

OSIRIS THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 03/27/17 for the Period Ending 03/27/17

Address	7015 ALBERT EINSTEIN DRIVE COLUMBIA, MD 21046
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Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, DC 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, 2017**

OSIRIS THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Maryland
(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
(Zip Code)

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

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 (*see* General Instruction A.2. below):

- 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 240.14a-12)
 - 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 2.02. Results of Operations and Financial Condition.

On March 27, 2017, Osiris Therapeutics, Inc. (the “Company”) filed an amendment (the “Form 10-K/A”) to its Annual Report on Form 10-K for the year ended December 31, 2014. The Form 10-K/A includes restated financial statements as of and for the year ended December 31, 2014. As a result of the filing of the Form 10-K/A, the Company intends to formally engage Ernst & Young LLP as its new independent registered public accounting firm, subject to completion of its standard client acceptance procedures which are ongoing.

On November 7, 2016, the Company issued a press release announcing its preliminary revenue expectations of approximately \$46 million to \$50 million and \$85 million to \$90 million for the years ended December 31, 2014 (restated) and December 31, 2015, respectively, and also that it expected revenue for the year ended December 31, 2016 to be between \$100 million and \$110 million. In the Form 10-K/A, the Company reported revenue of \$50.8 million for 2014. On March 27, 2017, the Company issued a press release announcing, among other things, that it currently expects to report revenue of approximately \$89 million to \$92 million for 2015 and approximately \$110 million to \$114 million for 2016.

Item 7.01. Regulation FD.

On March 1, 2017, the Company, together with Peter Friedli, Jay M. Moyes, Thomas M. Brandt and Yves Huwyler (the “Directors” and together with the Company, the “Defendants”) entered into a Settlement Agreement (the “Settlement Agreement”) with Brian C. Lee (the “Plaintiff”) regarding the settlement of a shareholder complaint filed in the Circuit Court for Howard County Maryland (the “Court”) against the Defendants captioned *Brian C. Lee v. Osiris Therapeutics, Inc., et al.*, No. 13-C-16108356. The Plaintiff alleged that the Defendants failed to schedule or hold an annual meeting within the time period allegedly required by the Company’s bylaws and Maryland law. The Company was not able to hold its annual meeting in 2016 due to the pending restatement of its financial statements.

Pursuant to the terms of the Settlement Agreement, without agreeing that any of the claims in the lawsuit have merit or that any disclosure is required under any applicable statute, rule, regulation or law, the Company has agreed to make available certain additional information to the Company’s shareholders, as disclosed in this Current Report on Form 8-K, and the Plaintiff has agreed to settle the lawsuit and release the Defendants from all related claims. The Settlement Agreement further provides for the voluntary dismissal of the outstanding litigation with prejudice.

Without admitting in any way that the disclosures below are material or otherwise required by law, the Company makes the following disclosures:

Updated Revenue Estimates (Unaudited)

As noted above, the Company currently expects to report revenue of approximately \$89 million to \$92 million for 2015 and approximately \$110 million to \$114 million for 2016.

Total Assets, Total Debt, and Cash Information (Unaudited)

As of December 31, 2016, the Company had between \$72 million and \$75 million in total assets and \$27 million in cash and cash equivalents. The Company has no debt other than a capital lease obligation of approximately \$20,000 which expires in 2017.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to the beneficial ownership of the Company’s common stock as of March 27, 2017 for (a) each of the Company’s directors and each person currently serving as Chief Executive Officer or Chief Financial Officer and the other most highly compensated executive officers (the “named executive officers”), (b) all of the Company’s current directors and named executive officers as a group, and (c) each stockholder that it knows to be the beneficial owner of more than 5% of the Company’s

common stock. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. The Company deems shares of common stock that may be acquired by an individual or group within 60 days of March 27, 2017 pursuant to the exercise of options to be outstanding for the purpose of computing the percentage ownership of such individual or group, but those shares are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, the Company believes that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to the Company by these stockholders. Percentage of ownership is based on 34,525,886 shares of common stock outstanding on March 27, 2017.

