EDGAR pro
by EDGAR Online

ONCOMED PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 03/08/17 for the Period Ending 03/08/17

Address	800 CHESAPEAKE DRIVE REDWOOD CITY, CA 94063
Telephone	650-995-8200
CIK	0001302573
Symbol	OMED
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

Powered By EDGAR Online
http://www.edgar-online.com
© Copyright 2017, EDGAR Online, Inc. All Rights Reserved.
Distribution and use of this document restricted under EDGAR Online, Inc. Terms of Use.

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): March 8, 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 2.02. Results of Operations and Financial Condition.

On March 8, 2017, OncoMed Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2016. 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 Current Report on 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 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: March 8, 2017

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 Pharmaceuticals Announces Fourth Quarter and Full Year 2016 Financial Results

Demcizumab and Tarextumab Randomized Phase 2 Data Expected 1H 2017

Anti-TIGIT IND Accepted; GITRL-Fc IND Expected 1H 2017

OncoMed Management to Host Conference Call/Webcast this Afternoon at 4:30 p.m. ET/1:30 p.m. PT

REDWOOD CITY, Calif., March 8, 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 financial results for the fourth quarter and full year ended December 31, 2016. As of December 31, 2016, cash and short-term investments totaled $184.6 million.

“With eight OncoMed-discovered therapeutic candidates in the clinic, 14 ongoing clinical trials and active discovery efforts continuing, we are committed to discovering and developing novel drugs that will improve the lives of patients with cancer. 2017 is an important year for OncoMed. We expect to deliver data from a total of three randomized Phase 2 trials for demcizumab and tarextumab in the first half of the year,” said Paul J. Hastings, Chairman and Chief Executive Officer of OncoMed. “We are also making important progress for our immuno-oncology candidates and expect to dose patients with anti-TIGIT and file an IND for GITRL-Fc trimer in the first half of the year. Simultaneously, we continue development of multiple other therapeutic candidates.”

Recent Accomplishments

- Filed an Investigational New Drug (IND) application for anti-TIGIT (OMP-313M32) immuno-oncology antibody in December 2017 and received clearance to proceed from the U.S. Food and Drug Administration (FDA).

- Began enrollment of patients in two Phase 1b clinical trials of anti-DLL4/VEGF bispecific antibody (OMP-305B83), now known as navicixizumab, plus standard-of-care chemotherapy for the treatment of second-line colorectal and platinum-resistant ovarian cancers.

- Enrolled the first patient in a Phase 1b clinical trial of brontictuzumab (anti-Notch1, OMP-52M51) combined with trifluridine and tipiracil tablets (Lonsurf ®) in third-line colorectal cancer. T he trial will include enrollment of biomarker-positive patients whose tumors express the activated form of Notch1.

Financial Guidance and Potential Partner Opt-Ins

As stated in January 2017, OncoMed expects operating cash burn to be less than $100 million for the full year 2017. The company’s current cash is estimated to be sufficient to fund operations through the third quarter of 2018, without taking into account future potential milestone payments from partners.

In 2017, up to five clinical-stage programs, demcizumab (anti-DLL4, OMP-21M18) and anti-RSPO3 (OMP- 131R10) with Celgene, tarextumab (anti-Notch2/3, OMP- 59R5) with GlaxoSmithKline (GSK) and vantictumab (anti-Fzd, OMP-18R5) and ipafricept (FZD8-Fc, OMP-54F28) with Bayer, may be eligible for potential partner opt-ins worth more than $170 million in total.

Key Potential Upcoming Milestones and Events by Program

Demcizumab (anti-DLL4, OMP-21M18)

- Report top-line data, including median progression-free survival (mPFS), interim median overall survival (mOS) and response rate, in the first half of 2017 from the Phase 2 YOSEMITE clinical trial of demcizumab in combination with gemcitabine plus Abraxane ® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) in patients with first-line metastatic pancreatic cancer.

- Submit the demcizumab Phase 2 data package in the first half of 2017 to Celgene for opt-in consideration.
    - The Phase 2 YOSEMITE clinical trial data are expected to form the basis of the demcizumab data package. The data package will also include available data from the Phase 2 DENALI clinical trial of demcizumab plus carboplatin and pemetrexed in first-line non-small cell lung cancer (NSCLC), as well as interim safety and efficacy data from the ongoing Phase 1b clinical trial of demcizumab plus pembrolizumab (anti-PD1, Keytruda ®).
    - OncoMed would be entitled to a $70 million opt-in payment if Celgene exercises its option to co-develop and co-commercialize demcizumab. Following option exercise, OncoMed would be responsible for one-third of global development costs, while Celgene would be responsible for the remaining two-thirds, and OncoMed and Celgene would co-commercialize demcizumab in the U.S., sharing profits 50/50, while Celgene would lead development and commercialization outside the U.S. In addition, OncoMed would be eligible for potential future milestones of up to $651 million and ex-U.S. double-digit royalties.

- Complete enrollment in the Phase 1b demcizumab plus pembrolizumab clinical trial.

