

# OSIRIS THERAPEUTICS, INC.

## **FORM 8-K** (Current report filing)

Filed 11/03/17 for the Period Ending 11/02/17

Address	7015 ALBERT EINSTEIN DRIVE COLUMBIA, MD, 21046
Telephone	443-545-1819
CIK	0001360886
Symbol	OSIR
SIC Code	2836 - Biological Products, (No Diagnostic Substances)
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, DC 20549

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**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 2, 2017**

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**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)

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

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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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 7.01. Regulation FD Disclosure**

On November 2, 2017, Osiris Therapeutics, Inc. (the “Company”) announced the resolution of the previously disclosed investigation by the Securities and Exchange Commission (the “SEC”) into the Company’s historical accounting practices. The press release announcing the resolution with the SEC is furnished herewith as Exhibit 99.1 and attached hereto.

The Company has agreed to settle with the SEC, without admitting or denying the allegations of the SEC, by consenting to the entry of a final judgment, subject to court approval, that permanently restrains and enjoins the Company from violating Section 17(a) of the Securities Act of 1933 and Sections 10(b), 13(a), and 13(b) (2) of the Securities Exchange Act of 1934 and Rules 10b-5, 12b-20, 13a-1, 13a-11 and 13a-13 thereunder. As part of the resolution, the Company also has agreed to pay a civil penalty in the amount of \$1,500,000. This resolution, if approved by the Court, will resolve, as to the Company, the matters alleged by the SEC in the complaint.

The Company cooperated fully with the SEC during its investigation. Since the SEC’s investigation began, the Company has made numerous important changes to its internal control over financial reporting and disclosure practices, hired a new chief executive officer, chief financial officer and general counsel, and enhanced staff in its accounting and finance departments.

The Company’s resolution with the SEC relates only to the SEC. As previously disclosed, there is an ongoing criminal investigation being conducted by the U.S. Attorney’s Office for the Southern District of New York relating to matters that were also investigated by the SEC, and the Company is cooperating fully with the investigation by the U.S. Attorney’s Office.

The information included in this Item 7.01 (including Exhibit 99.1) shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

*Forward-Looking Statements*

This Form 8-K contains forward-looking statements. Forward-looking statements include statements about the Company’s expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as “anticipate,” “believe,” “continue,” “ongoing,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project” or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Such forward-looking statements include, without limitation, the effectiveness of the Company’s remediation measures, including the effectiveness of completed and planned improvements in its internal control over financial reporting. Forward-looking statements are subject to known and unknown risks and uncertainties and could cause actual results to differ materially from those expressed or implied by the 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 for the 2015 quarterly and interim periods, changes or additional errors uncovered by the Company or its independent registered accounting firm, 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 Company’s audited financial statements for 2015, 2016 and 2017 or subsequent events that would require us to make adjustments. In addition, the Company’s independent registered accounting firm may determine that other adjustments or errors exist in previously reported 2015 interim periods or other prior periods. Other risk factors affecting the Company are discussed in detail in the Company’s filings with the SEC, including its Form 10-K/A for 2014. Accordingly, you should not unduly rely on these forward-looking statements. The Company undertakes no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this press release or to reflect the occurrence of unanticipated events, except as required by law.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits

99.1 [Press Release, dated November 2, 2017](#)

**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.

OSIRIS THERAPEUTICS, INC.

By: /s/ Linda Chang  
Linda Chang  
Chief Financial Officer

Date: November 2, 2017



### **Osiris Therapeutics, Inc. Announces Resolution of SEC Investigation**

**COLUMBIA, MARYLAND.** — **November 2, 2017** - Osiris Therapeutics, Inc. (OTC Pink: OSIR) (the “Company”), a leading regenerative medicine company focused on developing and marketing products for wound care, orthopedics, and sports medicine, today announced the resolution of the previously disclosed investigation by the Securities and Exchange Commission (the “SEC”) into the Company’s historical accounting practices.

