

ZIOPHARM ONCOLOGY INC

FORM 8-K (Current report filing)

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Address	ONE FIRST AVENUE PARRIS BUILDING 34, NAVY YARD PLAZA BOSTON, MA 02129
Telephone	646-214-0700
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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**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, 2017

ZIOPHARM Oncology, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33038
(Commission
File Number)

84-1475642
(IRS Employer
Identification No.)

One First Avenue, Parris Building 34, Navy Yard Plaza
Boston, Massachusetts
(Address of Principal Executive Offices)

02129
(Zip Code)

(617) 259-1970
(Registrant's telephone number, including area code)

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- 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 7.01 Regulation FD Disclosure

On March 27, 2017, ZIOPHARM Oncology, Inc., or the Company, issued a press release announcing the receipt of positive guidance from an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) for its lead gene therapy product candidate, Ad-RTS-hIL-12 plus orally administered veledimex (V), to harness and control IL-12 production for the investigational treatment of recurrent glioblastoma (GBM), an aggressive form of brain cancer with few treatment options.

The information contained in the press release furnished as Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any of the Company’s filings, whether made before or after the date hereof, regardless of any general incorporation language in any such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 27, 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.

ZIOPHARM Oncology, Inc.

By: /s/ Kevin G. Lafond

Name: Kevin G. Lafond

Title: Senior Vice President, Chief Accounting Officer and Treasurer

Date: March 27, 2017

INDEX OF EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 27, 2017



ZIOPHARM Oncology, Inc.

ZIOPHARM Announces Successful End-of-Phase 2 Meeting with FDA for Ad-RTS-hIL-12 Gene Therapy in Recurrent Glioblastoma

BOSTON, MA – March 27, 2017 – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), a biopharmaceutical company focused on new immunotherapies, today announced the receipt of positive guidance from an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) for its lead gene therapy product candidate, Ad-RTS-hIL-12 plus orally administered veledimex (V), to harness and control IL-12 production for the investigational treatment of recurrent glioblastoma (GBM), an aggressive form of brain cancer with few treatment options.

“We are pleased with our productive interactions with the FDA and the valuable direction we received at the End-of-Phase 2 meeting. Our controlled approach utilizing the RheoSwitch® platform represents the next-generation of gene therapy enabling IL-12 to be regulated through a transcriptional switch. We appreciate the FDA’s feedback surrounding our plans to advance Ad-RTS-hIL-12-based therapy to a pivotal registration study for patients with recurrent GBM in 2017 and look forward to establishing the benefits of this novel therapeutic approach,” said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of ZIOPHARM.

“The median overall survival remains very promising and continues to be greater than 12 months for these heavily compromised patients,” said Francois Lebel, M.D., Chief Medical Officer of ZIOPHARM. He added, “After positive meetings with both FDA and European regulators, the Company is working towards finalization of the optimal pathway for our pivotal trial for Ad-RTS-hIL-12 + veledimex.”

In collaboration with its investigators and regulators, the Company is currently assessing its protocol design options for the pivotal trial, including the potential for a single-arm study comparing Ad-RTS-hIL-12 + V to historical controls in a subpopulation of patients with recurrent GBM. Details of the pivotal Phase 3 trial will be made available following evaluation and completion of discussions with clinical advisors as well as regulators.

About Glioblastoma:

GBM represents approximately 15% of all primary brain tumors and remains a high unmet clinical need that affects roughly 74,000 people worldwide annually. GBM is an aggressive form of brain cancer with recurrence rates near 90%, and prognosis for patients is poor with treatment often combining multiple approaches including surgery, radiation, and chemotherapy. Median overall survival (OS) is only 6 to 7 months in patients who have experienced multiple recurrences, and the prognosis is even poorer for patients who have failed temozolomide and bevacizumab, or equivalent salvage chemotherapy with a median OS of approximately 3 to 5 months.

About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a Boston, Massachusetts-based biotechnology company employing novel gene expression, control and cell technologies to deliver safe, effective and scalable cell- and viral-based therapies for the treatment of cancer and graft-versus-host-disease. The Company's immuno-oncology programs, in collaboration with Intrexon Corporation (NYSE:XON) and the MD Anderson Cancer Center, include chimeric antigen receptor T cell (CAR-T) and other adoptive cell-based approaches that use non-viral gene transfer methods for broad scalability. The Company is advancing programs in multiple stages of development together with Intrexon Corporation's RTS[®] technology, a switch to turn on and off, and precisely modulate, gene expression in order to improve therapeutic index. The Company's pipeline includes a number of cell-based therapeutics in both clinical and preclinical testing which are focused on hematologic and solid tumor malignancies.

Forward-Looking Safe-Harbor Statement:

This press release contains certain forward-looking information about ZIOPHARM Oncology, Inc. that is intended to be covered by the safe harbor for "forward-looking statements" provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding the Company's plans and expectations regarding its securities offerings, fundraising activities and financial strategy, the progress, timing and results of preclinical and clinical trials involving the Company's drug candidates, and the progress of the Company's research and development programs. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied by, the forward-looking statements. These risks and uncertainties include, but are not limited to: our ability to finance our operations and business initiatives and obtain funding for such activities, whether chimeric antigen receptor T cell (CAR-T) approaches, Ad-RTS-hIL-12, TCR and NK cell-based therapies, or any of our other therapeutic candidates will advance further in the preclinical or clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether chimeric antigen receptor T cell (CAR-T) approaches, Ad-RTS-hIL-12, TCR and NK cell-based therapies, and our other therapeutic products will be successfully marketed if approved; the strength and enforceability of our intellectual property rights; competition from other pharmaceutical and biotechnology companies; and the other risk factors contained in our periodic and interim reports filed from time to time with the Securities and Exchange Commission, including but not limited to, our Annual Report on Form 10-K for the fiscal year ended December 31, 2016. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

Trademarks

RheoSwitch Therapeutic System[®] and RTS[®] are registered trademarks of Intrexon Corporation.

Contact:

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