ZIOPHARM ONCOLOGY INC
Form 8-K
October 09, 2018

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): October 5, 2018

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)).
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act (17 CFR 230.405) or Rule 12b-2 of the Exchange Act (17 CFR 240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

In connection with the entry by Ziopharm Oncology, Inc., or the Company, into a new strategic transaction with Precigen, Inc., or Precigen, which is further described in the press release referenced in Item 7.01 below, on October 5, 2018, Randal J. Kirk resigned from the Company s Board of Directors, or the Board, effective immediately. Mr. Kirk has served as a member of the Board since 2011 and his decision to resign was not due to any disagreement with the Company s operations, policies or practices. The Company thanks Mr. Kirk for his service.

Item 7.01 Regulation FD Disclosure.

On October 9, 2018, the Company, together with Precigen, a wholly owned subsidiary of Intrexon Corporation, issued a press release announcing the amendment of their prior collaborations and entry into an exclusive license agreement. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K. Members of management of the Company plan to hold a conference call on October 9, 2018 at 8:00 a.m. Eastern time to discuss the new transaction. Information about how to access the conference call is in the press release attached as Exhibit 99.1. Presentation slides will be used in connection with the conference call and are available on the Company s website at www.ziopharm.com, and furnished herewith as Exhibit 99.2.

The information contained in this Item 7.01, including Exhibits 99.1 and 99.2, are being furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, or the Exchange Act, or otherwise subject to the liability of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, or the Securities Act. The information in this Item 7.01, including Exhibits 99.1 and 99.2, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in any such filing.

Item 8.01 Other Events.

Clinical Programs Update

In the press release described above, the Company updated guidance on the timing of its response to the request for more information from the U.S. Food and Drug Administration, or the FDA, regarding the clinical hold placed on the investigational new drug, or IND, application for the Company s third-generation Phase 1 trial to evaluate CD19-specific CAR-T therapies under technology referred to as point-of-care. The Company expects to respond to the FDA s request for more information in the second half of 2019.

The Company also updated its guidance on its planned Phase 1 trial of Sleeping Beauty-modified TCRs to treat solid tumors. As previously disclosed, the IND application for this Phase 1 trial, which is being led by and conducted at the National Cancer Institute, or the NCI, remains on track to be submitted in the fourth quarter of 2018. The Company today updated that it currently expects the NCI to initiate the trial and begin treating patients in 2019 following IND clearance.

The information contained in this Current Report on Form 8-K speaks only as of the date hereof. While the Company may elect to update the information in this Current Report on Form 8-K in the future, the Company disclaims any obligation to do so except to the extent required by applicable law.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can be identified by the use of words such as may, will, expect, project, estimate, anticipate, plan, believe, potential, should, continue versions of those words or other comparable words. These forward-looking statements include, but are not limited to, statements regarding the expected timing of the completion of clinical trials or studies related to Sleeping Beauty-modified TCRs and CD19-specific CAR-T therapies, the expected timing for the Company s response to the FDA, the expected timing for the filings or amendments of its IND applications and the expected timing for the initiation and readouts of the Company s upcoming clinical trials. These forward-looking statements are not guarantees of future actions or performance. These forward-looking statements are based on information currently available to the Company and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. 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: the expected benefits of the strategic transaction; changes in the Company s financial condition and cash needs, funding or other strategic opportunities that become available to the Company, the Company s ability to finance its 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 other product candidates will advance further in the preclinical research or clinical trial process, including receiving clearance from the FDA to conduct its clinical trials and whether and when, if at all, they will receive final approval from the FDA 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 the Company s other therapeutic products it develops will be successfully marketed if approved; the strength and enforceability of the Company s intellectual property rights; competition from other pharmaceutical and biotechnology companies; as well as other risk factors contained in the Company s periodic and interim reports filed from time to time with the Securities and Exchange Commission, including but not limited to, the risks and uncertainties set forth in the Risk Factors section of the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and subsequent reports that the Company may file with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and the Company does 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release of Ziopharm Oncology, Inc. dated October 9, 2018.
99.2	Presentation slides dated October 9, 2018.

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.

Date: October 9, 2018

By: /s/ Robert Hadfield
Name: Robert Hadfield
Title: General Counsel and Secretary