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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): April 10, 2017

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 April 10, 2017, OncoMed Pharmaceuticals, Inc. (the "Company") issued a press release announcing top-line results from the Company's randomized Phase 2 "YOSEMITE" clinical trial of demcizumab (anti-DLL4, OMP-21M18) in combination with Abraxane ® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus gemcitabine in previously untreated patients with metastatic pancreatic cancer as well as a conference call/webcast to review these results (the "Demcizumab Press Release"). A copy of the Demcizumab Press Release is attached to this Current Report on Form 8-K as Exhibit 99.1. In the Demcizumab Press Release, the Company reported that the Phase 2 YOSEMITE trial did not meet the primary endpoint of progression-free survival and that the interim median overall survival analysis did not show a benefit for demcizumab in combination with Abraxane plus gemcitabine compared to the Abraxane, gemcitabine plus placebo arm in patients with first-line metastatic pancreatic cancer. The Company also reported that it will be discontinuing the Phase 2 YOSEMITE trial and will conduct additional analyses, together with its partner for demcizumab, Celgene Corporation, to understand the outcomes of the Phase 2 YOSEMITE trial. The Company further reported that it will also discontinue any additional enrollment in its other ongoing clinical trials of demcizumab and will conduct analyses of the data from those trials as planned.

Also on April 10, 2017, the Company issued a press release announcing that Bayer Pharma AG had notified the Company of its decision not to exercise its option to license vantictumab (anti-Fzd, OMP-18R5) and ipafricept (Fzd8-Fc, OMP-54F28) (the "Bayer Press Release"). A copy of the Bayer Press Release is attached to this Current Report on Form 8-K as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits .

Exhibit No.	Description
99.1	Press release dated April 10, 2017 entitled "OncoMed's Phase 2 Demcizumab Pancreatic Cancer Trial Misses Primary Endpoint"
99.2	Press release dated April 10, 2017 entitled "OncoMed Pharmaceuticals Announces Bayer Terminates its Option to License Vantictumab or Ipafricept"

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: April 10, 2017

ONCOMED PHARMACEUTICALS, INC.

By: /s/ Alicia J. Hager
Alicia J. Hager, J.D., Ph.D.
Senior Vice President and General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated April 10, 2017 entitled "OncoMed's Phase 2 Demcizumab Pancreatic Cancer Trial Misses Primary Endpoint"
99.2	Press release dated April 10, 2017 entitled "OncoMed Pharmaceuticals Announces Bayer Terminates its Option to License Vantictumab or Ipafricept"

Exhibit 99.1

FOR IMMEDIATE RELEASE

OncoMed's Phase 2 Demcizumab Pancreatic Cancer Trial Misses Primary Endpoint

OncoMed Management to Host Conference Call/Webcast
at 8:30 a.m. ET/5:30 a.m. PT to Review Top-line Results

REDWOOD CITY, Calif., April 10, 2017 – OncoMed Pharmaceuticals, Inc. (Nasdaq: OMED), a clinical-stage biopharmaceutical company focused on discovering and developing novel anti-cancer stem cell and immuno-oncology therapeutics, today reported top-line results from the company's Phase 2 YOSEMITE clinical trial of demcizumab (anti-DLL4, OMP-21M18) in combination with Abraxane ® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus gemcitabine in previously untreated patients with metastatic pancreatic cancer. The randomized Phase 2 "YOSEMITE" trial was designed to assess the efficacy and safety of demcizumab plus standard-of-care chemotherapy in first-line metastatic pancreatic cancer with the primary endpoint of progression-free survival and a secondary endpoint of overall survival. The trial did not meet the primary endpoint of progression-free survival. Additionally, the interim median overall survival analysis did not show a benefit for demcizumab in combination with Abraxane plus gemcitabine compared to the Abraxane, gemcitabine plus placebo arm in patients with first-line metastatic pancreatic cancer.

