

OSIRIS THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **December 9, 2006**

OSIRIS THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other jurisdiction of
incorporation)

001-32966
(Commission File Number)

71-0881115
(IRS Employer
Identification No.)

2001 Aliceanna Street, Baltimore, Maryland
(Address of principal executive offices)

21231
(Zip Code)

Registrant's telephone number, including area code: **(410) 522 - 5005**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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ITEM 7.01 Regulation FD Disclosure

On December 9, 2006, Osiris Therapeutics, Inc. issued a follow-on press release announcing updates on the Phase II trial evaluating Prochymal for the treatment of acute graft vs. host disease. The study found that patients were twice as likely to have total clinical resolution of their disease when Prochymal was added to steroid therapy, compared to reported results for steroids alone. The study also found that patients experiencing this complete response had a survival rate of over 90% at day 120. The press release is attached hereto as an exhibit to this Current Report on Form 8-K and is being filed pursuant to this Item 8.01 as Exhibit 99.1 to this Current Report on Form 8-K.

The information included herein, including Exhibit 99.1 furnished herewith, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference into any filing pursuant to the Securities Act of 1933, as amended, or the Exchange Act, regardless of any incorporation by reference language in any such filing, except as expressly set forth by specific reference in such filing.

ITEM 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 Registrant’s press release dated December 9, 2006

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OSIRIS THERAPEUTICS, INC.

Dated: December 12, 2006

By: /s/ CARY J. CLAIBORNE
Cary J. Claiborne
Chief Financial Officer

EXHIBIT INDEX

Exhibit No. Description

99.1 Registrant's press release dated December 9, 2006

Osiris Therapeutics Provides Update on Phase II Trial Evaluating PROCHYMAL™ for the Treatment of Acute Graft vs. Host Disease

Data to be featured at the 48th Annual Meeting of the American Society of Hematology

BALTIMORE, Maryland — December 9, 2006 — Osiris Therapeutics, Inc. (NASDAQ:OSIR) announces follow-on data for its ongoing Phase II trial evaluating PROCHYMAL for the treatment of acute Graft vs. Host Disease. The study found that patients were twice as likely to have total clinical resolution of their disease when PROCHYMAL was added to steroid therapy, compared to reported results for steroids alone. Furthermore, patients experiencing this complete response had a survival rate of over 90% at day 120. The data will be featured during a poster presentation at the 48th Annual Meeting of the American Society of Hematology.

Graft vs. Host Disease or GVHD is a life threatening immunological reaction that occurs in certain patients who have received a bone marrow transplant. GVHD is a form of rejection in which immune cells from the donated bone marrow attack the recipient's own organs and tissues. There are no approved treatments for GVHD. As a result, it is one of the leading causes of death in bone marrow transplant patients.

The Phase II trial is a randomized, prospective, open label trial, being conducted at 16 leading cancer centers in the US. In addition to standard care including steroids, patients were given two infusions of PROCHYMAL, three days apart at the onset of moderate to severe (grades II-IV) GVHD. Endpoints of the study include response of GVHD to treatment with PROCHYMAL, survival, and the safety and tolerability of the drug.

A total of 32 patients were enrolled in the trial with 31 available for evaluation. As previously reported, 29 of 31, or 94% responded after receiving two infusions of PROCHYMAL, with 23 patients, or 74% achieving a complete response, meaning the patients had experienced total clinical resolution of the disease. Six patients, or 19% had a partial response and 2 patients, or 6% did not respond. A study previously published in *Biology of Blood and Marrow Transplantation* (MacMillan et al, 2002) evaluated 443 patients with acute GVHD, grades II-IV, and found that only 35% of patients had a complete response to steroids by day 28.

There were a total of 8 patient deaths during the first 120 days following treatment. None of the deaths were attributed to PROCHYMAL. Patients experiencing a complete response rate by day 28 had a statistically significant improvement in survival as compared to patients experiencing a partial or non-response (91.3% survival vs. 25% survival, $p < 0.001$). Overall survival for the study was 74% at day 120.

