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 5, 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 2.02. Results of Operations and Financial Condition.

On January 5, 2016, OncoMed Pharmaceuticals, Inc. (the "Company") announced selected financial data as of December 31, 2015. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is located on the Company's website at www.oncomed.com under "Investors – Press Releases."

The information in Item 2.02 of this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing, regardless of any general incorporation language in any such filing, unless the Company expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 7.01. Regulation FD.

The Company's management will present at the 34th Annual J.P. Morgan Healthcare Conference in San Francisco on Thursday, January 14, 2016 at 10:00 am PT/1:00 pm ET and provide an overview of the company and recent pipeline progress, selected financial data as of December 31, 2015 and milestones. A webcast of the presentation (audio only) will be accessible through a link in the Investor Relations section of the OncoMed website: http://www.oncomed.com. The webcast will also be recorded and available for replay on the OncoMed website for up to 45 days.

The information in Item 7.01 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing, regardless of any general incorporation language in any such filing, unless the Company expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 8.01. Other Events.

On January 5, 2016, the Company announced the achievement of the $70 million safety milestone (the "Safety Milestone") under its Master Research and Collaboration Agreement (the "Collaboration Agreement") with Celgene Corporation based on an analysis of available Phase 1b and blinded interim Phase 2 clinical trial safety data associated with the Company's demcizumab (anti-DLL4, OMP-21M18) program. The Company also announced the achievement of a $2.5 million milestone under the Collaboration Agreement for clinical candidate designation of an undisclosed preclinical immuno-oncology program (together with the Safety Milestone, the "Milestones"). Including the Milestones, the Company's pro forma cash balance as of December 31, 2015 was $227.2 million.

In addition, upon the achievement of the Safety Milestone, restricted stock unit awards (the "RSU Awards") held by certain officers and employees of the Company vested as to 25% of the shares of common stock thereunder (the "Shares"). Pursuant to sell-to-cover elections made at the time of the initial grants of the RSU Awards, such officers and employees are required to sell, as soon as practicable after the vesting of the Shares, a portion of the Shares to satisfy their tax withholding obligations.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release

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 5, 2016

ONCOMED PHARMACEUTICALS, INC.

By: /s/ Sunil Patel

Sunil Patel
Chief Financial Officer, Senior Vice President, Corporate Development and Finance

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release

Exhibit 99.1

For Immediate Release

OncoMed Achieves $72.5 Million in Milestone Payments from Celgene;
Announces Year-End Cash Balance

$70 Million Safety and $2.5 Million Clinical Candidate Designation Milestones Achieved

Enters 2016 with $227 Million in Pro-Forma Cash

REDWOOD CITY, Calif. – January 5, 2016 – OncoMed Pharmaceuticals Inc. (NASDAQ: OMED), today announced the achievement of two milestones from Celgene Corporation and pre-announced its 2015 year-end pro-forma cash balance and key anticipated events for 2016.

OncoMed achieved the $70 million safety milestone from Celgene based on an analysis of available Phase 1b and blinded interim Phase 2 clinical trial safety data associated with the demcizumab (anti-DLL4, OMP-21M18) program. The data from the pancreatic, non-small cell lung and ovarian cancer clinical trials showed no demcizumab-related Grade 3 or higher cardio-pulmonary toxicities among 155 patients treated with truncated dosing. Of those, 68 patients have received at least two cycles of demcizumab at the Phase 2 dose or higher and have been followed for at least 100 days. OncoMed also achieved a $2.5 million milestone for clinical candidate designation of an undisclosed preclinical immuno-oncology program, "IO#2". This is OncoMed's second immuno-oncology program to reach clinical candidate designation, and both programs are advancing in IND-enabling studies.

Including the Celgene milestones, OncoMed ended 2015 with approximately $227.2 million in pro-forma cash, representing approximately 1.5 years of cash, without taking into account future potential milestone payments from partners, and exceeding its 2015 guidance predicting a year-end cash balance of greater than $120 million. Full-year operating expenses for 2015 are anticipated to be approximately $110 million, in accordance with previous guidance. OncoMed plans to provide full-year 2016 guidance during its 2015 fourth quarter earnings call in the first quarter of 2016.