The Company has agreed to settle with the SEC, without admitting or denying the allegations of the SEC, by consenting to the entry of a final judgment, subject to court approval, that permanently restrains and enjoins the Company from violating certain provisions of the federal securities laws. As part of the resolution, the Company also has agreed to pay a civil penalty in the amount of \$1,500,000. This resolution, if approved by the Court, will resolve, as to the Company, the matters alleged by the SEC in the complaint.

The Company cooperated fully with the SEC during its investigation. Since the SEC’s investigation began, the Company has made numerous important changes to its internal control over financial reporting and disclosure practices, hired a new chief executive officer, chief financial officer and general counsel, and enhanced staff in its accounting and finance departments.

“We are very pleased to have reached the resolution announced today, which relates to activities that occurred during the tenure of the Company’s former management team,” said Peter Friedli, Chairman of the Board of the Company. “We have instituted broad remedial measures designed to detect and prevent the issues that led to the matter being resolved, and this resolution allows us to continue moving forward with the Company’s critical mission of making advances in the area of cellular and regenerative medicine.”

The resolution announced today relates only to the SEC. As previously disclosed, there is an ongoing criminal investigation being conducted by the U.S. Attorney’s Office for the Southern District of New York relating to matters that were also investigated by the SEC, and the Company is cooperating fully with the investigation by the U.S. Attorney’s Office.

### **About Osiris Therapeutics**

Osiris Therapeutics, Inc., based in Columbia, Maryland, is a world leader in researching, developing, and marketing regenerative medicine products that improve health and lives of patients and lower overall healthcare costs. Having developed the world’s first approved stem cell drug, the Company continues to advance its research and development in biotechnology by focusing on innovation in regenerative medicine — including bioengineering, stem cell research and viable tissue based products. Osiris has achieved commercial success with products in wound care, orthopedics, and sports medicine, including Grafix®, Stravix®, BIO(4)® (available exclusively through Stryker), and Cartiform® (available exclusively through Arthrex). Osiris, Grafix, Stravix and Cartiform are registered trademarks of Osiris Therapeutics, Inc., and BIO(4) is a registered trademark of Howmedica Osteonics Corp. Osiris makes no claims concerning functional activities of Grafix or Stravix. Although well characterized in scientific literature and studies, preservation of tissue integrity including cells may not be indicative of clinical outcome. More information can be found on the Company’s website, [www.Osiris.com](http://www.Osiris.com). (OSIR-G)

7015 Albert Einstein Drive • Columbia, Maryland 21046 • Ph 443.545.1800 • Fax 443.545.1701 • [www.Osiris.com](http://www.Osiris.com)

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## **Forward-Looking Statements**

This press release contains forward-looking statements. Forward-looking statements include statements about the Company's expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as "anticipate," "believe," "continue," "ongoing," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project" or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Such forward-looking statements include, without limitation, statements regarding the Company's ability to move forward with its business activities, the effectiveness of the Company's remediation measures, including the effectiveness of completed and planned improvements in its internal control over financial reporting. Forward-looking statements are subject to known and unknown risks and uncertainties and could cause actual results to differ materially from those expressed or implied by the 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 for the 2015 quarterly and interim periods, changes or additional errors uncovered by the Company or its independent registered accounting firm, 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 Company's audited financial statements for 2015, 2016 and 2017 or subsequent events that would require us to make adjustments. In addition, the Company's independent registered accounting firm may determine that other adjustments or errors exist in previously reported 2015 interim periods or other prior periods. Other risk factors affecting the Company are discussed in detail in the Company's filings with the SEC, including its Form 10-K/A for 2014. Accordingly, you should not unduly rely on these forward-looking statements. The Company undertakes no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this press release or to reflect the occurrence of unanticipated events, except as required by law.

### **For additional information, please contact:**

Diane Savoie  
Osiris Therapeutics, Inc.  
(443) 545-1834  
OsirisPR@Osiris.com

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