"Patients in all three arms of the Phase 2 YOSEMITE trial surpassed the published median overall survival rates for Abraxane plus gemcitabine in first-line metastatic pancreatic patients. While the interim median overall survival was 13.2 months in the pooled demcizumab arms, the interim median overall survival of Abraxane plus gemcitabine was not reached at the time of these analyses. Based on the lack of benefit over standard-of-care, which performed remarkably well, we will be discontinuing this trial. We will conduct additional analyses, together with our partner, Celgene, to understand these outcomes. We will also discontinue any additional enrollment in our other ongoing demcizumab trials and conduct analyses of the data from those trials as planned," said Paul J. Hastings, Chairman and CEO of OncoMed Pharmaceuticals. "OncoMed remains focused on completing and analyzing the results of the two randomized Phase 2 clinical trials, PINNACLE and DENALI, that are anticipated in the first half of this year and in continuing the advancement of our portfolio of biotherapeutic candidates."

OncoMed management will host a conference call today at 8:30 a.m. ET/5:30 a.m. PT to discuss the YOSEMITE clinical trial data.

Summary of Key Findings

- *Progression-Free Survival* : The median progression-free survival (mPFS) was essentially the same across all arms of the study. For patients receiving demcizumab (either one or two truncated courses) in combination with Abraxane plus gemcitabine the mPFS was 5.5 months compared to a mPFS of 5.5 months for those in the Abraxane, gemcitabine plus placebo group (HR=0.93). In addition, no significant differences were observed when the individual treatment arms were compared to the Abraxane, gemcitabine plus placebo arm: in patients receiving a single truncated course of demcizumab the mPFS was 5.4 months (HR=1.03), and the mPFS was 5.5 months (HR=0.83) in patients receiving two truncated courses of demcizumab.

- *Interim Overall Survival:* The interim median overall survival (mOS) for patients receiving either one or two truncated courses of demcizumab in combination with Abraxane plus gemcitabine (n =136) was 13.2 months, while a mOS was not reached for the Abraxane, gemcitabine plus placebo arm (HR=1.02). No significant differences were observed when the individual treatment arms were compared: an interim mOS of 10.6 months was observed with a single course of demcizumab (n=71) (HR=1.2) and an interim mOS of 13.3

months was seen among patients receiving two courses of demcizumab (n=65) (HR=0.87). These results are based on an analysis that occurred at the 125th PFS event at which time there were 75 deaths.

- *Response and Clinical Benefit Rates:* Overall response rate (defined as complete responses and partial responses) was 33.1% (45 of 136 patients) in the combined demcizumab, Abraxane plus gemcitabine groups and 41.2% (28 of 68 patients) in the Abraxane, gemcitabine plus placebo group. The overall clinical benefit rate (defined as complete responses, partial responses and stable disease) was slightly higher in the pooled demcizumab arms at 74.3% (101 of 136 patients) compared to 70.6% (48 of 68 patients) in the Abraxane, gemcitabine plus placebo group. Response was measured using the RECIST 1.1 criteria and is based on unconfirmed investigator assessment.

- *Safety and tolerability:* Demcizumab, Abraxane plus gemcitabine were generally well tolerated with nausea, diarrhea, anemia and fatigue being the most common reported toxicities. The incidence of Grade 3 or greater heart failure, pulmonary hypertension and bleeding were (3.7% vs. 0%), (0.7% vs 0%) and (8.1% vs. 1.5%) in the pooled demcizumab, Abraxane plus gemcitabine arms and the Abraxane, gemcitabine plus placebo arm, respectively.

“Pancreatic cancer has proven to be a uniquely challenging disease, and these data appear to reflect some of those disease and treatment complexities. The safety data seen in the YOSEMITE trial were generally consistent and in line with our expectations. We continue to analyze these data, and look forward to presenting the full study findings at a future scientific congress,” said Robert Stagg, PharmD, Senior Vice President of Clinical Research and Development. “We would like to sincerely thank the patients and their families, investigators and staff for their support and participation in this study.”