"The achievement of the demcizumab $70 million safety milestone is based on extensive Phase 1b and blinded Phase 2 data, and positions OncoMed to rapidly enroll its Phase 2 randomized YOSEMITE and DENALI clinical trials, as well as the Phase 1b demcizumab plus pembrolizumab (anti-PD1) trial, and also to explore the potential of demcizumab in ovarian cancer," said Paul J. Hastings, OncoMed's Chairman and Chief Executive Officer. "We enter 2016 in a strong cash position to support all seven internally discovered programs through clinical trials, including four randomized Phase 2 clinical studies, and to advance two immuno-oncology candidates toward IND filings while maintaining ongoing discovery efforts. Over the course of this year, we anticipate completing and reporting on our first randomized Phase 2 clinical trial, the tarextumab ALPINE study in pancreatic cancer, presenting additional data from our ongoing clinical- and discovery-stage programs, filing at least one new IND and achieving additional milestones related to our collaborations."

2016: Anticipated Key Financial Milestones and Pipeline Progress by Program

Demcizumab (anti-DLL4, OMP-21M18)

- Present updated Phase 1b survival data for demcizumab in combination with Abraxane ® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus gemcitabine in previously untreated pancreatic cancer at the Gastrointestinal Cancer Symposium (ASCO GI) being held January 21-23, 2016 in San Francisco, CA. OncoMed's presentation, titled "A Phase 1b study of the anti-cancer stem cell agent demcizumab (DEM) and gemcitabine (GEM) +/- nab-paclitaxel in patients with pancreatic cancer (Abstract 341)," will be presented by Dr. Manuel Hidalgo during Poster Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract on Friday, January 22, 2016.

- Initiate Phase 1b clinical trial of demcizumab plus anti-PD1 pembrolizumab in the first quarter of 2016.
- Update survival data from the demcizumab Phase 1b non-small cell lung cancer (NSCLC) clinical trial.
    - At the ASCO meeting in June 2015, OncoMed reported Phase 1b clinical trial data in NSCLC for 23 advanced-stage patients who received continuous dosing of demcizumab plus standard-of-care chemotherapy. These data showed that 43 percent (10 of 23) of patients were alive past two years, demonstrating prolonged survival in this subset of patients. A recent update of continuous dosing data revealed one additional death with 39 percent (9 of 23) of patients alive past 2 years.
    - In August, 2015, OncoMed updated survival data for 23 patients who received truncated doses of demcizumab plus chemotherapy and were showing a similar trend toward improved survival. At that time, fifty-two percent (12 of 23) of patients who received truncated doses of demcizumab plus carboplatin and pemetrexed remained alive from 8-30 months after initial dosing. A recent update of these data has revealed four additional deaths. Currently, 35 percent (8 of 23) of patients remain alive between 12 and 34 months after the initiation of treatment and median overall survival is 11.6 months. Although these data represent a Phase 1b clinical trial in small numbers of patients, they suggest that a subset of patients treated with the demcizumab truncated dosing regimen in NSCLC continues to derive long-term benefit. These data continue to support and enable the current randomized Phase 2 “DENALI” trial.
- Complete enrollment in the randomized Phase 2 “YOSEMITE” clinical trial of demcizumab in combination with Abraxane and gemcitabine in patients with first-line pancreatic cancer by year end. Data from this study are expected to be available by early 2017.
- Continue enrollment in the Phase 2 “DENALI” clinical trial of demcizumab plus carboplatin and pemetrexed in first-line non-squamous NSCLC.
- Report results from the ovarian cancer Phase 1b trial of demcizumab plus paclitaxel.

The next potential financial milestone for demcizumab is an opt-in payment from Celgene that may occur through the end of either of the Phase 2 pancreatic cancer or NSCLC trials. Following option exercise, OncoMed and Celgene will co-develop and co-commercialize demcizumab in the U.S., sharing profits 50/50, while Celgene would lead development and commercialization outside the U.S.

Tarextumab (anti-Notch 2/3, OMP-59R5)

- Present updated survival data from the Phase 1b clinical trial of tarextumab plus chemotherapy in small cell lung cancer at the time of the IASLC 16 th Annual Targeted Therapies of Lung Cancer Meeting being held February 17-21, 2016.
- Report top-line results from the Phase 2 “ALPINE” clinical trial of tarextumab in combination with Abraxane plus gemcitabine in advanced pancreatic cancer during the second half of 2016.

GlaxoSmithKline (GSK) may exercise the option for tarextumab through the end of either of the randomized Phase 2 clinical trials in pancreatic or small cell lung cancers. If GSK elects to exercise its option, OncoMed is eligible to receive a $25 million payment, and GSK would lead and fully fund further development and commercialization.

