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 3, 2014

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

Delaware	001-33038	84-1475672
(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 7.01 Regulation FD Disclosure

On December 3, 2014, ZIOPHARM Oncology, Inc., or the Company, together with Intrexon Corporation, announced the presentation of clinical and preclinical studies from their immuno-oncology programs at the American Association for Cancer Research (AACR) 2014 Immunology and Immunotherapy Meeting taking place December 1-4, 2014 in Orlando, Florida.

A copy of the above referenced press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. 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 the Company dated December 3, 2014

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 3, 2014

INDEX OF EXHIBITS

Exhibit No.	Description
99.1	Press Release of the Company dated December 3, 2014

INTREXON

ZIOPHARM Oncology, Inc.

ZIOPHARM and Intrexon Present Clinical and Preclinical Data from Immuno-Oncology Programs at AACR Tumor Immunology and Immunotherapy Meeting

BOSTON, Ma. and GERMANTOWN, Md. – December 3, 2014 – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, and Intrexon Corporation (NYSE: XON), a leader in synthetic biology, today announced the presentation of clinical and preclinical studies from their immuno-oncology programs at the American Association for Cancer Research (AACR) 2014 Immunology and Immunotherapy Meeting taking place December 1-4, 2014 in Orlando, Florida. Presentations include:

- Clinical results from the Ad-RTS-hIL-12 + veledimex studies in patients with advanced breast cancer and melanoma demonstrating local and systemic IL-12-mediated anti-cancer activity, as well as safety through control of both immune- and IL-12-mediated toxicity with use of the RheoSwitch Therapeutic System® (RTS®) gene switch (Abstract #B11);
- Preclinical data supporting the potential for cytolytic activity against solid tumor targets with allogeneic, genetically-modified stem cells enabled for controlled release of cell-linking moieties (CLMs) within the tumor micro-environment (Abstract #B25); and
- Preclinical data describing the development of a novel, high-throughput screening technology for rapidly identifying bi-specific antibodies capable of inducing targeted immunologic activity through the activation of T-cells or other immune cells against tumors (Abstract #B16).

“The goal of immuno-oncology is to produce powerful immune responses to cancer. Controlling these immune responses and being able to keep patients out of the ICU during treatment would be an important advance,” said James Armitage, M.D., Professor, Department of Internal Medicine, Joe Shapiro Distinguished Chair of Oncology, University of Nebraska Medical Center, ZIOPHARM Medical Board member, and Past President of ASCO and the American Society for Blood and Marrow Transplantation. “A key to achieving this is to tightly control immune system effectors, activating and modulating the intensity of the response as necessary. These data demonstrate the ability to do just that, showing novel control over effector expression, not only in the lab, but also in the clinic.”

Interim clinical trial results continue to validate dose-dependent oral veledimex control of the Interleukin-12 (IL-12) gene program module and the rapid reversibility of cytokine expression and associated adverse events in patients upon withdrawal of the activator ligand. Together the Companies intend to integrate this RTS-hIL-12 veledimex-controlled cytokine module into a suite of next generation cellular products armed with tumor specific targeting and signaling through chimeric antigen receptor (CAR), T-Cell Receptor (TCR), and cell linking moiety (CLM) platforms.

“Through the rational design of molecularly directed T-cell therapies, such as CAR-T and CLM, and controlled expression of cytokine adjuvants with our clinically validated RTS® platform, we

plan to advance cellular therapies that overcome the challenges of treating solid tumor malignancies and improve upon the limitations of current hematologic approaches within immuno-oncology," stated Gregory Frost, Ph.D., Senior Vice President and Head of Intrexon's Health Sector.

Results in detail

"Ad-RTS-hIL-12 + Veledimex Regulation of IL-12 Expression in Advanced Breast Cancer (BC) and Melanoma Patients" (Abstract #B11)

In two open-label Phase II clinical studies, twelve patients with metastatic advanced stage breast cancer and twenty-six patients with metastatic melanoma were administered Ad-RTS-hIL-12, a novel DNA-based therapeutic candidate for the controlled expression of IL-12, a potent cytokine for stimulating an anti-cancer T-cell immune response. Following intra-tumoral injection of Ad-RTS-hIL-12, expression of IL-12 within patients was controlled by the RheoSwitch Therapeutic System® (RTS®) gene switch using the oral activator ligand, veledimex, at doses ranging from 5mg to 160mg. All subjects had heavy tumor burden and disease progression at the time of enrollment, with mean number of prior therapies at 14 and 10 for breast cancer and melanoma patients, respectively. Treatment with Ad-RTS-hIL-12 + veledimex resulted in an increase in the immune cytokine IL-12 and downstream cytokines, IFNg, IP-10 and IL-10, resulting in a significant increase in the number of CD8+ T-cells.

Among seven evaluable subjects in the Phase II clinical study of Ad-RTS-IL-12 + veledimex in patients with recurrent or metastatic breast cancer, three had stable disease, including one triple negative BC subject who crossed the primary endpoint of 16 week progression free survival, for a disease control rate (stable disease or better) of 43%. Target lesions and tumor burden were significantly reduced in approximately 40% of patients. In the Phase I/II study of Ad-RTS-hIL-12 + veledimex in subjects with unresectable stage III/IV melanoma, of eighteen evaluable subjects, one had a partial response and six had stable disease, for a disease control rate of 39%. In melanoma patients for whom a response was observed, there was evidence of local and systemic anti-cancer activity.

