on capital lease obligations                                       | -                        | (3)                |
| Restricted cash   | 129                      | 145                |
| Proceeds from the exercise of stock options   | 22                       | 2                  |
| Net cash provided by financing activities   | <u>151</u>               | <u>144</u>         |
| Net decrease in cash  | (39)                     | (218)              |
| Cash at beginning of period   | 1,442                    | 1,306              |
| Cash at end of period   | <u>\$ 1,403</u>          | <u>\$ 1,088</u>    |