OSIRIS THERAPEUTICS, INC. Form 8-K March 15, 2016

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): $March\ 14,\ 2016$

OSIRIS THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Maryland 001-32966
(State or other jurisdiction of incorporation) (Commission File Number) (IRS

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 (<i>see</i> General Instruction A.2. below): |
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| 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 240.14a-12) |
| 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)) |
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Item 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

(b) On March 15, 2016, Osiris Therapeutics, Inc. (the $\underline{\text{Company}}$) notified The NASDAQ Stock Market (NASDAQ) of the Company s anticipated failure to timely file its Annual Report on Form 10-K for the year ended December 31, 2015 ($\underline{\text{2015 Form 10-K}}$) in compliance with NASDAQ s Marketplace Rule 5250(c)(1), which requires that NASDAQ-listed companies file their required periodic financial reports with the Securities and Exchange Commission ($\underline{\text{SE}C}$) on a timely basis.

The Company expects to file today with the SEC a Form 12b-25 Notification of Late Filing to disclose that it will not be able to file its 2015 Form 10-K on the prescribed due date or within the 15-day extension period provided by SEC rules. As a result of this late filing and the matters described below, the Company expects to receive a written notice of deficiency for noncompliance with NASDAQ listing qualifications for the failure to timely file periodic financial reports with the SEC. The Company plans to avail itself of the process provided by NASDAQ to maintain its listing while working to regain compliance with the listing qualifications by filing its 2015 Form 10-K and completing amendments to certain other SEC filings as disclosed below. There can be no assurance regarding the ultimate outcome of this process or the ability of the Company to successfully maintain its NASDAQ listing.

Item 4.02. Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

(a) On March 14, 2016, the Audit Committee (the <u>Audit Committee</u>) of the Board of Directors of the Company, in consultation with management, concluded that the Company s unaudited interim and audited annual financial statements previously issued for 2014 and its unaudited interim financial statements previously issued for the three and nine months ended September 30, 2015 should not be relied upon due to errors identified in such financial statements related to the timing of revenue recognition under contracts with distributors. In its Current Report on Form 8-K filed on November 20, 2015, the Company previously disclosed its conclusion that its unaudited interim financial statements for the quarters ended March 31, 2015 and June 30, 2015 should not be relied upon for similar reasons. The previously issued financial statements that should not be relied upon were included in the Company s Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014, its Annual Report on Form 10-K for the year ended December 31, 2014 and its Quarterly Report on Form 10-Q for the quarters ended March 31, 2015, June 30, 2015 and September 30, 2015 (the <u>Non-Reliance Periods</u>). Accordingly, investors, analysts and other persons should not rely upon the Company s previously released financial statements and other financial data for the Non-Reliance Periods, nor any press releases, investor presentations or other communications that relate to that information.

The Company identified these errors during the course of its ongoing review of its accounting for revenue recognition under contracts with distributors that was previously disclosed in November 2015 in the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 and its Current Report on Form 8-K filed with the SEC on November 20, 2015. In those reports, the Company previously disclosed its intention to restate its previously issued interim financial statements for the first quarter and second quarter of 2015 and to make immaterial modifications to its audited financial statements for the year ended December 31, 2014.

The Company anticipates that it will file restated financial statements covering the Non-Reliance Periods as soon as possible. Based on its review to date, the Company preliminarily anticipates that the restatements will focus on the timing of revenue recognition under contracts with distributors in accordance with Generally Accepted Accounting Principles and is expected to result in restating certain revenues under a cash, rather than accrual, basis of accounting, which means that revenues are recognized based upon actual cash receipt. The anticipated

adjustments are expected to reduce distributor revenues previously recognized in 2014 and 2015 and defer recognition of those amounts to 2015 or in future periods in 2016. The revenue adjustments will necessitate corresponding changes to other items in the financial statements including cost of goods sold, commission expense, accounts receivable and inventory. The Company is working diligently to quantify the expected revisions and have them audited or reviewed by its former independent registered public accounting firm. At present, the Company is unable to quantify the impact of the revisions on previously issued financial statements and can provide no assurance that other errors will not be identified. The Company intends to disclose additional details as soon as practicable.

The Audit Committee and management have discussed the matters disclosed in this Item 4.02(a) with BDO USA, LLP, its former independent registered public accounting firm.

Item 8.01 Other Information.

Legal Proceedings

On November 23, 2015, a putative class action lawsuit was filed in the United States District Court for the District of Maryland by a single plaintiff, individually and on behalf of other persons similarly situated, against the Company and three current or former executive officers of the Company. The action, captioned *Kiran Kumar Nallagonda v. Osiris Therapeutics, Inc. et al.*, Case 1:15-cv-03562 (the Nallagonda Action), alleges, among other things, that the defendants made materially false or misleading statements and material omissions in the Company s SEC filings in violation of the federal securities laws. The plaintiff seeks certification as a class action, unspecified damages and reimbursement of attorneys fees.

On March 2, 2016, a shareholder derivative complaint was filed in the Circuit Court for Howard County in the State of Maryland (Case No. 13C16106811) by a single plaintiff, derivatively and on behalf of the Company, against individual members of the Company s board of directors and certain executive officers. This action, captioned *Kevin Connelley v. Lode Debrabandere et al.*, alleges that each of the individual directors and officers named as defendants (i) violated their fiduciary duties to the Company s shareholders; (ii) abused their ability to control and influence the Company; (iii) engaged in gross mismanagement of the assets and business of the Company; and (iv) was unjustly enriched at the expense of, and to the detriment of, the Company. The alleged claims generally relate to the matters that are the subject of the Nallagonda Action. The plaintiff seeks, among other things, unspecified monetary damages, reimbursement of attorneys fees and shareholder votes on amendments to the Company s Articles of Incorporation and Bylaws with respect to various corporate governance policies.

The Company intends to vigorously defend each action.

SEC Investigation

The Company has received a subpoena from the SEC, which is conducting a non-public investigation relating to our historic accounting practices. The Company is cooperating fully with the SEC 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 outcome of the NASDAQ listing qualification deficiency process or the ability of the Company to successfully

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maintain its NASDAQ listing, the outcome of the legal proceedings and the SEC investigation, the outcome of the restatement, including the materiality, significance, nature, subject matter, timing or quantitative effects of the Company's restated financial statements, and any anticipated conclusions of the Company, the Audit Committee or management. We caution 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, include the identification of additional errors in the restated financial statements, 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, the preparation of our restated financial statements or other subsequent events that would require us to make additional adjustments. 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. We undertake 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 to | his report to be signed on its behalf by the |
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| undersigned hereunto duly authorized. | |

OSIRIS THERAPEUTICS, INC.

By: /s/ GREGORY I. LAW

Gregory I. Law Chief Financial Officer

Date: March 15, 2016

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