“In this trial, approximately twice the number of patients achieved a complete response when given PROCHYMAL as we would expect with steroids alone,” Hans Klingemann, M.D., Ph.D., Director, Bone Marrow and Hematopoietic Cell Transplant Program, Tufts New England Medical Center. “But what is most important is that this improvement in response carried over into high survival rates.”

In the study, 22 of the 31, or 71% of the patients received only PROCHYMAL and steroids for the treatment of GVHD. In this group there were only two deaths reported by day 120. One was the result of an accidental fall and the other was related to the relapse of the patient's underlying disease. Importantly, there were no deaths from infection. Nine patients received 2nd line therapeutic agents for GVHD in addition to treatment with PROCHYMAL. Only 3 of the 9 patients in this group survived to day 120. Four patients in this group died from infection and 2 died from pulmonary complications. Patients spared additional second line treatments for GVHD had significantly improved rates of survival at 120 days (90.9% vs. 33%, $p=0.001$).

“In this study, many of the patients who received additional immunosuppressive therapies developed severe complications associated with these treatments, such as infection, said Rod Monroy, Ph.D., Sr. Director for PROCHYMAL. “We were pleased to see that we could achieve higher complete response rates with PROCHYMAL, without the mortality that often arises as a result of more aggressive immunosuppression.”

“We are very optimistic about the survival data that continues to emerge from this study,” said C. Randal Mills, Ph.D., President and CEO of Osiris. “The American Society for Hematology provides an excellent opportunity for us to share this exciting information with our physician investigators conducting the ongoing Phase III trial. We also wanted to make sure that interested parties who are not able to attend the conference had access to this additional data.”

The information contained within this release will be the focus of the poster session being held Monday, December 11th. Due to the early filing deadline for the conference, the abstract published in the conference proceedings was compiled from an analysis of preliminary data. As a result, the abstract does not reflect the current status of the trial. An electronic version of the poster will be available for review on our website at www.Osiris.com starting Monday, December 11, 2006.

PROCHYMAL is a preparation of mesenchymal stem cells specially formulated for intravenous infusion. The stem cells are obtained from the bone marrow of healthy adult donors. PROCHYMAL is currently being evaluated in a double-blind, placebo controlled Phase III study for the treatment of GVHD. The ongoing Phase III study for GVHD is anticipated to be the final trial before the product is submitted to FDA, Canadian and European regulatory agencies for full approval. PROCHYMAL has been granted both Fast Track and Orphan Drug status by FDA for GHVD. FDA established the Fast Track program to accelerate the development of drugs that show promise for treating life-threatening conditions. Orphan Drug designation provides incentives to companies that develop drugs for underserved patient populations. PROCHYMAL is also being evaluated for the treatment of Crohn's Disease and has completed a Phase II trial, which demonstrated positive results, including a significant reduction in the Crohn's Disease Activity Index.

GVHD is a T-cell mediated inflammatory process that results in high levels of pro-inflammatory chemical signals called cytokines. These cytokines cause the unbalanced activation of certain immune cells that results in tissue damage. Delivered intravenously, PROCHYMAL is able to target areas of active inflammation. Laboratory data indicates that PROCHYMAL is able to down-regulate the production of pro-inflammatory cytokines, including tumor necrosis factor-alpha or TNF-alpha and interferon-gamma. Additional data indicates that PROCHYMAL up-regulates the production of beneficial anti-inflammatory cytokines, specifically interleukin-10 and interleukin-4. When the stem cells found in PROCHYMAL are delivered into an inflammatory environment, they appear to change the course of the disease by altering the cytokine secretion profile of the dendritic and T cell subsets, thereby resulting in a shift from a pro-inflammatory to an anti-inflammatory state and arresting disease progression. Furthermore, it is believed that PROCHYMAL facilitates the repair of previously damaged tissue through the secretion of growth factors that promote tissue regeneration.

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[®] for regenerating bone in orthopedic indications. Prochymal[™] 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[™] for regenerating cartilage in the knee, and Provacel[™], 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 46 U.S. and 164 foreign patents owned or licensed. More information can be found on the company's website, www.Osiris.com. (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; 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 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 Erica Elchin at 410.522.5005, extension 610
