OSIRIS THERAPEUTICS, INC.
Form 8-K
March 27, 2009

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): March 27, 2009

OSIRIS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-32966**	**71-0881115**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

7015 Albert Einstein Drive, Columbia, Maryland	**21046**
(Address of principal executive offices)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On March 27, 2009, Osiris Therapeutics, Inc. (Osiris or Company) announced that it had elected to end enrollment at 210 patients in its Phase III clinical trial evaluating Prochymal for Crohn s disease. Osiris ended enrollment because it believes that there is a design flaw in the trial resulting in significantly higher than expected placebo response rates. The decision was made after the trial s final scheduled interim analysis showed that one of the two Prochymal dose arms had crossed a futility boundary. The dose arm was unlikely to achieve the primary endpoint of remission because of the high placebo response rate. This latest analysis continued to show that no serious safety concerns with the therapy and safety was not a factor in the decision to stop enrollment.

After careful discussions with the United States Food and Drug Administration, the Company elected to discontinue enrollment rather than attempt to re-power the trial. The Company will keep the trial blinded and expects a solid data package for use in designing future trials in Crohn s disease and to bolster Prochymal s safety database.

The Prochymal Crohn s program consists of two separate but related trials. The first trial, described above, evaluates patients initial response to two dose levels of Prochymal as compared to placebo. This trial was originally designed to enroll 270 subjects. Patients responding to the initial therapy were then eligible to participate in a second, longer-term trial evaluating Prochymal as a maintenance therapy. Because the current standard for determining response of Crohn s patients is largely subjective, there may have been response bias in order to meet the eligibility requirements for continuation of therapy in the longer-term maintenance trial. Accordingly, enrollment in the second trial has also ended.

Information presented in this Current Report on Form 8-K may contain forward-looking statements and certain assumptions upon which such forward-looking statements are in part based. 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. Additional factors that could cause our actual results to differ materially from those anticipated in forward-looking statements, include the factors described in the sections entitled Risk Factors in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission. You should not unduly rely on forward-looking statements.

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: March 27, 2009	By:	/s/ PHILIP R. JACOBY, JR. Philip R. Jacoby, Jr. Vice President of Finance (Principal Accounting Officer)