Wnt programs – Vantictumab (anti-Fzd7, OMP-18R5) and Ipafricept (Fzd8-Fc, OMP-54F28)

- Advance vantictumab and ipafricept through multiple ongoing Phase 1b clinical studies.

Bayer can elect to exercise its options on vantictumab and ipafricept at any point through completion of Phase 1b trials. OncoMed and Bayer amended their agreement November 2015 to enroll up to 24 additional subjects in the ongoing Phase 1b clinical trials of vantictumab in breast cancer and ipafricept in ovarian cancer. Bayer has agreed to reimburse OncoMed for all out-of-pocket expenses to support this additional patient enrollment. OncoMed anticipates presenting opt-in packages to Bayer for both vantictumab and ipafricept in late 2016/early 2017.

Brontictuzumab (anti-Notch1, OMP-52M51)

- Initiate Phase 1b clinical trial of brontictuzumab combined with FOLFIRI in colorectal cancer patients including an expansion cohort of biomarker-selected subjects based on promising data presented in November 2015 at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.

GSK may currently elect to opt in brontictuzumab at the end of Phase 1a, for a fee of $18.75 million or at the conclusion of Phase 2 for a fee of $25 million. GSK and OncoMed have agreed to share out-of-pocket costs on the Phase 1b clinical trial described above, and are currently discussing a potential extension of GSK's Phase 1a option through the end of Phase 1b.

Anti-DLL4/VEGF bispecific (OMP-305B83)

- Aim to present data from the Phase 1a dose-escalation clinical trial of anti-DLL4/VEGF bispecific. Presentation of data will be contingent on the number of dose cohorts needed to identify a Phase 2 single-agent dose and abstract acceptance at a scientific conference.

Through the conclusion of the Phase 1a and 1b clinical trials, Celgene may exercise its option to co-develop and co-commercialize anti-DLL4/VEGF bispecific.

Anti-RSPO3 (OMP-121R10)

- Initiate enrollment of Phase 1a biomarker-selected expansion cohort
- Aim to present Phase 1a data at an upcoming medical meeting in the second half of 2016, contingent upon dose-escalation and abstract acceptance.
- Initiate enrollment of Phase 1b component in the first-in-human trial of anti-RSPO3 in combination with FOLFIRI chemotherapy in subjects with colorectal cancer including biomarker-positive subjects.

As with the anti-DLL4/VEGF bispecific, Celgene may exercise its option to co-develop and co-commercialize anti-RSPO3 through the conclusion of the Phase 1 clinical trial.

Immuno-oncology Pipeline

- Advance either the immuno-oncology product candidate that is part of OncoMed's collaboration with Celgene (IO#2) or OncoMed's wholly owned GITRL-Fc program to an Investigational New Drug (IND) application filing by the end of 2016. Both programs are currently advancing in IND-enabling preclinical studies.

OncoMed estimates that over the course of the next two-to-three years (2016, 2017 and 2018), the company may be eligible to receive more than $168 million in potential opt-in payments from its collaboration with Celgene, $60 million in potential opt-in and milestone payments from Bayer and $43 million in potential opt-in payments from GSK. Overall, in future years, OncoMed is eligible for more than $5 billion in total potential milestone and option payments from its partners under its collaboration agreements with Celgene, Bayer, and GSK. To date, OncoMed has received over $450 million from its existing partners.

Reminder: OncoMed Chairman and CEO Paul J. Hastings will present at the 34 th Annual JP Morgan Healthcare Conference in San Francisco on Thursday, January 14, 2016 at 10:00 am Pacific Time. The presentation will be webcast live and available for replay from the OncoMed website in the Investor Relations section.

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 program (IO#2) that is part of OncoMed's collaboration with Celgene 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 its ability to advance and rapidly enroll its demcizumab clinical trials; the period during which cash will be available to fund OncoMed's operating expenses and capital expenditures; the timing of completion of, and the reporting of data from, the ALPINE clinical trial; the timing of when data will be reported from OncoMed's other clinical trials and programs, including the YOSEMITE clinical trial; the advancement of OncoMed's anti-RSPO3 and immuno-oncology programs, including the advancement of one immuno-oncology program to an IND filing in 2016; OncoMed's achievement of additional milestones related to its collaborations; the possibility of a subset of NSCLC patients treated with truncated dosing of demcizumab deriving long term benefit; initiation of a Phase 1b clinical trial for brontictuzumab; and the timing of OncoMed's presentation of opt-in data packages to Bayer. 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; OncoMed's ability to discover, develop and commercialize additional 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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