

# ONCOMED PHARMACEUTICALS INC

## **FORM 8-K** (Current report filing)

Filed 05/05/16 for the Period Ending 05/05/16

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

---

---

**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): May 5, 2016**

---

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

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-35993**  
(Commission  
File Number)

**38-3572512**  
(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 May 5, 2016, OncoMed Pharmaceuticals, Inc. (the “Company”) announced its financial results for the quarter ended March 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](http://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 .**

<u>Exhibit No.</u>	<u>Description</u>
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: May 5, 2016

ONCOMED PHARMACEUTICALS, INC.

By: /s/ Sunil Patel

Sunil Patel

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

---

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release



FOR IMMEDIATE RELEASE

**OncoMed Pharmaceuticals Announces  
First Quarter 2016 Financial Results**

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

*Highlights AACR Presentations – Including Novel GITRL-Fc Candidate*

*Clinical Data on Vantictumab, Ipafricept, Demcizumab and Tarextumab  
Accepted for Presentation at ASCO*

**REDWOOD CITY, Calif., May 5, 2016** – OncoMed Pharmaceuticals, Inc. (Nasdaq:OMED), a clinical-stage company developing novel anti-cancer stem cell (CSC) and immuno-oncology therapeutics, today reported first quarter financial results. The company also highlighted data presentations related to six oncology drug candidates, including robust preclinical anti-tumor activity data presented at the AACR Annual Meeting for its wholly owned GITRL-Fc candidate and upcoming presentations at the ASCO Annual Meeting from clinical trials of vantictumab, ipafricept, demcizumab and tarextumab. As of March 31, 2016, cash, cash equivalents and short-term investments totaled \$193.5 million.

“Recent highlights include the presentation of new and compelling data at the AACR Annual Meeting for our proprietary GITRL-Fc immuno-oncology therapeutic. We observed highly differentiated preclinical data including robust single-agent activity for GITRL-Fc compared to an alternate GITR agonist antibody strategy. We look forward to filing INDs on two distinct IO agents, GITRL-Fc and an undisclosed agent, termed ‘IO#2’, with the first of these IND filings by year-end.” said Paul J. Hastings, Chairman and Chief Executive Officer. “Looking ahead, we have a steady stream of data presentations planned, starting with several at the ASCO Annual Meeting for ongoing clinical trials, including new data from two of our Phase 1b combination studies for Wnt inhibitors vantictumab and ipafricept, as well as updated Phase 1b survival data for demcizumab in NSCLC.”

**Corporate Update and Recent Highlights**

- Initiated a Phase 1b clinical trial of demcizumab (anti-DLL4, OMP-21M18) plus anti-PD-1 (pembrolizumab) in solid tumor patients
- Presented five posters at the American Association of Cancer Research (AACR) Annual Meeting:
  - Preclinical data comparing efficacy and immune system activation of OncoMed’s wholly owned GITRL-Fc to GITR agonist antibodies and evaluating GITRL-Fc alone and in combination with anti-PDL1 and anti-PD1
  - Predictive biomarker assays for anti-RSPO3 (OMP-131R10) in solid tumors and vantictumab (anti-Fzd7, OMP-18R5) in pancreatic cancer
  - Preclinical data detailing anti-DLL4’s activity in non-small cell lung cancer, including immunomodulatory mechanism
- Announced acceptance of several clinical abstracts for presentation at the upcoming American Society of Clinical Oncology (ASCO) 2016 Annual Meeting being held June 3-7, 2016 in Chicago, IL. Presentations include:
  - The first clinical data from Phase 1b trials of the company’s Wnt pathway inhibitors, vantictumab and ipafricept (FZD8-Fc, OMP-54F28), in combination therapy in breast cancer and ovarian cancer, respectively
  - Updated survival data from OncoMed’s Phase 1b clinical trials of demcizumab (OMP-21M18, anti-DLL4) in non-small cell lung cancer (NSCLC) and of tarextumab (anti-Notch2/3, OMP-59R5) in small cell lung cancer

**First Quarter 2016 Financial Results**

**Cash**, cash equivalents and short-term investments totaled \$193.5 million as of March 31, 2016, compared to \$157.3 million as of December 31, 2015. During the quarter, OncoMed received a \$70 million payment from Celgene related to the demcizumab safety milestone achieved in the fourth quarter of 2015. This milestone was recorded as deferred revenue and will be amortized over the performance period.

