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): May 18, 2016

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

Delaware	**001-33038**	**84-1475642**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One First Avenue, Parris Building 34, Navy Yard Plaza
Boston, Massachusetts **02129**
(Address of Principal Executive Offices) **(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)).

Item 8.01 Other Events

On May 18, 2016, ZIOPHARM Oncology, Inc., or the Company, issued a press release announcing clinical data highlighting favorable interim survival results from the Company's ongoing Phase 1, multi-center dose-escalation study of the gene therapy candidate Ad-RTS-hIL-12 + orally-administered veledimex in patients with recurrent or progressive glioblastoma, and that such results will be presented at the American Society of Clinical Oncology Annual Meeting to be held June 3-7, 2016, at McCormick Place in Chicago, Illinois.

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

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 18, 2016

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: May 18, 2016

INDEX OF EXHIBITS

Exhibit No.	Description
99.1	Press Release dated May 18, 2016

Exhibit 99.1

ZIOPHARM Oncology, Inc.

ZIOPHARM Announces Clinical Data Highlighting Favorable Interim Survival Results with Gene Therapy Candidate Ad-RTS-hIL-12 in Brain Cancer

– Data to be Presented at the 2016 ASCO Annual Meeting –

– Company to Discuss Results with Regulators after Additional Follow Up –

BOSTON, MA – May 18, 2016 – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) today announced that interim results from the Company's ongoing Phase 1, multi-center dose-escalation study of the gene therapy candidate Ad-RTS-hIL-12 + orally-administered veledimex in patients with recurrent or progressive glioblastoma will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting held June 3-7, 2016, at McCormick Place in Chicago, Illinois. Ad-RTS-hIL-12 + veledimex is a novel viral gene therapy candidate for the controlled expression of interleukin 12 (IL-12), a pro-inflammatory cytokine critical for stimulating anti-cancer immune responses.

Glioblastoma is an aggressive primary brain tumor affecting approximately 74,000 people worldwide each year.[i, ii] Recurrent glioblastoma is an aggressive cancer with one of the lowest 3-year survival rates, at 3%, among all cancers.[iii] For patients who have experienced multiple recurrences the prognosis is particularly poor, with a median overall survival (OS) of 6-7 months, while OS in patients that have failed temozolomide and bevacizumab, or equivalent salvage chemotherapy, is approximately 3-5 months.[iv, v]

The primary objective of the study is to determine the safety and tolerability of a single intra-tumoral Ad-RTS-hIL-12 injection activated upon dosing with oral veledimex. Secondary objectives are to determine the Ad-RTS-hIL-12 + veledimex maximum tolerated dose, the immune responses elicited by Ad-RTS-hIL-12 + veledimex, and assessment of biologic response. Eleven patients with recurrent high-grade gliomas (one with grade III and ten with grade IV) have been treated to date with Ad-RTS-hIL-12 through direct injection into their brain tumors, including seven patients in the first dose cohort (veledimex dosed at 20 mg) and four in the ongoing second dose cohort (veledimex dosed at 40 mg). Veledimex was taken orally to activate the production of IL-12 from the tumor site and stimulate an immune response.

Patients enrolled in this multi-center study have all failed standard therapy, with nine of eleven patients failing additional salvage treatments, for a mean of 2.7 prior lines of therapy in cohort one and 2.0 prior lines in cohort two. No enrollment restrictions were placed on tumor size or location within the supratentorial space. Overall median follow-up for patients enrolled in the trial is 6.2 months with 10 of 11 alive. In the fully-enrolled cohort one, 6 of 7 (86%) patients remain alive with a median follow up of 6.8 months. Enrollment in cohort two is ongoing. Even at its lowest dose, the presence of IL-12 in the bloodstream could be detected, demonstrating that veledimex is bioavailable and crosses the blood brain barrier at sufficient levels to turn on the RheoSwitch (RTS®) and generate IL-12, which could be measured in the blood stream.

Furthermore, for those patients that experienced adverse events associated with the treatment, discontinuing veledimex reversed these adverse events.