About the Phase 2 YOSEMITE Trial
The randomized Phase 2 “YOSEMITE” trial was designed to assess the efficacy and safety of demcizumab in combination with Abraxane plus gemcitabine, compared to Abraxane, gemcitabine plus placebo i n first-line pancreatic cancer patients with metastatic disease. Two-hundred and seven patients were randomized and 204 patients were treated in one of three study arms: 1) Abraxane, gemcitabine plus placebo, 2) Abraxane, gemcitabine plus one 70-day truncated course of demcizumab (given once every 2 weeks with the last dose given on Day 70) or 3) Abraxane, gemcitabine plus two 70-day truncated courses of demcizumab (separated by a 98 day period without demcizumab) with the last demcizumab dose given on day 238.

The primary endpoint of YOSEMITE was progression-free survival. Secondary and exploratory endpoints were overall survival, response rate, pharmacokinetics, immunogenicity, safety and biomarker analyses. The YOSEMITE Phase 2 trial was conducted at 49 clinical sites in the U.S., Canada, Europe and Australia. OncoMed initiated YOSEMITE in April 2015 and completed enrollment of patients in September 2016.

Conference Call Today
OncoMed management will host a conference call today beginning at 8:30 a.m. ET/5:30 a.m. PT to review top-line results from the Phase 2 YOSEMITE clinical trial.

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# 5625895. A webcast of the conference call will be accessible through a link in the Investor Relations section of the OncoMed website: http://www.oncomed.com . An audio replay of the conference call can be accessed by dialing 1-855-859-2056 (domestic) or 1-404-537-3406 utilizing the conference ID number listed above. The web broadcast of the conference call will be available for replay through 90 days via the OncoMed website.

About Pancreatic Cancer
Pancreatic cancer is the third leading cause of cancer-related deaths. According to the American Cancer Society, each year in the United States there are approximately 54,000 new cases of pancreatic cancer and 43,000 deaths. The majority of patients with pancreatic cancer are diagnosed after their cancer has spread locally and/or metastasized to distant organs. The average life expectancy after the diagnosis of metastatic pancreatic cancer is less than one year.

About Demcizumab

Demcizumab is a humanized monoclonal antibody targeting Delta-like Ligand 4 (DLL4), a key member of the Notch signaling pathway. Based on preclinical studies, demcizumab may have a multi-pronged mechanism of action: halting cancer stem cell growth and reducing cancer stem cell frequency, disrupting angiogenesis in the tumor and augmenting anti-tumor immune responses by decreasing tumor myeloid-derived suppressor cells (MDSCs).

Demcizumab is currently being studied in two randomized Phase 2 clinical trials. The YOSEMITE trial is testing demcizumab with Abraxane plus gemcitabine versus Abraxane plus gemcitabine alone in first-line advanced pancreatic cancer patients. The DENALI trial is testing demcizumab with pemetrexed and carboplatin versus pemetrexed and carboplatin alone in first-line advanced non-small cell lung cancer patients. A Phase 1b trial combining demcizumab with the anti-PD1 antibody pembrolizumab in solid tumor patients was also initiated in early 2016. Demcizumab is part of OncoMed's collaboration with Celgene Corporation.

About OncoMed Pharmaceuticals

OncoMed Pharmaceuticals is a clinical-stage biopharmaceutical company focused on discovering and developing novel anti-cancer stem cell and immuno-oncology therapeutics. OncoMed has internally discovered a broad pipeline of investigational drugs intended to address the fundamental biology driving cancer's growth, resistance, recurrence and metastasis. Demcizumab (anti-DLL4, OMP-21M18), navicixizumab (anti-DLL4/VEGF bispecific, OMP-305B83), rosmantuzumab (anti-RSPO3, OMP-131R10) and anti-TIGIT (OMP-313M32) are part of the company's strategic alliances with Celgene Corporation. Tarextumab (anti-Notch2/3, OMP-59R5) is in Phase 2 testing and is partnered with GlaxoSmithKline (GSK). OncoMed is independently developing vantictumab (anti-Fzd, OMP-18R5), ipafricept (Fzd8-Fc, OMP-54F28), brontictuzumab (anti-Notch1, OMP-52M51) and GITRL-Fc (OMP-336B11), as well as continuing to pursue new drug discovery research. For further information about OncoMed Pharmaceuticals, please see www.oncomed.com .

