



## Osiris Announces Second Quarter Results

### Osteocel<sup>®</sup> sales growth exceeds 50% for the 4<sup>th</sup> consecutive quarter

**BALTIMORE, Maryland – September 12, 2006** – 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 financial results for the second quarter and six months ended June 30, 2006.

At the end of the second quarter Osiris had cash and short-term investments of \$28.6 million. Following the close of the quarter, Osiris completed an initial public offering with net proceeds of an additional \$34.2 million.

For the second quarter ended June 30, 2006, sales of Osteocel<sup>®</sup> grew 55% from the first quarter to \$1.7 million. Osiris reported a loss of \$11.6 million for the second quarter of 2006 compared to a loss of \$3.4 million for the second quarter of fiscal 2005. For the six month period ended June 30, 2006, the company reported a loss of \$16.7 million compared to a loss of \$7.3 million for the corresponding six month period in fiscal 2005. The loss was largely driven by a significant increase in clinical trial activity. During the first six months of 2006 the company completed enrollment in five clinical trials and initiated a pivotal Phase 3 trial for its lead drug candidate Prochymal<sup>™</sup>.

"The first six months of 2006 have been a period of excellent progress for the Osiris team," said C. Randal Mills, Ph.D., President and CEO of Osiris Therapeutics. "We are pleased with the continued strong sales growth of Osteocel. We will now continue to execute our plan to bring our drug candidates to market."

### **2006 Highlights to Date**

Osiris has made significant progress thus far in fiscal 2006. Among some of our more notable achievements during this period include the following:

- Achieved \$2.8 Million in year to date Osteocel Sales
- Completed enrollment in five clinical trials:
  - Prochymal Phase 2 trial for the treatment of steroid refractory Graft versus Host Disease (GvHD)
  - Prochymal Phase 2 trial as an add-on therapy to steroids for the first-line treatment of acute GvHD
  - Prochymal Phase 2 trial for the treatment of Crohn's disease
  - Chondrogen<sup>™</sup> Phase 2 trial for the regeneration of meniscus, a type of cartilage that cushions the knee joint
  - Provacel<sup>™</sup> Phase 1 trial for the repair of heart muscle in patients who have suffered a heart attack
- Initiated a pivotal Phase 3 trial of Prochymal for the treatment of steroid refractory GvHD, a life threatening immune system reaction that commonly affects the skin, gastrointestinal tract, and liver in patients who have received a bone marrow transplant.
- Successfully completed initial public offering of common stock



### ***Financial Highlights for Second Quarter 2006***

Osteocel sales for the quarter ended June 30, 2006 were \$1.7 million compared to zero in the second quarter of 2005. Other revenues for the quarter ended June 30, 2006 were \$0.3 million compared to \$1.3 million for the second quarter of 2005.

Research and development expenses were \$10.9 million for the second quarter of 2006 compared to \$3.6 million for the second quarter of fiscal 2005. The increase in expenses from 2005 was primarily due to the advancement of our clinical programs. Selling, general and administrative expenses were \$1.2 million for the second quarter of 2006 compared to \$0.5 million for the second quarter of 2005. The increase in these expenses in the 2006 quarter reflects additional personnel and related costs to support growth and in preparation for the initial public offering. Net interest expense was \$0.7 million for both the second quarter of 2006 and the second quarter of 2005.

The Company has scheduled a web cast and conference call to discuss its financial results tomorrow, September 13, 2006 at 8:00 AM EDT. To access the web cast, please log on to the Company's website at [www.Osiris.com](http://www.Osiris.com) and go to the Investor Relations section. Alternatively, callers may participate in the conference call by dialing 800-819-9193 (U.S. participants) or 913-981-4911 (international participants).