**Revenues** for the first quarter 2016 totaled \$6.4 million, as compared to \$9.7 million in the first quarter of 2015. The decrease in revenue over the same period in 2015 was primarily due to achievement in 2015 of a \$5.0 million milestone from GlaxoSmithKline related to brontictuzumab, partially offset by increased amortization of revenue from Celgene related to the demcizumab safety milestone.

**Research and development (R&D) expenses** for the first quarter 2016 were \$28.4 million compared with \$19.4 million for the same period in 2015. Higher R&D expenditures during the first quarter 2016 compared to the first quarter of 2015 were attributable to increased Phase 2 costs for the demcizumab and tarextumab programs as well as IND-enabling manufacturing and toxicology costs for the GITRL-Fc and IO#2 programs.

**General and administrative (G&A) expenses** for the quarter ended March 31, 2016 were \$5.2 million, compared to \$4.8 million for the same period in 2015. Increased costs during the first quarter 2016 were due to higher employee-related costs including stock-based compensation expenses.

**Net loss** for the first quarter 2016 was \$27.2 million (\$0.90 per share), compared to \$14.5 million (\$0.49 per share) for the same period of 2015. The change in net loss from the prior year quarter was due to an increase in operational expenses, primarily research and development costs, and lower collaboration revenues.

### 2016 Financial Guidance

OncoMed reiterated financial guidance for the full year 2016. Based on its current plans and expectations, OncoMed anticipates:

- Cash expenses in the range of approximately \$110-\$120 million
- 2016 year-end cash balance of more than \$100 million, without taking into account potential future milestones or payments from partners
- Existing cash is anticipated to fund company operations through the first quarter of 2018, without taking into account potential future milestones or payments from partners

Potential milestone and opt-in payments from partners GSK, Bayer and Celgene over the course of 2016, 2017, and 2018 total over \$270 million.

### 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 first quarter 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# 3262691. 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 June 30, 2016 via the OncoMed website.

### 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 therapeutic 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 is advancing its wholly owned GITRL-Fc candidate and an undisclosed immuno-oncology candidate (IO#2) toward clinical trials in the 2016-2017 timeframe. OncoMed has formed strategic alliances with Celgene Corporation, Bayer Pharma AG and GlaxoSmithKline (GSK).

Additional information can be found at the company's website: [www.oncomed.com](http://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 OncoMed's expectations and guidance regarding projected expenses for 2016 and year-end cash for 2016; the period during which cash will be available to fund OncoMed's operating expenses and capital expenditures; the timing of when data from OncoMed's clinical trials will be available and presented; OncoMed's ability to achieve future milestones and opt-in payments from its partners, and the timing of those potential milestones and opt-in payments; and OncoMed's ability to advance its GITRL-Fc candidate and IO#2 candidate toward clinical trials in 2016/2017, including filing the first of the IND applications by the end of 2016. 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 Executive Vice President, Research and Development, 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, 2015, filed with the Securities and Exchange Commission (SEC) on March 10, 2016, and OncoMed's other 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	
	March 31,	
	2016	2015
Total revenue:	\$ 6,350	\$ 9,687
Operating expenses:		
Research and development	28,398	19,433
General and administrative	5,199	4,794
Total operating expenses	<u>33,597</u>	<u>24,227</u>
Loss from operations	(27,247)	(14,540)
Interest and other income, net	37	22
Loss before income taxes	(27,210)	(14,518)
Income tax provision	3	11
Net loss	<u>\$ (27,213)</u>	<u>\$ (14,529)</u>
Net loss per common share, basic and diluted	\$ (0.90)	\$ (0.49)
Shares used to compute net loss per common share, basic and diluted	30,221,634	29,908,307

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

	March 31, 2016	December 31, 2015
Cash, cash equivalents and short-term investments	\$ 193,503	\$ 157,279
Prepaid and other assets	35,505	80,608
Total assets	<u>\$ 204,930</u>	<u>\$ 237,887</u>
Deferred revenue	\$ 195,806	\$ 201,155
Other liabilities	28,935	33,181
Stockholders' equity (deficit)	(19,811)	3,551
Total liabilities and stockholders' equity	<u>\$ 204,930</u>	<u>\$ 237,887</u>