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): August 7, 2018

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

Delaware	**000-31141**	**33-0655706**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

784 Memorial Drive, Cambridge, MA	**02139**
(Address of principal executive offices)	**(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 August 7, 2018, we issued a press release announcing our results for the quarter ended June 30, 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:

Exhibit No.	Description
99.1	Press release dated August 7, 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: August 7, 2018

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

www.infi.com

Infinity Pharmaceuticals Provides Company Update and Second Quarter 2018 Financial Results

–Dr. Samuel Agresta Appointed as Chief Medical Officer –
–More Mature Data from Combination Expansion Cohorts of the On-Going IPI-549 MARIO-1 Phase 1/1b Study Expected in the Second Half of 2018 –

Cambridge, Mass. – August 7, 2018 – Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) today announced its second 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/myeloid-derived suppressor cells (MDSCs).

"We are particularly pleased to welcome Sam Agresta to the Infinity team as Chief Medical Officer. Sam brings extensive experience in novel oncology drug development, having led the recent approvals of Agios's two targeted therapies based on compelling Phase 1 data," said Adelene Perkins, Chief Executive Officer and Chair of Infinity Pharmaceuticals. "We continue to be encouraged by our progress in all aspects of our business. Building on the datasets we presented at the recent American Society of Clinical Oncology (ASCO) Annual Meeting, including showing that IPI-549 was well-tolerated, clinically active and on-mechanism as a monotherapy and in combination with nivolumab, we look forward to presenting more mature data from the combination expansion cohorts in the second half of this year. We are also enthusiastic about partnering with Arcus and testing IPI-549 in combination with its very promising novel agents, in a new collaboration we established in June."

Infinity is evaluating IPI-549 as a monotherapy and in combination with Opdivo® (nivolumab), a PD-1 immune checkpoint inhibitor, in collaboration with Bristol-Myers Squibb, in the MARIO-1 Phase 1/1b study in approximately 200 patients with advanced solid tumors. In addition, Arcus Biosciences will initiate two triple combinations investigating IPI-549 with their dual adenosine receptor antagonist, AB928, anti-PD-1 antibody, AB122, and chemotherapy in triple negative breast cancer and ovarian cancer. One triple combination therapy will evaluate IPI-549 in combination with AB928 and AB122 and the second will evaluate IPI-549 in combination with AB928 and chemotherapy, with topline data expected in 2019.

Recent developments include the following:

IPI-549

- **Continued Progress with the MARIO-1 Phase 1/1b Study of IPI-549:** The monotherapy and combination dose-escalation portions of this study have been

completed. Enrollment is complete in the mesothelioma combination expansion cohort and is ongoing for the other five disease-specific combination expansion cohorts currently underway, as well as for the seventh combination expansion cohort of patients pre-selected for having high baseline blood levels of myeloid derived suppressor cells (MDSCs), which began enrolling patients in May 2018.

Second Quarter 2018 Financial Results

- At June 30, 2018, Infinity had total cash, cash equivalents and available-for-sale securities of $49.2 million, compared to $47.8 million at March 31, 2018.
- R&D expense for the second quarter of 2018 was $3.7 million, compared to $3.9 million for the same period in 2017. The decrease in R&D expense was primarily due to a reduction in bonus and stock compensation offset by an increase in clinical development expense for IPI-549.
- General and administrative expense was $3.4 million for the second quarter of 2018, compared to $6.2 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 second quarter of 2018 was $7.0 million, or a basic and diluted loss per common share of $0.12, compared to a net loss of $17.0 million, or a basic and diluted loss per common share of $0.34 for the same period in 2017.

Financial Outlook

Infinity's 2018 financial guidance is:

- **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 through 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, August 7, 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 8037589. 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 August 7, 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.

INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	June 30, 2018	December 31, 2017
Cash, cash equivalents and available-for-sale securities	$49,165	$ 57,609
Other current assets	1,273	777
Property and equipment, net	103	219
Other long-term assets	725	748
Total assets	$51,266	$ 59,353
Accounts payable and accrued expenses	$ 5,679	$ 5,595
Note payable	—	6,000
Long-term liabilities	31	28
Total stockholders' equity	45,556	47,730
Total liabilities and stockholders' equity	$51,266	$ 59,353

INFINITY PHARMACEUTICALS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 3,749	$ 3,901	$ 9,660	$ 7,940
General and administrative	3,386	6,205	6,992	12,642
Total operating expenses	7,135	10,106	16,652	20,582
Loss from operations	(7,135)	(10,106)	(16,652)	(20,582)
Other income (expense):				
Investment and other income	172	334	331	637
Interest expense	—	(300)	(93)	(602)
Other expense	—	(6,882)	—	(6,882)
Total other income (expense)	172	(6,848)	238	(6,847)
Net loss	$ (6,963)	$ (16,954)	$ (16,414)	$ (27,429)
Basic and diluted loss per common share	$ (0.12)	$ (0.34)	$ (0.30)	$ (0.54)
Basic and diluted weighted average number of common shares outstanding	55,966,910	50,455,832	53,936,520	50,439,682

Contact

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1 Kaneda, M., Messer, K., Ralainirina, N., Li, H., et al. PI3Kγ 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 PI3Kγ in myeloid cells. Nature, 2016 Nov;539:443-447.
3 www.clinicaltrials.gov, NCT02637531.