“Early results observed in the limited number of patients who have been treated with Ad-RTS-hIL-12 + veledimex are very encouraging for a Phase 1 study,” said Ennio Antonio Chiocca, M.D., Ph.D., Harvey W. Cushing Professor of Neurosurgery, Department of Surgery, Harvard Medical School, Surgical Director, Center for Neuro-oncology, Dana-Farber Cancer Institute, Chairman, Neurosurgery, Brigham And Women’s Hospital and Co-Director, Institute for the Neurosciences, Brigham And Women’s Hospital. “Virus-based gene therapy used to stimulate an immunological response in the brain is at the frontier of innovation in treatment, with Ad-RTS-hIL-12 offering perhaps the most controllable approach within this field. In this study, we see encouraging signs of immune activation following the administration of Ad-RTS-hIL-12 + veledimex.”

Overall Ad-RTS-hIL-12 + veledimex was well tolerated. All serious adverse events and Grade 3 related toxicities were rapidly reversible upon discontinuation of veledimex. The most common related adverse events included headache, nausea/vomiting, fever, white blood cell/leukocyte count decrease, platelet count decreased and liver function test increase. Four subjects had related serious adverse events.

“Because the brain is a segregated and fragile environment, the ability to turn an immune response on and off is critical to balancing efficacy and tolerability,” said Francois Lebel, M.D., Executive Vice President, Research and Development, Chief Medical Officer at ZIOPHARM. “As we continue to follow patients with extremely guarded prognoses in this multi-center trial, we hope that these promising early trends in survival are maintained. Our goal, once we reach an optimal dose, will be to promptly initiate registration trial discussions with regulators.”

Dr. Laurence Cooper, M.D., Ph.D., Chief Executive Officer of ZIOPHARM, added: “Basing our approach on the genetic engineering of adenovirus offers a simpler strategy than replicating viral-therapy options, one that can be rapidly controlled via a drug activating a gene switch, and one that does not rely on intra-tumoral catheterization. We look forward to testing Ad-RTS-hIL-12 + veledimex not just on its own, but in combination with other immuno-oncology approaches, including checkpoint inhibitors and natural killer cells, in clinical trials that we plan to start this year and next. Our data suggest that patients can take a drug by mouth to activate the immune response in their tumors with exciting results.”

Ad-RTS-hIL-12 + veledimex has been granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of patients with malignant glioma.

ASCO Presentation Details

Title: Effect of controlled intratumoral viral delivery of Ad-RTS-hIL-12 + oral veledimex in subjects with recurrent or progressive glioma
Poster Session: Central Nervous System Tumors
Date and Time: Saturday, June 4, 2016 1:00 PM - 4:30 PM CT
Abstract Number: 2052
Poster: #239
Location: Hall A

In addition to the GBM study, a study design for the Company's Phase 1b/2 clinical trial of Ad-RTS-hIL-12 + veledimex in locally advanced or metastatic breast cancer will be outlined at the ASCO annual meeting. The study, which is being conducted at the Memorial Sloan Kettering Cancer Center in New York, is designed to examine the safety, tolerability and efficacy of Ad-RTS-hIL-12 immunotherapy given following standard of care chemotherapy in up to 40 women with locally advanced or metastatic breast cancer of all subtypes. The Company expects that outcome data from this study will be presented at a scientific meeting in the second half of the year.

Title: Phase 1b/2 study of intratumoral Ad-RTS-hIL-12 + veledimex in patients with chemotherapy-responsive locally advanced or metastatic breast cancer
Poster Session: Developmental Therapeutics—Immunotherapy
Date and Time: Sunday, June 5, 2016 8:00 AM – 11:30 AM CT
Abstract Number: TPS3097
Poster: #418a
Location: Hall A

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. 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 RheoSwitch Therapeutic System® 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 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: 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 pre-clinical 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 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, 2015, and our Quarterly Report for the quarter ended March 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® (RTS®) technology is a registered trademark of Intrexon Corporation.

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ii. McCubrey JA, LaHair MM, Franklin RA. OSU–0312 in the treatment of glioblastoma. Mol Pharmacol. 2006;70:437-439.
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