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, without limitation, OncoMed's intentions and expectations regarding the advancement of OncoMed's portfolio; the discontinuation of, or discontinuation of enrollment in, demcizumab clinical trials; future analyses of demcizumab clinical trials; the timing of additional Phase 2 readouts; and the presentation of additional study results. 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 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 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 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 filed with the U.S. Securities and Exchange Commission (SEC) on March 9, 2017 and OncoMed's other current and periodic reports filed with the SEC.

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# # #

Exhibit 99.2

OncoMed Pharmaceuticals Announces Bayer Terminates its Option to License Vantictumab or Ipafricept

OncoMed Retains Worldwide Rights to Both Wnt Pathway Programs

Redwood City, CA, – April 10, 2017 – OncoMed Pharmaceuticals, Inc. (XNAS: OMED), a clinical-stage biopharmaceutical company focused on discovering and developing novel anti-cancer stem cell and immuno-oncology therapeutics, announced today that Bayer Pharma has notified OncoMed of its decision not to exercise its option to license the first-in-class Wnt pathway inhibitors vantictumab (anti-Fzd, OMP-18R5) and ipafricept (Fzd8-Fc, OMP-54F28) for strategic reasons. Effective June 2017, OncoMed will retain worldwide development and commercialization rights to vantictumab, ipafricept and all other Wnt pathway biologics under the collaboration. The small molecule program under the companies' collaboration continues without change.

"Under our collaboration with Bayer, we have received over $90 million in upfront and milestone payments that have fully funded the development of vantictumab and ipafricept. While we had looked forward to collaborating with the Bayer team on the late-stage development of these biotherapeutics, we are very pleased to have worldwide rights to two promising Phase 2-ready assets," said Paul J. Hastings, Chairman and CEO of OncoMed. "We will be conducting an internal portfolio review and prioritization as we determine next steps for all our programs, including vantictumab and ipafricept.

Vantictumab and ipafricept are selective inhibitors of the Wnt pathway. In Phase 1a and Phase 1b clinical trials, vantictumab and ipafricept have each demonstrated safety and tolerability alone and in combination with standard-of-care chemotherapies in several solid tumors.. The company is completing two Phase 1b combination clinical trials of vantictumab – one in HER2-negative breast cancer (vantictumab + paclitaxel) and one in advanced pancreatic cancer (vantictumab + gemcitabine + Abraxane ®) – and two Phase 1b combination clinical trials of ipafricept – one in ovarian cancer (ipafricept + carboplatin + paclitaxel) and one in pancreatic cancer (ipafricept + gemcitabine + Abraxane ®). Interim data presented from each of these trials during the 2016 ASCO Annual Meeting and the ESMO 2016 Congress showed early indications of anti-tumor activity. In preclinical studies, OncoMed researchers have observed evidence of synergies when these Wnt inhibitor compounds are administered sequentially following the use of taxane-based chemotherapies. Published preclinical studies also point to the Wnt pathway as being a possible potentiator of immune response in tumors.

About OncoMed Pharmaceuticals

OncoMed Pharmaceuticals is a clinical-stage biopharmaceutical company focused on discovering and developing novel anti-cancer stem cell and immuno-oncology therapeutics. OncoMed has internally discovered a broad pipeline of investigational drugs intended to address the fundamental biology driving cancer's growth, resistance, recurrence and metastasis. Demcizumab (anti-DLL4, OMP-21M18), navicixizumab (anti-DLL4/VEGF bispecific, OMP-305B83), rosmantuzumab (anti-RSPO3, OMP-131R10) and anti-TIGIT (OMP-313M32) are part of the company's strategic alliance with Celgene Corporation. Tarextumab (anti-Notch2/3, OMP-59R5) is in Phase 2 testing and is partnered with GlaxoSmithKline (GSK). OncoMed is independently developing vantictumab (anti-Fzd, OMP-18R5), ipafricept (Fzd8-Fc, OMP-54F28), brontictuzumab (anti-Notch1, OMP-52M51) and GITRL-Fc (OMP-336B11), as well as continuing to pursue new drug discovery research. For further information about OncoMed Pharmaceuticals, please see www.oncomed.com .

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