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

- Report top-line data, including mPFS, mOS, response rate and exploratory biomarkers, in the first half of 2017 from the Phase 2 PINNACLE clinical trial of tarextumab in combination with cisplatin/carboplatin and etoposide for the treatment of first-line small cell lung cancer (SCLC).

- Submit the tarextumab data package in the first half of 2017 to GSK for opt-in consideration.
    - If GSK exercises its option to obtain an exclusive license to tarextumab, OncoMed would be entitled to receive a $25 million opt-in payment, and would be eligible for potential future milestones of up to $294.5 million and worldwide royalties in the low double digits to high teens. Following exercise of its option, GSK would lead and fully fund further development and commercialization of tarextumab.

Vantictumab (anti-Fzd, OMP-18R5)

- Submit vantictumab data package to Bayer in the first half of 2017 for opt-in consideration. Bayer has until June 2017 to exercise its option on vantictumab.
    - If Bayer exercises its option to obtain an exclusive license to vantictumab, OncoMed would be entitled to receive a $25 million opt-in payment. Upon option exercise, Bayer would lead and fully fund further development and commercialization of vantictumab, and OncoMed would be eligible for potential future milestone payments of up to $332.5 million and worldwide royalties in the low double digits to high teens.

Ipafricept (Fzd8-Fc, OMP-54F28)

- Submit ipafricept data package to Bayer in the first half of 2017 for opt-in consideration. Bayer has until June 2017 to exercise its option on ipafricept.
    - If Bayer exercises its option to obtain an exclusive license to ipafricept, OncoMed would be entitled to receive a $15 million opt-in payment for ipafricept. Upon option exercise, Bayer would lead and fully fund further development and commercialization of ipafricept, and OncoMed would be eligible for potential future milestone payments of up to $332.5 million and worldwide royalties in the mid-single digits to low double digits.

Anti-RSPO3 (OMP-131R10)

- Continue enrollment in the anti-RSPO3 Phase 1a/1b clinical trial . Upon the achievement of certain enrollment objectives, OncoMed plans to submit a data package to Celgene for opt-in consideration.
    - If Celgene exercises its option on anti-RSPO3, OncoMed would be entitled to receive a payment of approximately $37.8 million, and the two companies would co-develop and co-commercialize anti-RSPO3 in the U.S., sharing profits 50/50, while Celgene would lead development and commercialization outside the U.S. Following option exercise, OncoMed would also be eligible for potential future milestones of up to $402.5 million and ex-U.S. royalties in the mid-single digits to mid-teens and would be responsible for one-third of global development costs, while Celgene would be responsible for the remaining two-thirds.

Immuno-Oncology Pipeline

- Initiate dosing of patients in the Phase 1 clinical trial of anti-TIGIT (OMP-313M32) in the first half of 2017.

- File an IND for OncoMed's wholly owned GITRL-Fc trimer (OMP-336B11) program in the first half of 2017.

Fourth Quarter and Full Year 2016 Financial Results

Cash and short-term investments totaled $184.6 million as of December 31, 2016, compared to $157.3 million as of December 31, 2015 and $207.6 million as of September 30, 2016. Full-year cash expenses for 2016 were $115 million, consistent with the company's 2016 guidance.

Revenues for the full year 2016 totaled $25.2 million, compared to $25.9 million in 2015. For the fourth quarter of 2016, revenue was $6.2 million, compared to $6.8 million for the fourth quarter of 2015. The decrease in revenue for the full year and fourth quarter were primarily attributable to a $2.5 million milestone for clinical candidate designation of anti-TIGIT recognized in 2015 and the achievement of a $70 million safety milestone for demcizumab received in the fourth quarter of 2015, which was recorded as deferred revenue and has been amortized over the performance period under our collaboration with Celgene.

Research and development (R&D) expenses for the full year 2016 were $109.7 million compared to $92.9 million in 2015. Increased expenditures in 2016 were primarily attributable to external manufacturing, clinical and toxicology study costs associated with the advancement of OncoMed's clinical-stage product candidates and preclinical pipeline.

R&D expenses were $24.2 million for the fourth quarter of 2016 compared with $26.7 million for the same period in 2015. Lower R&D expenditures during the fourth quarter 2016 were attributable to timing of production of materials used in the various clinical studies and a decrease in personnel-related costs.

General and administrative (G&A) expenses for the full year 2016 and 2015 were $18.8 million and $18.6 million, respectively. The increase in 2016 was associated with higher employee-related costs, including an increase in stock-based compensation expenses. The increased expenses were offset by a decrease in legal fees related to patent filings.

For the fourth quarter of 2016, G&A expenses were $4.4 million, compared to $5.0 million for the same period in 2015. Lower G&A expenses during the fourth quarter 2016 were attributable to lower personnel costs and decreased legal costs related to patent filings.

Net loss for the year ended December 31, 2016 was $103.1 million ($3.14 per share), compared to $85.4 million ($2.84 per share) for the year ended December 31. 2015. The change in year-over-year net loss was primarily due to increases in operational expenses and lower milestone revenue.

Net loss for the fourth quarter of 2016 was $22.3 million ($0.60 per share), compared to $24.8 million ($0.82 per share) for the same period of 2015. The change in net loss was primarily attributable to a decrease in R&D expenses.

