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 10, 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 2.02 Results of Operations and Financial Condition

On May 10, 2016, ZIOPHARM Oncology, Inc., or the Company, issued a press release announcing its financial condition and results of operations for the three months ended March 31, 2016. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

This information, including 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

Exhibit No.	Description
99.1	Press Release of ZIOPHARM Oncology, Inc. dated May 10, 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 Finance, Chief Accounting Officer and Treasurer

Date: May 10, 2016

INDEX OF EXHIBITS

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99.1	Press Release of ZIOPHARM Oncology, Inc. dated May 10, 2016

ZIOPHARM Oncology, Inc.

ZIOPHARM Reports First-Quarter 2016 Financial Results and Provides Update on Recent Activities

BOSTON, MA – May 10, 2016 – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) today announced financial results for the first quarter ended March 31, 2016, and provided an update on the Company's recent activities.

"We have solid momentum in each of our cell and gene therapy programs, with the potential to move our lead gene therapy, Ad-RTS-IL-12 + veledimex, into a pivotal study next year," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of ZIOPHARM. "Ad-RTS-IL-12 + veledimex continues to yield encouraging results as we recruit additional patients into an ongoing dose-escalation study in recurrent glioblastoma, and we look forward to presenting this data to the American Society of Clinical Oncology (ASCO) at its annual meeting in June of this year. Given the dire outcomes in this patient population, a potential therapeutic benefit may be quickly assessed and, if these results remain durable, our goal would be to move into a registration study, following discussions with regulators."

Dr. Cooper added: "As this promising program moves forward, we continue to test the potential of our cell therapy platform and technologies in collaboration with leading partners in industry and academia. This includes clinical-stage platforms unique to ZIOPHARM, such as the non-viral *Sleeping Beauty* (SB) system, that are fundamental to making immune cell therapy a cost-effective, widely-available treatment modality. These technologies are particularly important in leveraging T-cell receptors (TCRs) to target neoantigens in solid tumors which requires individualizing this immunotherapy, an approach that is possible with our customizable, easy-to-manufacture non-viral gene transfer system. We expect to initiate or continue prosecuting up to six clinical trials across multiple platforms in 2016 and look forward to sharing data and outcomes from these trials throughout the year."

The SB transposon-transposase is a unique non-viral system for introducing genes encoding CARs and TCRs into lymphocytes and is exclusively licensed by Intrexon Corporation (NYSE: XON) through MD Anderson and accessed as part of ZIOPHARM's collaboration with Intrexon. This non-viral approach has several potential advantages over viral-based delivery systems, including a lower cost of generating genetically modified T cells as well as the ability to generate T cells with minimal *ex vivo* processing and can serve as a conduit to targeting solid tumor neoantigens using TCRs.

Program Updates

Gene Therapies

Ad-RTS-hIL-12 + veledimex is a gene therapy candidate for the controlled expression of interleukin 12 (IL-12), a critical protein for stimulating an anti-cancer immune response, using the RheoSwitch Therapeutic System® (RTS®) gene switch. ZIOPHARM is currently enrolling

patients in two studies of Ad-RTS-hIL-12 + veledimex: a multi-center Phase 1 study in patients with recurrent or progressive glioblastoma multiforme (GBM), an aggressive form of brain cancer, and a Phase 1b/2 study for the treatment of patients with locally advanced or metastatic breast cancer following standard chemotherapy.

- **Preclinical studies combining Ad-RTS-IL-12 + veledimex and checkpoint inhibitors in brain tumor models presented at ASGCT.** In an oral presentation, ZIOPHARM presented data from preclinical studies of Ad-RTS-IL-12 + veledimex combined with immune checkpoint inhibitors (iCPI) in GBM mouse models at the 2016 Meeting of the American Society of Gene and Cell Therapy (ASGCT) in Washington D.C. held last week. Results demonstrated that survival of mice treated with Ad-RTS-IL-12 + veledimex and anti-PD-1 therapy was superior to either treatment alone, with a combination showing 100% survival. Because Ad-RTS-IL-12 and anti-PD-1 are clinically available, these data provide impetus for evaluating this combination immunotherapy in humans. ZIOPHARM plans to initiate a combination study in 2016 and is currently in discussion with partners to provide anti-PD-1 therapy.
- **Encouraging data from Phase 1 brain tumor study to be presented at ASCO.** ZIOPHARM expects to present data from a multicenter, Phase 1 gene therapy study of Ad-RTS-IL-12 in patients with recurrent or progressive GBM or Grade III malignant glioma at the 2016 ASCO Annual Meeting in June. Following reporting of encouraging data from the first cohort of the study at the initial dosing of Ad-RTS-IL-12 + veledimex, the Company announced last March that the first patient had been enrolled in the study's second dose cohort. The Company continues to enroll patients in the study and remains encouraged by the survival results observed to date.

Adoptive Cell Therapies

ZIOPHARM is developing various immuno-oncology programs, including chimeric antigen receptor T-cell (CAR-T), TCR, and natural killer (NK) adoptive cell-based therapies. These programs are being advanced in collaboration with Intrexon, MD Anderson Cancer Center, and the biopharmaceutical business of Merck KGaA, Darmstadt, Germany (CAR-T only).