A replay of the conference call will be available approximately two hours after the completion of the call through Wednesday, September 20, 2006. Callers can access the replay by dialing 888-203-1112 (U.S. participants) or 719-457-0820 (international participants). The audio replay passcode is 5865554. 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<sup>®</sup> for regenerating bone in orthopedic indications. Prochymal<sup>™</sup> is in Phase 3 clinical trials and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen<sup>™</sup> for regenerating cartilage in the knee, and Provacel<sup>™</sup>, for repairing heart tissue following a heart attack. Osiris is a fully integrated company, having developed stem cell capabilities in research and development, manufacturing, marketing and distribution. 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 45 U.S. and 163 foreign patents owned or licensed. (OSIR-G)

### ***Forward Looking Statements***

This press release contains forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. 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; 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 MSCs and biologic drug candidates; our cash needs; patents and proprietary rights; ability of our potential products to treat disease; 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. 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 Registration Statement on Form S-1, File No: 333-134037, as filed with the United States Securities and Exchange Commission and declared effective on August 3, 2006. 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 Lisa Rodemann at 410.522.5005, extension 610.**



**OSIRIS THERAPEUTICS, INC.**  
**CONDENSED BALANCE SHEETS**

(Amounts in thousands)

	<b>June 30,</b>	<b>December 31,</b>
	<b><u>2006</u></b>	<b><u>2005</u></b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash	\$814	\$597
Short-term investments	27,765	42,774
Accounts receivable, inventory and other current assets	2,644	1,341
Total current assets	31,223	44,712
Property and equipment, net	3,746	3,792
Restricted cash	309	190
Deferred financing costs, net and other assets	1,937	2,320
Total assets	\$37,215	\$51,014
 <b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$5,835	\$4,565
Notes payable, current portion	65	65
Other current liabilities	2,029	1,979
Total current liabilities	7,929	6,609
Notes payable, net of current portion	47,379	47,411
Long-term interest payable and other liabilities	7,596	6,389
Mandatorily redeemable convertible preferred stock Series D, 3,750 shares designated, 3,213 shares issued and outstanding in 2006 and 2005	64,267	64,267
Total liabilities	127,171	124,676
Stockholders' deficit:		
Convertible preferred stock, \$.001 par value, 16,250 shares authorized, 12,250 shares designated and 10,651 shares outstanding—2006 and 2005	32,746	32,746
Common stock, \$.001 par value, 90,000 shares authorized, 9,176 shares outstanding in 2006, 9,153 shares outstanding in 2005	9	9
Additional paid-in capital	36,559	36,404
Deferred compensation	--	(277)
Accumulated deficit	(159,270)	(142,544)
Total stockholders' deficit	(89,956)	(73,662)
Total liabilities and stockholders' deficit	\$37,215	\$51,014



**OSIRIS THERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**

(Amounts in thousands, except per share amounts)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2006</u>	<u>2005</u>	<u>2006</u>	<u>2005</u>
	(Unaudited)		(Unaudited)	
Product sales .....	\$1,689	\$ -	\$2,794	\$ -
Cost of goods sold .....	762	-	1,251	-
Gross profit.....	<u>927</u>	<u>-</u>	<u>1,543</u>	<u>-</u>
Revenue from collaborative research licenses and grants	<u>298</u>	<u>1,339</u>	<u>593</u>	<u>1,724</u>
Operating expenses:				
Research and development .....	10,922	3,592	15,290	6,249
General and administrative .....	1,209	487	2,347	1,239
Total operating expenses .....	<u>12,131</u>	<u>4,079</u>	<u>17,637</u>	<u>7,488</u>
Loss from operations.....	(10,906)	(2,740)	(15,501)	(5,764)
Interest expense, net	(699)	(654)	(1,225)	(1,498)
Net loss.....	<u>\$(11,605)</u>	<u>\$(3,394)</u>	<u>\$(16,726)</u>	<u>\$(7,262)</u>
Basic and diluted net loss per share .....	<u>\$(1.27)</u>	<u>\$(0.38)</u>	<u>\$(1.83)</u>	<u>\$(0.81)</u>
Weighted average common stock outstanding, in thousands (basic and diluted).....	<u>9,158</u>	<u>8,964</u>	<u>9,146</u>	<u>8,948</u>