Conference Call Today

OncoMed management will host a conference call today beginning at 4:30 p.m. ET/1:30 p.m. PT to review fourth quarter and year end 2016 financial results and recent progress.

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#80803820. 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 April 30, 2017 via the OncoMed website.

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), tarextumab (anti-Notch2/3, OMP-59R5), navicixizumab (anti-DLL4/VEGF bispecific, OMP-305B83), vantictumab (anti-FZD, OMP-18R5), ipafricept (FZD8-Fc, OMP-54F28), anti-RSPO3 (OMP-131R10) and anti-TIGIT (OMP-313M32) are part of the company's strategic alliances with Celgene Corporation, Bayer Pharma AG and GlaxoSmithKline (GSK). OncoMed is independently developing brontictuzumab (anti-Notch1, OMP-52M51) and GITRL-Fc (OMP-336B11), as well as continuing to pursue new drug discovery research efforts. For further information about OncoMed Pharmaceuticals, please see www.oncomed.com .

Forward-Looking Statement
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 period of time during which cash will be available to fund OncoMed's operations; OncoMed's operating cash burn for 2017; the timing of the availability and reporting of Phase 2 clinical trial data for demcizumab and tarextumab; the timing of delivery of opt-in data packages to OncoMed's partners, and the data to be included in those packages; OncoMed's ability to complete enrollment in the demcizumab plus pembrolizumab clinical trial and continue enrollment in the anti-RSPO3 clinical trial; OncoMed's ability to discover and develop novel drugs that will improve the lives of patients with cancer; OncoMed's progress with its immuno-oncology candidates, including dosing patients with anti-TIGIT and filing an Investigational New Drug (IND) application for GITRL-Fc; the timing of initiation of dosing with anti-TIGIT and submission of the GITRL-Fc IND; the eligibility of OncoMed's programs in 2017 for potential partner opt-ins and the potential outcomes of opt-in decisions by Oncomed's partners; and OncoMed's ability to receive opt-in payments and other milestones from its partners. 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 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 10, 2016, OncoMed's Quarterly Report on Form 10-Q filed with the SEC on November 1, 2016, and OncoMed's other current and periodic reports filed with the SEC.

Contact:
Michelle Corral
Senior Director, Investor Relations and Corporate Communications
OncoMed Pharmaceuticals
michelle.corral@oncomed.com
(650) 995-8373

ONCOMED PHARMACEUTICALS, INC.
Condensed Statements of Operations
(Unaudited)
(Amount in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	**2015**	**2016**	**2015**
Total revenue:	$ 6,219	$ 6,838	$ 25,153	$ 25,899
Operating expenses:				
Research and development	24,246	26,683	109,713	92,873
General and administrative	4,362	4,976	18,827	18,583
Total operating expenses	28,608	31,659	128,540	111,456
Loss from operations	(22,389)	(24,821)	(103,387)	(85,557)
Interest and other income (expense), net	53	27	299	170
Loss before income taxes	(22,336)	(24,794)	(103,088)	(85,387)
Income tax provision (benefit)	(2)	(15)	14	20
Net loss	$ (22,334)	$ (24,779)	$ (103,102)	$ (85,407)
Net loss per common share, basic and diluted	$ (0.60)	$ (0.82)	$ (3.14)	$ (2.84)
Shares used to compute net loss per common share, basic and diluted	37,100,709	30,108,765	32,859,554	30,028,684

ONCOMED PHARMACEUTICALS, INC.
Condensed Balance Sheets
(Unaudited)
(Amount in thousands)

	December 31, 2016	December 31, 2015
Cash and short-term investments	$ 184,573	$ 157,279
Prepaid and other assets	10,909	80,608
Total assets	$ 195,482	$ 237,887
Deferred revenue	$ 179,883	$ 201,155
Other liabilities	38,627	33,181
Stockholders' equity (deficit)	(23,028)	3,551
Total liabilities and stockholders' equity (deficit)	$ 195,482	$ 237,887

ONCOMED PHARMACEUTICALS, INC.
Reconciliation of Non-GAAP Financial Measures
(Unaudited)
(Amount in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	**2015**	**2016**	**2015**
Reconciliation of non-GAAP financial measures				
GAAP net loss	$ (22,334)	$ (24,779)	$ (103,102)	$ (85,407)
Adjustment:				
Stock-based compensation	2,363	3,451	11,131	10,766
Depreciation and amortization	436	427	1,764	1,643
Deferred rent adjustment	1,002	(171)	450	(679)
Deferred revenue	(5,303)	66,345	(21,272)	52,284
Non-GAAP net income (loss)	$ (23,836)	$ 45,273	$ (111,029)	$ (21,393)
GAAP net loss per share	$ (0.60)	$ (0.82)	$ (3.14)	$ (2.84)
Shares used to compute GAAP net loss per common share, basic and diluted	37,100,709	30,108,765	32,859,554	30,028,684
Non-GAAP net income (loss) per share	$ (0.64)	$ 1.50	$ (3.38)	$ (0.71)
Shares used to compute Non-GAAP net income (loss) per common share, basic and diluted	37,100,709	30,108,765	32,859,554	30,028,684

###