- **Preclinical study showing evolution of the *Sleeping Beauty* (SB) non-viral transposon-transposase system in a mouse model of leukemia presented at ASGCT.** In an oral presentation, MD Anderson researchers in collaboration with ZIOPHARM presented data from preclinical studies demonstrating the ability to address the challenges of streamlining the manufacture of cell based therapy by leveraging the non-viral SB system to reduce cell culture time. The results were presented at the 2016 Meeting of the ASGCT in Washington D.C. held last week. These data also demonstrated an improvement in the anti-tumor activity of the CD19-specific CAR by modifying the "stalk" of the CAR.
- **Molecular Therapy Publication Highlights the Potential of *Sleeping Beauty* to Personalize TCR Gene Therapy.** In March, the Company announced the publication of an article describing the use of SB non-viral gene transfer technology to genetically modify T cells to target neoantigens present within solid tumors. This approach unlocks the potential for rapid and individualized TCR gene therapy aimed at unique mutations within each patient's cancer cells. The article, titled "Stable, non-viral expression of mutated tumor neoantigen-specific T-cell receptors using the Sleeping Beauty transposon/transposase system," was published in the journal *Molecular Therapy* (5 March 2016, doi:10.1038/mt.2016.51), and is available online.

- **First patient enrolled in Phase 1 study of second generation non-viral CD19-specific CAR T-cell therapy for advanced lymphoid malignancies.** In February 2016, ZIOPHARM announced that the first patient was enrolled in a new Phase 1 clinical study of its second generation non-viral CD19-specific CAR modified T-cell therapy in patients with advanced lymphoid malignancies (ClinicalTrials.gov Identifier: NCT02529813). T cells were modified using the SB system to stably express a CAR targeting CD19. This second-generation study at MD Anderson employs a CAR construct with a stalk revised to improve persistence and anti-tumor response over the first generation therapy. This investigational treatment is independent of hematopoietic stem-cell transplantation and includes patients with advanced disease.
- ***Sleeping Beauty* non-viral gene transfer technology featured in *Nature Medicine*.** In January 2016, the SB non-viral gene transfer technology was featured in a perspectives article in the journal *Nature Medicine* (Volume 22, Number 1, 26-36), titled "Prospects for gene-engineered T cell immunotherapy for solid cancers." The article describes how adoptive transfer of TCR-engineered T cells for solid tumors may come from the "arduous task of targeting the unique set of mutations that cause each patient's cancer." Because of the challenges of achieving this goal, the authors note that non-viral integration systems will likely be considerably cheaper to manufacture and easier to implement for single-use applications compared with viral vectors and that, among non-viral platforms, SB has advanced furthest in clinical development.

Milestones

ZIOPHARM expects the following milestones to occur in 2016:

- Intra-tumoral IL-12 RheoSwitch® programs:
  - Clinical update at ASCO 2016 for Phase 1 study of GBM
  - Update at ASCO 2016 for Phase 1/2 study in breast cancer with standard of care
- CAR-T programs:
  - Continuation of CD19 CAR+ T-cell clinical study
  - Initiate a CAR+ T-cell clinical study for myeloid malignancies
  - Initiate CAR+ T-cell preclinical studies for other hematological malignancies and solid tumors
  - Initiate preclinical studies of allogeneic, off-the-shelf (OTS) T-cell studies in 2016
- TCR-T programs
  - Initiate TCR-modified T-cell preclinical studies
- NK cell programs
  - Initiate a Phase 1 study of OTS NK cells for AML
- GvHD programs
  - Initiate preclinical studies

The Company is also evaluating additional potential preclinical candidates and continuing discovery efforts aimed at identifying other potential product candidates under its Exclusive Channel Agreement with Intrexon. In addition, the Company may seek to enhance its pipeline in immuno-oncology through focused strategic transactions, which may include acquisitions, partnerships and in-licensing activities.

First-Quarter 2016 Financial Results

- Net loss for the first quarter of 2016 was $12.0 million, or $(0.09) per share, compared to a net loss of $78.2 million, or $(0.69) per share, for the first quarter of 2015. During the first quarter ended 2015, the company incurred a one-time non-cash charge of $67.3 million, or $(0.59) per share, related to a license agreement with The University of Texas M.D. Anderson Cancer Center.
- Research and development expenses were $10.2 million for the first quarter of 2016 compared to $74.2 million for the first quarter of 2015. The decrease in research and development expenses in the current year primarily relates to a one-time charge of $67.3 million related to the M.D. Anderson license agreement in 2015.
- General and administrative expenses were $3.8 million for the first quarter of 2016 compared to $4.3 million for the first quarter of 2015. The decrease was primarily due to a reduction in contracted outside service costs in 2016.
- The Company ended the quarter with cash and cash equivalents of approximately $124.8 million, which the Company believes will be sufficient to fund its currently planned activities into the fourth quarter of 2017.

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-IL-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-IL-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.

ZIOPHARM Oncology, Inc.
Condensed Statements of Operations
(in thousands except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Revenue	$ 1,969	$ 272
Operating expenses:		
Research and development	10,199	74,249
General and administrative	3,810	4,250
Total operating expenses	14,009	78,499
Loss from operations	(12,040)	(78,227)
Other income (expense), net	21	(4)
Net loss	$ (12,019)	$ (78,231)
Basic and diluted net loss per share	$ (0.09)	$ (0.69)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	130,157,927	113,410,250

ZIOPHARM Oncology, Inc.
Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2016	December 31, 2015
Cash and cash equivalents	124,846	140,717
Working capital	123,115	134,398
Total assets	141,682	153,724
Total stockholders' equity	77,813	87,371

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