The adverse event profile of Ad-RTS-hIL-12 + veledimex in both melanoma and breast cancer was predictable, reversible and characteristic of immune activation. The most common ³ Grade 3 treatment emergent adverse events (TEAEs) in breast cancer and melanoma included neutropenia and electrolyte abnormalities (21%) each, LFTs increased (16%), leukopenia (13%) and pyrexia, hypotension, lymphopenia, anemia, and cytokine release syndrome (11%) each. Importantly, all TEAEs and SAEs ³ Grade 3 reversed rapidly upon discontinuation of veledimex oral dosing.

Based on these results, ZIOPHARM expects to initiate a Phase 1b/2 clinical trial of Ad-RTS-hIL-12 + veledimex in conjunction with standard-of-care treatment in subjects with earlier-stage, locally advanced or metastatic breast cancer. The Company also continues to work with regulators toward the initiation of a Phase I trial of Ad-RTS-IL-12 as a single agent in the treatment of patients with Glioblastoma Multiforme, anticipated to begin in the first half of 2015, and is exploring additional applications using the RTS® control system for IL-12 cell-based therapies.

"With potent, systemic anti-cancer immune activity and control of both immune- and IL-12-mediated toxicity established in heavily pretreated breast cancer and melanoma patients, our development strategy for this novel therapy is in sharp focus," said Francois Lebel, M.D., Senior

Vice President, Clinical Development and Medical Operations at ZIOPHARM. “These findings will be translated into a study of patients with early metastatic breast cancer responding to standard therapy, where an increase in tumor specific CD8+ T-cells may improve clinical outcomes. As we evolve this platform, we look forward to exploring its further clinical application in cancers where an IL-12 driven immune response is associated with anti-cancer immunity and where combination therapy may deliver significantly improved outcomes for patients.”

“Development of a High-Throughput Imaging Screen for the Functional Assessment of Cell-Linking Moieties Using Effector And Target Cells In A Cell Kill Assay” (Abstract #B16) and “Controlled Production of a Bispecific Antibody by a Genetically-modified Stem Cell Triggers T-cell Activation and Cytolysis in Non-small Cell Lung Carcinoma” (Abstract #B25)

Cell Linking Moieties (CLMs) are small bi-specific antibody fragments capable of directing potent T-cell mediated tumor lysis by bridging the immunologic synapses of T-cells and surface targets on tumor cells. Previous studies have shown that the systemic distribution and pharmacokinetic profile of bi-specific antibodies limit their utility for many target/effector combinations. In two preclinical studies, Intrexon and ZIOPHARM researchers interrogated a large number of CLM-based effectors for their ability to activate white blood cells from peripheral blood and lyse receptor target-positive tumor cells. Allogeneic, tumor targeting stem cells were then genetically modified to express CLMs within the tumor microenvironment using the RheoSwitch Therapeutic System® platform as a mechanism for providing spatial and temporal control.

The first study demonstrates the ability of Intrexon’s proprietary image-based screening systems and rapid DNA assembly to screen a large number of EGFR and HER2 receptor-targeted CLM variants for their ability to recruit CD3+ T-cells and mediate selective cell killing against target positive cells in peripheral blood co-cultures. The image-based screening platform allows for real time target cell killing information to be obtained, as well as kinetic cell morphologic analyses to understand the dynamics of killing activity, thereby shortening the developmental timeline to lead candidate selection.

The second study validated these CLM candidates in scalable, allogeneic endometrial regenerative cells (ERCs) genetically modified to express an anti-CD3-anti-EGFR CLM under RTS® ligand inducible control. Expression of CLMs under the RTS® inducible promoter provided effective control of CLM secretion and modulation of killing activity, with veledimex-dependent cytotoxicity of greater than 80% against an EGFR+ KRAS mutant lung cancer cell model. CLM-expressing ERCs were found to be effective in co-culture killing assays at cellular doses as low as 1% of target cells.

These data support the feasibility of localized cytolytic activity of CLM-secreting allogeneic cell therapy products against EGFR+ KRAS mutant solid tumor malignancies.

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® technology 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. The Company's synthetic immuno-oncology programs in collaboration with Intrexon also include chimeric antigen receptor T-cell (CAR-T) approaches.

About Intrexon Corporation

Intrexon Corporation (NYSE: XON) is a leader in synthetic biology focused on collaborating with companies in Health, Food, Energy, Environment, and Consumer Sectors to create biologically-based products that improve the quality of life and the health of the planet. Through the company's proprietary UltraVector® platform, Intrexon provides its partners with industrial-scale design and development of complex biological systems. The UltraVector® platform delivers unprecedented control over the quality, function, and performance of living cells. We call our synthetic biology approach and integrated technologies Better DNA®, and we invite you to discover more at www.dna.com.

Trademarks

Intrexon, UltraVector, RheoSwitch Therapeutic System, RTS, RheoSwitch, and Better DNA are trademarks of Intrexon and/or its affiliates. Other names may be trademarks of their respective owners.

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; our future presentations at industry meetings; financial projections and estimates and their underlying assumptions; and future performance. All of such statements include 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, or any of our other therapeutic discovery efforts 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, or any other therapeutic products we develop 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, 2013 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2014. 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.

Contact:

For ZIOPHARM

Lori Ann Occhiogrosso
ZIOPHARM Oncology, Inc.
617-259-1987
locchiogrosso@ziopharm.com

David Pitts
Argot Partners
212-600-1902
david@argotpartners.com

For Intrexon

Investor Contact:
Christopher Basta
Vice President, Investor Relations
Tel: +1 (561) 410-7052
Investors@intrexon.com

Corporate Contact:
Marie Rossi, Ph.D.
Senior Manager, Technical Communications
Tel: +1 (301) 556-9850
publicrelations@intrexon.com