OSIRIS THERAPEUTICS, INC.
Form 8-K
November 04, 2008

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): November 4, 2008

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 1.01 Entry into a Material Definitive Agreement.

General. On October 31, 2008, Osiris Therapeutics, Inc. (the Company) entered into a Collaboration Agreement (the Agreement) with Genzyme Corp. (Genzyme) for the development and commercialization of Prochymal® and Chondrogen®, two adult stem cell drug candidates in Phase II or III clinical trials for select indications, with significant potential to treat a wide range of diseases. These stem cell drug candidates are designed to provide therapeutic benefits by controlling inflammation, promoting tissue regeneration, and preventing scar formation.

Rights. Under the terms of the Agreement, the Company will retain its rights to commercialize Prochymal and Chondrogen in the United States and Canada (the Osiris Territory), and Genzyme has been granted exclusive rights to commercialize Prochymal and Chondrogen in all other countries, except with respect to Graft vs. Host Disease (GvHD) in Japan, where Prochymal has previously been licensed to another (the Genzyme Territory).

Milestone Payments. As partial consideration for the grant of these exclusive rights, the Company will receive a non-contingent, non-refundable payment of $130 million cash from Genzyme, with $75 million paid initially and $55 million to be paid on July 1, 2009. The Agreement also provides for contingent milestone payments of up to $1.25 billion in the aggregate, in addition to royalties on any sales by Genzyme, to be paid by Genzyme to the Company, as follows:

Prochymal: As respects Prochymal, the Company is eligible to receive up to $500 million in development and regulatory milestone payments and up to $250 million in sales based milestone payments, as follows:

- Total development milestones related to GvHD of up to $50 million, with $25 million payable upon marketing approval from the United States Food & Drug Administration (FDA), and $25 million payable upon marketing approval from the European Medicines Agency (EMEA).

- Total development milestones of up to $180 million related to Crohn s disease and Ulcerative Colitis, with $50 million payable upon achieving statistically significant endpoint(s) in a Phase III clinical trial for Crohn s disease, $100 million payable upon marketing approval by the EMEA for Crohn s disease, $10 million payable upon achieving statistically significant endpoint(s) in a Phase II or Phase III clinical trial for Ulcerative Colitis, and $20 million payable upon achieving marketing approval for Ulcerative Colitis by the EMEA.

- Total development milestones of up to $270 million related to the development of follow-on indications for Prochymal, with $20 million payable upon each success in a Phase II clinical trial for cardiac, type 1

diabetes or other follow-on indications, as agreed to by the Company and Genzyme, and $40 million payable upon receipt of each marketing approval by the EMEA for Prochymal for chronic obstructive pulmonary disease (COPD), cardiac, type 1 diabetes or other follow-on indications, as agreed to by the Company and Genzyme.

- Total sales based milestones of up to $250 million for Prochymal, with $100 million payable when annual Prochymal sales reach $500 million in the Genzyme Territory, and $150 million when annual Prochymal sales reach $1 billion in the Genzyme Territory.

Chondrogen: Upon receipt of the results of the planned Phase II/III clinical trial of Chondrogen, Genzyme may elect to opt-out of further Chondrogen development, at which point all rights to Chondrogen will revert to the Company with no further obligations between the companies with regard to Chondrogen. If Genzyme does not opt-out, the Company is eligible to receive up to $500 million in development, regulatory and sales based milestone payments for Chondrogen, as follows:

- Total development and regulatory milestones of up to $100 million, with $10 million payable if Genzyme does not opt-out, $10 million payable upon demonstration of disease modification in the current clinical trial program, $40 million payable upon marketing approval by either the FDA or EMEA for a pain reduction indication, and $40 million payable upon marketing approval by either the FDA or EMEA for a disease modification indication.

- Total sales milestones of up to $400 million, with $100 million payable when annual Chondrogen sales reach $500 million in the Genzyme Territory, $150 million when annual Chondrogen sales reach $1 billion in the Genzyme Territory, and $150 million when annual Chondrogen sales reach $2 billion in the Genzyme Territory.

Development Costs: The Agreement also provides that the Company will be responsible for ongoing clinical trial costs and future clinical trial costs with respect to both Prochymal and Chondrogen through Phase II clinical trials. The Company and Genzyme will share all costs of future Phase III and Phase IV clinical trials for agreed-upon indications (assuming in the case of Chondrogen that Genzyme does not opt-out), with the Company responsible for 60% of such costs and Genzyme responsible for 40% of such costs.

Product Royalties: Assuming successful development and marketing approval, the Company will receive escalating royalties on sales of Prochymal and Chondrogen within the Genzyme Territory.

Term: The Agreement provides that it will expire upon the completion of all development plans stipulated in the Agreement and the expiration of all payment obligations; however, Genzyme may terminate the Agreement early and without further obligation at any time after July 1, 2009, and either party may terminate the agreement due to non-performance, material breach or insolvency.

Miscellaneous: The Company and Genzyme previously entered into an agreement dated July 26, 2007, establishing a collaborative arrangement for the development of Prochymal for acute radiation syndrome (ARS). In January 2008,

the companies were awarded a contract from the U.S. Department of Defense (DOD) to develop and supply Prochymal for ARS. The DOD contract is fully valued at up to $224.7 million.

Risks: The performance by the Company and the ability of the Company to benefit from the Agreement is subject to and presents numerous risks and uncertainties, including the risks and uncertainties described or referred to in the paragraph appearing below.

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. Risks and uncertainties related to the collaborative agreement with Genzyme 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 early termination and opt-out rights; the ability of Osiris and Genzyme to successfully 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. 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 and periodic reports subsequently filed with the United States Securities and Exchange Commission. You should not unduly rely on forward-looking statements.

ITEM 7.01 **Regulation FD Disclosure.**

A copy of the press release dated November 4, 2008, announcing the collaboration agreement with Genzyme described in Item 1.01 of this Current Report on Form 8-K is attached hereto as Exhibit 99.1 and incorporated into this Item 7.01 by reference.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated October November 4, 2008 announcing the collaborative agreement by and between the Registrant and Genzyme Corp.

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: November 4, 2008	By:	/s/ PHILIP R. JACOBY, JR. Philip R. Jacoby, Jr. Vice President of Finance (Principal Accounting Officer)

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated November 4, 2008 announcing the collaboration agreement by and between the Company and Genzyme.