ONCOMED PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

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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): January 25, 2016

ONCOMED PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-35993**	**38-3572512**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

800 Chesapeake Drive
Redwood City, California 94063
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 995-8200

Check the appropriate box below if the Form 8-K filing 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 January 25, 2016, OncoMed Pharmaceuticals, Inc. (the "Company") issued a press release providing an update regarding the Company's Phase 2 clinical trial of tarextumab in pancreatic cancer (the "Press Release"). A copy of the Press Release is attached to this Current Report on Form 8-K as Exhibit 99.1, and the first four paragraphs of the Press Release are incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits .

Exhibit No.	Description
99.1	Press release, dated January 25, 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 25, 2016

ONCOMED PHARMACEUTICALS, INC.

By: /s/ Alicia J. Hager

Alicia J. Hager, J.D., Ph.D.
Vice President and General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release, dated January 25, 2016

Exhibit 99.1

For Immediate Release

OncoMed Provides Update on Tarextumab Phase 2
Pancreatic Cancer ALPINE Trial

Management to Conduct Conference Call at 8:30 am ET

REDWOOD CITY, Calif. – January 25, 2016 – OncoMed Pharmaceuticals Inc. (NASDAQ: OMED), a clinical-stage company developing novel anti-cancer stem cell and immuno-oncology therapeutics, announced an update on the Phase 2 ALPINE clinical trial following a pre-planned January 23 interim efficacy assessment of the clinical trial by an independent data safety monitoring board (DSMB). The DSMB assessed data from 172 patients treated as of a January 6, 2016 data cutoff date.

From a safety standpoint, the DSMB recommended that the study proceed to completion without modification. No unexpected safety findings emerged from its review.

However, the DSMB informed OncoMed of several findings regarding futility of the trial, notably:

- A statistically significant worsening of response rate and progression-free survival (PFS) in the treatment arm in the overall intent-to-treat population, as well as a negative trend in each Notch biomarker subgroup
- A strong trend to lack of benefit in the treatment arm for overall survival (OS), regardless of Notch biomarker levels, suggesting a low probability of achieving a statistically significant OS benefit based on analyses reviewed by the DSMB

Based on this information, OncoMed is in the process of unblinding the trial to carefully assess the current results and determine appropriate next steps for this fully enrolled trial. Eighteen patients remain on study drug treatment (tarextumab or placebo) between 172 and 527 days.

“The findings communicated by the DSMB suggest a low likelihood of a statistically significant benefit in overall survival in the tarextumab ALPINE pancreatic cancer trial,” said Paul J. Hastings, Chairman and CEO. “Our aim is to quickly unblind the trial and work with our clinical sites and investigators to verify, analyze, interpret, and fully understand the data, including Notch biomarker subgroup trends, and determine next steps.”

The Phase 2 ALPINE trial is a randomized, double-blinded, multicenter clinical trial designed to evaluate the efficacy of tarextumab in combination with Abraxane ® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus gemcitabine in patients with previously untreated Stage IV pancreatic cancer. The ALPINE study completed enrollment of 177 patients in August 2015. The trial was designed to compare the overall survival of patients receiving tarextumab 15 mg/kg every two weeks versus placebo in combination with Abraxane plus gemcitabine. Secondary and exploratory endpoints, including progression-free survival and overall response rate, pharmacokinetics, safety and other biomarkers, are to be evaluated. Overall survival, progression-free survival and overall response rates will be assessed using a predictive biomarker for high tumor Notch3 expression. Increased Notch3 expression is estimated to occur in approximately 70 percent of pancreatic tumors and is associated with poor patient outcomes.

Conference Call Today

OncoMed management will host a conference call today beginning at 8:30 a.m. ET/5:30 a.m. PT to answer investor and analysts questions regarding the ALPINE Phase 2 program.

Analysts and investors can participate in the conference call by dialing 1-855-420-0692 (domestic) and 1-484-756-4194 (international) using the conference ID# 37742080. The web broadcast of the conference call will be available for replay through February 15, 2016 via a link in the Investor Relations section of the OncoMed website.

About Tarextumab (anti-Notch2/3, OMP-59R5)

Tarextumab (anti-Notch2/3, OMP-59R5) is a fully human monoclonal antibody that targets the Notch2 and Notch3 receptors. Preclinical studies have suggested that tarextumab exhibits two mechanisms of action: (1) by downregulating Notch pathway signaling, tarextumab appears to have anti-cancer stem cell effects, and (2) tarextumab affects pericytes, impacting stromal and tumor microenvironment. Tarextumab is currently being studied in two randomized Phase 2 clinical trials. The "ALPINE" study (Antibody therapy in first-Line Pancreatic cancer Investigating anti-Notch Efficacy and safety) is assessing tarextumab with Abraxane ® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus gemcitabine in first-line advanced pancreatic cancer patients. The "PINNACLE" study (A Phase 1b/2 Study of OMP-59R5 in Combination with Etoposide and Platinum Therapy in Subjects with Untreated Extensive Stage Small Cell Lung Cancer) is testing tarextumab in combination with etoposide and cisplatin and etoposide and carboplatin in first-line extensive-stage small cell lung cancer patients. Tarextumab is part of OncoMed's collaboration with GlaxoSmithKline (GSK). GSK has an option to obtain an exclusive license to tarextumab during certain time periods through completion of the proof-of-concept Phase 2 trials.

About OncoMed Pharmaceuticals

OncoMed Pharmaceuticals is a clinical-stage company focused on discovering and developing novel anti-cancer stem cell and immuno-oncology therapeutics. OncoMed has seven anti-cancer product candidates in clinical development, including demcizumab (anti-DLL4, OMP-21M18), tarextumab (anti-Notch2/3, OMP-59R5), brontictuzumab (anti-Notch1, OMP-52M51), anti-DLL4/VEGF bispecific antibody (OMP-305B83), vantictumab (anti-FZD7, OMP-18R5), ipafricept (FZD8-Fc, OMP-54F28), and anti-RSPO3 (OMP-131R10), which each target key cancer stem cell signaling pathways including Notch, Wnt and R-spondin-LGR. OncoMed has formed strategic alliances with Celgene Corporation, Bayer Pharma AG and GlaxoSmithKline (GSK). OncoMed is advancing its wholly owned GITRL-Fc candidate and an undisclosed immuno-oncology candidate that is part of OncoMed's collaboration with Celgene (IO#2) toward clinical trials in the 2016-2017 timeframe.

Please see the company's website at www.oncomed.com for additional information.

Forward-Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding OncoMed Pharmaceuticals, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including OncoMed's expectations regarding the ALPINE clinical trial; and when OncoMed's GITRL-Fc candidate and IO#2 will advance to clinical trials. Such forward-looking statements involve substantial risks and uncertainties that could cause OncoMed's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the preclinical and clinical development process; OncoMed's dependence on its collaboration partners, including Celgene, GSK and Bayer, for the funding of its partnered programs; OncoMed's ability to raise additional capital to support the development of its unpartnered programs; OncoMed's reliance on third parties to conduct certain preclinical studies and all of its clinical trials; OncoMed's reliance on single source third-party contract manufacturing organizations to manufacture and supply its product candidates; and OncoMed's dependence on its Chairman and Chief Executive Officer, its Chief Scientific Officer, its Chief Medical Officer and other key executives. OncoMed undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to OncoMed's business in general, see OncoMed's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the Securities and Exchange Commission (SEC) on March 12, 2015, OncoMed's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2015, filed with the SEC on May 7, 2015, OncoMed's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015, filed with the SEC on August 10, 2015, and OncoMed's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2015, filed with the SEC on November 5, 2015.

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