Name and Address of Beneficial Owners	Amount and Nature of Beneficial Ownership	Percent of Class(2)
Named Executive Officers and Directors(1)		
Thomas M. Brandt	—	
Alla Danilkovitch	78,450(3)	
David A. Dresner	25,000	
Peter Friedli	14,810,455(4)	42.9%
Yves Huwyler	51,072(5)	
Thomas J. Knapp	—	
Gregory I. Law	10,100(6)	
Adrian P. Mollo	12,500(7)	
Jay M. Moyes	13,250	
Uwe Sommer	108,500	
All directors and executive officers as a group (10 persons)	15,109,327	43.8%
Other 5% Stockholders		
Venturetec, Inc. c/o Osiris Therapeutics, Inc. 7015 Albert Einstein Drive Columbia, Maryland 21046	4,103,301	11.9%
Thomas Schmidheiny Zurcherstrasse 156 8645 Jona Switzerland	3,060,767(8)	8.9%
BIH SA 3 Fauboug de'Hopital 2000 Neuchatel, Switzerland	2,658,113	7.7%

(1) Mailing address for all directors and officers is c/o Osiris Therapeutics, Inc., 7015 Albert Einstein Drive, Columbia, Maryland 21046.

(2) Percentage not provided if less than 1%.

(3) Represents 66,500 shares issuable upon exercise of options. Mr. Danilkovitch separately has 22,500 options that have not yet vested.

(4) Consists of 10,204,404 shares owned directly by Peter Friedli & Co., Inc., 4,103,301 shares held by Venturetec, Inc., 500,000 shares held by Mr. Friedli's minor daughter and 2,750 shares held by his spouse. Mr. Friedli is the sole owner of Peter Friedli & Co., Inc. and serves as its president. Mr. Friedli holds approximately a 2% interest in the parent of Venturetec, Inc. and through ownership of a convertible note holds another 19% interest in Venturetec, Inc., for which he serves as president. Mr. Friedli has disclaimed beneficial ownership in the shares held by his daughter and spouse and has disclaimed beneficial interest in the shares held by Venturetec, Inc., beyond the extent of his pecuniary interest therein.

(5) Includes 400 shares held by Mr. Huwyler's minor children.

(6) Represents 10,000 shares issuable upon exercise of options. Mr. Law separately has 10,000 options that have not yet vested.

- (7) Represents 12,500 shares issuable upon exercise of options. Mr. Mollo separately has 12,500 options that have not yet vested.
- (8) Consists of 402,654 shares owned directly by Mr. Schmidheiny and 2,658,113 shares owned by BIH SA. Mr. Schmidheiny is the Chairman and controlling shareholder of BIH SA.

Related Person Transactions

As required by the Company's Corporate Governance Principles, the Audit Committee (the "Audit Committee") of the Company's Board of Directors (the "Board") reviews and approves in advance all related person transactions, as defined by SEC rules. The Company's policy with respect to related person transactions is incorporated within the Audit Committee Charter, a copy of which is available on the Company's website at <http://investor.osiris.com/documents.cfm>.

The Audit Committee may approve only those related party transactions that are in, or are not inconsistent with, the best interests of the Company and its stockholders, as the Audit Committee determines in good faith. In making such a determination, the Audit Committee is required to consider all of the relevant facts and circumstances relating to the transaction including, but not limited to, the following:

- the benefits to the Company;
- if the transaction involves a director, a member of the director's immediate family or entity affiliated with the director, the impact on the director's independence;
- the availability of other sources for comparable products or services;
- the terms of the transaction; and
- the terms available to unrelated third parties.

