
**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 8, 2018

Infinity Pharmaceuticals, Inc.
(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction
of incorporation)

000-31141
(Commission
File Number)

33-0655706
(IRS Employer
Identification No.)

784 Memorial Drive, Cambridge, MA
(Address of principal executive offices)

02139
(Zip Code)

Registrant's telephone number, including area code: (617) 453-1000

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On May 8, 2018, we issued a press release announcing our results for the quarter ended March 31, 2018 and will conduct a previously announced, publicly available conference call to discuss those results. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information contained on the websites referenced in the press release is not incorporated herein.

This information and Exhibit 99.1 hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is included in this report:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated May 8, 2018

SIGNATURE

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

INFINITY PHARMACEUTICALS, INC.

Date: May 8, 2018

By: /s/ Seth A. Tasker
Seth A. Tasker
VP & General Counsel

www.infi.com

Infinity Pharmaceuticals Provides Company Update and First Quarter 2018 Financial Results

- Company to Present Data from Combination Dose Escalation Component of Study at American Society of Clinical Oncology Annual Meeting (ASCO) –
- Company Also to Provide an Update at ASCO on the Monotherapy Portion of the Trial and Initial Data from Combination Expansion Cohorts Initiated in Early 2018 –

Cambridge, Mass. – May 8, 2018 – Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) today announced its first quarter 2018 financial results and provided an update on the company, including its progress with IPI-549, a first-in-class oral immuno-oncology product candidate that selectively inhibits phosphoinositide-3-kinase-gamma (PI3K-gamma) and targets immune-suppressive tumor macrophages. Infinity is evaluating IPI-549 as a monotherapy and in combination with Opdivo® (nivolumab), a PD-1 immune checkpoint inhibitor, in a Phase 1/1b study in approximately 200 patients with advanced solid tumors.

“We continue to make important progress with IPI-549 and look forward to reporting clinical and translational data at the American Society of Clinical Oncology (ASCO) Annual Meeting in June from the combination dose escalation portion of the trial, in addition to providing an update on the monotherapy portion of the trial and initial data from combination expansion cohorts initiated in early 2018,” said Adelene Perkins, Chief Executive Officer and Chair of Infinity Pharmaceuticals. “We expect that these data will provide additional insights into the activity, durability, safety and mechanism of action of IPI-549, including in combination with nivolumab.”

Recent developments include the following:

IPI-549

- **Continued Progress with the Phase 1/1b Study:** The monotherapy portions of the study and combination dose escalation portion of the study have been completed. Enrollment, which began in 2018, is ongoing for six disease-specific combination expansion cohorts, along with a seventh combination expansion cohort of patients pre-selected for having high baseline blood levels of myeloid derived suppressor cells (MDSCs).

2018 Program Goals for IPI-549

- At ASCO report:
 - Data from the monotherapy expansion component of the study

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- Data from the combination dose-escalation component of the study
 - Initial data from six disease-specific combination expansion cohorts
 - Report more mature clinical and translational data (including insights from paired tumor biopsies) from the six disease-specific cohorts and initial data from the cohort of patients pre-selected for having high baseline blood levels of myeloid derived suppressor cells (MDSCs) in the combination expansion component of the study in the second half of 2018

First Quarter 2018 Financial Results

- At March 31, 2018, Infinity had total cash, cash equivalents and available-for-sale securities of \$47.8 million, compared to \$57.6 million at December 31, 2017.
- R&D expense for the first quarter of 2018 was \$5.9 million, compared to \$4.0 million for the same period in 2017. The increase in R&D expense was primarily due to higher clinical development expenses for IPI-549.
- General and administrative expense was \$3.6 million for the first quarter 2018, compared to \$6.4 million for the same period in 2017. The decrease in G&A expense was primarily due to a reduction in bonus and stock compensation.
- Net loss for the first quarter of 2018 was \$9.5 million, or a basic and diluted loss per common share of \$0.18, compared to a net loss of \$10.5 million, or a basic and diluted loss per common share of \$0.21 for the same period in 2017.

Financial Outlook

Infinity's 2018 financial guidance remains unchanged:

- **Net Loss:** Infinity expects net loss for 2018 to range from \$35 million to \$45 million.
- **Cash and Investments:** Infinity expects to end 2018 with a year-end cash, cash equivalents and available-for-sale securities balance ranging from \$15 million to \$25 million.
- **Cash Runway:** Based on its current operational plans, Infinity expects that its existing cash, cash equivalents and available-for-sale securities will be adequate to satisfy the company's capital needs into the third quarter of 2019. Infinity's financial guidance excludes additional funding or business development activities and does not include the potential \$22 million payment from Verastem upon the first regulatory approval of duvelisib, or a potential \$2 million payment from PellePharm, a private company, upon initiation of a Phase 3 study for the hedgehog inhibitor program, which Infinity licensed to PellePharm in 2013. Verastem announced that its New Drug Application for duvelisib was accepted by the U.S. Food and Drug Administration (FDA) and that it was given priority review with an FDA action date of October 5, 2018. With the potential Verastem payment, Infinity expects that its cash runway would extend into 2020.

Conference Call Information

Infinity will host a conference call today, May 8, 2018, at 4:30 p.m. ET to discuss these financial results and company updates. A live webcast of the conference call can be accessed in the “Investors/Media” section of Infinity’s website at www.infi.com. To participate in the conference call, please dial 1-877-316-5293 (domestic) or 1-631-291-4526 (international) five minutes prior to start time. The conference ID number is 2479309. An archived version of the webcast will be available on Infinity’s website for 30 days.

