

OSIRIS THERAPEUTICS, INC.  
Form 8-K  
October 26, 2007

**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): **October 25, 2007**

**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.)

**7015 Albert Einstein Drive, Columbia, Maryland**  
(Address of principal executive offices)

**21046-1707**  
(Zip Code)

Registrant's telephone number, including area code: **(443) 545 - 1800**

**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))

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- o 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 October 25, 2007, Osiris Therapeutics, Inc. announced the initiation of a Phase II clinical trial evaluating Prochymal as a treatment for type 1 diabetes. The registrant also announced entering into a collaborative agreement with the Juvenile Diabetes Research Foundation International (JDRF) which provides for JDRF to provide up to \$4 million in funding to support the development of Prochymal as a treatment for the preservation of insulin production in patients with newly diagnosed type 1 diabetes mellitus.

The Phase II trial will evaluate the safety and efficacy of Prochymal in conjunction with standard of care in preserving insulin production in patients recently diagnosed with type 1 diabetes mellitus. The design will be a double-blind, placebo-controlled trial with a target enrollment of 60 patients. The primary endpoint will be the measurement of C-peptide produced during a Mixed Meal Tolerance Test in patients treated with Prochymal, compared to those receiving placebo. It is estimated that type 1 diabetes currently affects as many as 3 million people in the United States.

JDRF is a not-for-profit organization and its principal charitable mission is the discovery and development of a cure for diabetes and its complications through the support of research. Since its founding in 1970, JDRF has provided more than \$1.2 billion to diabetes research worldwide.

Under the agreed upon terms, the registrant shall be solely responsible for the conduct of the Phase II clinical trial and JDRF shall provide up to \$4 million in financial support, consultation and advice, and use its communications channels to make the diabetes community aware of the clinical trial and clinical sites. 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 7.01 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 The Registrant's press release dated October 25, 2007

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**SIGNATURES**

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

**OSIRIS THERAPEUTICS, INC.**

Dated: October 26, 2007

By: */s/ Cary J. Claiborne*  
Cary J. Claiborne  
Chief Financial Officer

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**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	The Registrant's press release dated October 25, 2007

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