
**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): December 6, 2013

ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33038
(Commission
File Number)

84-1475672
(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 8.01 Other Events

On December 4, 2013, the National Institutes of Health's Recombinant DNA Advisory Committee voted unanimously to approve ZIOPHARM Oncology, Inc.'s initiation of a Phase 1 study of Ad-RTS-IL-12, an adenoviral vector engineered to express interleukin-12 under the control of veledimex, an oral activator, in subjects with recurrent or progressive glioblastoma or grade III malignant glioma (brain cancer). On December 6, 2013, ZIOPHARM Oncology, Inc., or the Company, issued a press release announcing the committee's approval. The Company has announced plans to launch a Phase 1 study of Ad-RTS-IL-12 in malignant glioma in the first half of 2014.

A copy of the above referenced press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated December 6, 2013

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: Vice President, Chief Accounting Officer
and Treasurer

Date: December 6, 2013

INDEX OF EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated December 6, 2013



ZIOPHARM Oncology, Inc.

**ZIOPHARM Announces Unanimous Recombinant DNA Advisory Committee
(RAC) Approval for Phase 1 Study of Ad-RTS-IL-12 in Subjects with
Recurrent or Progressive Glioblastoma**

BOSTON, December 6, 2013 – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) today announced the unanimous approval of the National Institutes of Health's Recombinant DNA Advisory Committee (RAC) for the initiation of a Phase 1 study of Ad-RTS-IL-12, an adenoviral vector engineered to express interleukin-12 under the control of veledimex, an oral activator, in subjects with recurrent or progressive glioblastoma or grade III malignant glioma (brain cancer). ZIOPHARM has announced plans to launch a Phase 1 study of Ad-RTS-IL-12 in malignant glioma in the first half of 2014. The Company is currently studying Ad-RTS-IL-12 in Phase 2 studies in melanoma and breast cancer.

“Malignant gliomas remain one of the deadliest forms of cancer. The stimulation of an immune response is a novel and intriguing therapeutic approach,” said E. Antonio Chiocca, M.D., Ph.D., Chairman, Department of Neurosurgery, and Co-Director of the Institute for the Neurosciences, Brigham and Women's Hospital/ Dana Farber Cancer Institute, and Harvey Cushing Professor of Neurosurgery, Harvard Medical School. “Important variables to the efficacy and safety of such therapies include the immune-privileged status of the central nervous system, the processes that contribute to the suppression of immune responses and the ability to modulate a brain tumor specific immune response. In animal tumor models, Ad-RTS-IL-12 and veledimex demonstrate a significant ability to overcome these barriers by localizing and tightly controlling expression of the potent immune cytokine interleukin-12. I look forward to seeing this promising therapeutic approach move quickly into clinical trials in patients with malignant brain tumors.”

ZIOPHARM is developing Ad-RTS-IL-12 using Intrexon Corporation's (NYSE: XON) RheoSwitch Therapeutic System® (RTS®) platform to control the expression of interleukin-12 and enable its safe and effective delivery as an anti-tumor agent. ZIOPHARM and Intrexon recently presented preclinical study results at the 2013 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, supporting the capability of Ad-RTS-IL-12 in the treatment of glioma. These studies showed both the ability for veledimex to penetrate the blood brain barrier and a dose-related increase in survival in a mouse GL-261 glioma model. Animals treated with Ad-RTS-IL-12 survived

throughout the duration of the study (100% survival at 75 days) with no significant adverse clinical signs observed. In contrast, the mean survival in the control groups was 22 (\pm 3) days. These findings support localized regulated IL-12 production as an approach for the treatment of malignant glioma.

“The NIH Committee’s decision is an important step forward in bringing Ad-RTS-IL-12, a potentially transformative new DNA-based therapeutic, to the treatment of gliomas,” said Francois Lebel, M.D., Senior Vice President, Clinical Development and Medical Operations at ZIOPHARM. “In tumor models, Ad-RTS-IL-12 and veledimex demonstrate a unique ability to overcome these barriers by localizing and tightly controlling expression of the potent cytokine interleukin-12. Our preclinical data to date demonstrate both a precisely controlled biologic response using this gene expression system as well as a remarkable effect on these tumors, suggesting further evaluation in the clinic. We expect to initiate a multicenter Phase 1 study in the first half of next year, and look forward to understanding the clinical potential of this therapy in brain cancers.”

About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a Boston, Massachusetts-based biotechnology company employing novel gene expression and control technology to deliver DNA for the treatment of cancer. ZIOPHARM’s technology platform employs Intrexon Corporation’s RheoSwitch Therapeutic System® platform to turn on and off, and precisely modulate, gene expression at the cancer site in order to improve the therapeutic index. This technology is currently being evaluated in Phase 2 clinical studies of the immune system cytokine interleukin-12 for the treatment of breast cancer and advanced melanoma. Multiple new Investigational New Drug applications for new targets using synthetic biology technology with monogenic and multigenic approaches are expected in 2014 and 2015. ZIOPHARM is also developing novel small molecules as potential cancer therapeutics.

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. Words such as “expect(s),” “feel(s),” “believe(s),” “will,” “may,” “anticipate(s)” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding our ability to successfully develop and commercialize our therapeutic products; our ability to expand our long-term business opportunities; financial projections and estimates and their underlying assumptions; and future performance. 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 or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to: whether Ad-RTS-IL-12, DC-RTS-IL-12, palifosfamide, darinaparsin, indibulin, or any of our other therapeutic products will advance further in the 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 Ad-RTS-IL-12, DC-RTS-IL-12, palifosfamide, darinaparsin, indibulin, and our other therapeutic products will be successfully marketed if approved; whether any of our other therapeutic product discovery and development efforts will be successful; our ability to achieve the results contemplated by our collaboration agreements; the strength and enforceability of our intellectual property rights; competition from other pharmaceutical and biotechnology companies; the development of, and our ability to take advantage of, the market for our therapeutic products; our ability to raise additional capital to fund our operations on terms acceptable to us; general economic conditions; and the other risk factors contained in our periodic and interim SEC 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, 2012, and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2013. 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.

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