About IPI-549 and the Ongoing Phase 1/1b Study

IPI-549 is an investigational first-in-class, oral, immuno-oncology product candidate targeting tumor-associated myeloid cells through selective phosphoinositide-3-kinase-gamma (PI3K-gamma) inhibition, thereby reducing pro-tumor macrophage function and increasing anti-tumor macrophage function. In preclinical studies, IPI-549 demonstrated the ability to reprogram macrophages from a pro-tumor (M2), immune suppressive function, to an anti-tumor (M1) immune activating function and enhance the activity of, and overcome resistance to, checkpoint inhibitors.^{1, 2} As such, IPI-549 may have the potential to treat a broad range of solid tumors and represents a potentially additive or synergistic approach to restoring anti-tumor immunity in combination with other immunotherapies such as checkpoint inhibitors.

The ongoing Phase 1/1b study being conducted by Infinity is designed to evaluate the safety, tolerability, activity, pharmacokinetics and pharmacodynamics of IPI-549 as a monotherapy and in combination with Opdivo in approximately 200 patients with advanced solid tumors.³ The study includes monotherapy and combination dose-escalation components, in addition to monotherapy expansion and combination expansion components. The monotherapy dose-escalation and expansion components are complete. The combination dose-escalation component is also complete, and combination expansion cohorts are enrolling.

The combination expansion component of the study includes multiple cohorts designed to evaluate IPI-549 in patients with specific types of cancer, including patients with non-small cell lung cancer (NSCLC), melanoma and head and neck cancer whose tumors show initial resistance or initially respond to but subsequently develop resistance to immune checkpoint blockade therapy. The combination expansion component also includes a cohort of patients with triple negative breast cancer (TNBC) who have not been previously treated with immune checkpoint blockade therapy, a cohort of patients with mesothelioma, a cohort of patients with adrenocortical carcinoma and a cohort of patients with high baseline blood levels of MDSCs.

IPI-549 is an investigational compound and its safety and efficacy has not been evaluated by the U.S. Food and Drug Administration or any other health authority.

About Infinity

Infinity is an innovative biopharmaceutical company dedicated to advancing novel cancer treatments. Infinity is advancing IPI-549, a potentially transformative immuno-oncology approach that aims to reprogram tumor-associated macrophages by selectively inhibiting PI3K-gamma. A Phase 1/1b study in approximately 200 patients with advanced solid tumors is ongoing. For more information on Infinity, please refer to Infinity’s website at www.infi.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding: the therapeutic potential of PI3K-gamma selective inhibition and IPI-549, alone and in combination with checkpoint inhibitors, including Opdivo; clinical trial plans regarding IPI-549; plans to report clinical and translational data of IPI-549; 2018 financial guidance; and the company's ability to execute on its strategic plans. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the company's current expectations. For example, there can be no guarantee that IPI-549 will successfully complete necessary preclinical and clinical development phases or that Infinity will receive any of the benefits of its agreement with Verastem, Inc., including the receipt of milestone and royalty payments. Further, there can be no guarantee that any positive developments in Infinity's product portfolio will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: Infinity's results of clinical trials and preclinical studies; a failure of Infinity and/or Verastem to fully perform under the license agreement; the content and timing of decisions made by the U.S. FDA and other regulatory authorities; Infinity's ability to obtain and maintain requisite regulatory approvals and to enroll patients in its clinical trials; unplanned cash requirements and expenditures; development of agents by Infinity's competitors for diseases in which Infinity is currently developing or intends to develop IPI-549; and Infinity's ability to obtain, maintain and enforce patent and other intellectual property protection for IPI-549. These and other risks which may impact management's expectations are described in greater detail under the caption "Risk Factors" included in Infinity's quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 8, 2018, and other filings filed by Infinity with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Infinity expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

OPDIVO® is a registered trademark of Bristol-Myers Squibb.

INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	March 31, 2018	December 31, 2017
Cash, cash equivalents and available-for-sale securities	\$ 47,814	\$ 57,609
Other current assets	1,248	777
Property and equipment, net	156	219
Other long-term assets	748	748
Total assets	<u>\$ 49,966</u>	<u>\$ 59,353</u>
Note payable	\$ —	\$ 6,000
Other current liabilities	4,542	5,595
Long-term liabilities	27	28
Total stockholders' equity	<u>45,397</u>	<u>47,730</u>
Total liabilities and stockholders' equity	<u>\$ 49,966</u>	<u>\$ 59,353</u>

INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(*unaudited*)

	Three Months Ended March 31,	
	2018	2017
Operating expenses:		
Research and development	\$ 5,911	\$ 4,039
General and administrative	3,606	6,437
Total operating expenses	9,517	10,476
Loss from operations	(9,517)	(10,476)
Other income (expense):		
Investment and other income	159	303
Interest expense	(93)	(302)
Total other income	66	1
Net loss	\$ (9,451)	\$ (10,475)
Basic and diluted loss per common share:	\$ (0.18)	\$ (0.21)
Basic and diluted weighted average number of common shares outstanding:	51,883,570	50,423,353

Contact

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- ¹ Kaneda, M., Messer, K., Ralainirina, N., Li, H., et al. PI3K γ is a molecular switch that controls immune suppression. Nature, 2016 Nov;539:437–442.
- ² De Henau, O., Rausch, M., Winkler, D., Campesato, L., et al. Overcoming resistance to checkpoint blockade therapy by targeting PI3K γ in myeloid cells. Nature, 2016 Nov;539:443-447.
- ³ www.clinicaltrials.gov, NCT02637531.