The following were the related person transactions of the Company during 2015:

Prolexys Pharmaceuticals, Inc. During the third quarter of fiscal 2011 the Company entered into a contract research agreement with Prolexys Pharmaceuticals, Inc. ("Prolexys") under which the Company is conducting for Prolexys an early stage clinical trial investigating a novel compound as a product candidate for cancer therapeutics. This contract was filed as an exhibit to and discussed in a Current Report on Form 8-K filed by the Company with the SEC on September 14, 2011 primarily because of the related nature of the management and ownership of Prolexys with the Company and its management and with certain of its significant stockholders, and not because the Company's rights or obligations under the contract research agreement with Prolexys are otherwise material to the Company. The Company did not incur any third party costs related to its work with Prolexys and it was primarily contributing only the efforts of employees. All third party costs associated with the Prolexys clinical trial and related work were paid directly by Prolexys. The amount of internal resources the Company contributed to Prolexys was not material. During 2015, the clinical trial ended and the Company ceased contributing efforts of its employees to Prolexys and the agreement with Prolexys was terminated during 2016. This arrangement was part of the Company's efforts to expand its portfolio of product candidates, but it never considered this arrangement to be material to the Company.

Prolexys is 35.7% owned by BIH SA, which owns 7.7% of the Company's outstanding common stock; 24.3% owned by Peter Friedli who is the Chairman of the Board and direct owner of 29.6% of the Company's common stock; and 13.8% owned by Venturetec, Inc., which holds 11.9% of the Company's common stock. Peter Friedli is the President and an approximately 2% owner of Venturetec, Inc. Yves Huwyler, who serves on the Company's Board, owns less than 1% of Prolexys and serves on its board of directors.

The Board and Audit Committee, including all of the Company's independent directors, but with Mr. Friedli abstaining, unanimously approved this transaction.

BioForceRX LLC . The Company paid BioForceRX LLC, a professional recruiting and consulting firm, approximately \$129,500 in 2015 for various recruiting services, primarily involving the Company's sales force. The owner of BioForceRX LLC is Kathleen Czworka, the spouse of Frank Czworka, the Company's former Vice President and General Manager of Wound Care from August 2011 to February 2016. Mr. Czworka was also served as the Company's Chief Operating Officer from February 2, 2016 until March 6, 2016 when the Chief Operating Officer position was eliminated.

Ongoing Search for Permanent Chief Executive Officer

As previously reported, the Company is conducting a search to identify a permanent Chief Executive Officer. On June 10, 2016, the Company announced that the Board had appointed David A. Dresner to serve as Interim President and Chief Executive Officer.

SEC and U.S. Attorney's Office Investigations

As disclosed in the Company's Current Report on Form 8-K filed on March 15, 2016, the Company has received a subpoena from the SEC relating to a non-public investigation relating to its historic accounting practices, which have been under independent review (the "Independent Review") by the Audit Committee with the assistance of outside professionals. Counsel to the Audit Committee also has voluntarily advised the SEC about the Independent Review. The Company is cooperating fully with the SEC in this matter.

As disclosed in the Company's Current Report on Form 8-K filed on May 27, 2016, the Company has been advised by the United States Attorney's Office for the Southern District of New York (the "U.S. Attorney") that a criminal investigation has been opened by that office into what the Company understands to be the matters of the SEC Investigation. The Company is cooperating fully with the U.S. Attorney in this matter.

Forward Looking Statements

Certain matters discussed in this Current Report on Form 8-K constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on management's current beliefs, assumptions and expectations regarding future events, which in turn are based on information currently available to management. Such forward-looking statements include statements regarding the timing or outcome of pending legal proceedings and government investigations, the Company's estimated range of revenues for 2015 and 2016, the timing or outcome of the Company's search for a permanent Chief Executive Officer and the timing or outcome of the restatements, including the materiality, significance, nature, subject matter, timing or quantitative effects of the Company's restated financial statements. The Company cautions you not to place undue reliance on any such forward-looking statements. Several factors could cause actual results to differ materially from those expressed in or contemplated by the forward-looking statements. Such factors include, but are not limited to, the identification of additional errors in the restatement process, changes in the scope or focus of the accounting adjustments, the risk that additional information may arise prior to the expected filing with the SEC of the restated financial statements and the 2015 and 2016 financial statements, the outcome of the presently pending investigations by SEC and U.S. Department of Justice, or subsequent events that would require us to make adjustment. Other risk factors affecting the Company are discussed in detail in the Company's filings with the SEC, including its Annual Reports on Form 10-K. The Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

SIGNATURES

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

By: /s/ GREGORY I. LAW
Gregory I. Law
Chief Financial Officer

Date: March 27, 2017