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 8, 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. ☐

Forward Looking Statements

This Form 8-K and the exhibit attached hereto contain forward-looking statements of Infinity Pharmaceuticals, Inc. ("Infinity" or the "Company") that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Form 8-K and the exhibit attached hereto, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: the Company's estimate regarding its cash balances for the year ended December 31, 2017 and other expectations regarding its business, plans, prospects and strategies. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes due to a number of important factors, including those Risk Factors discussed in Infinity's quarterly report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on November 7, 2017, and its other filings with the SEC. The forward-looking statements in this Form 8-K and the exhibit attached hereto represent the Company's views as of the date of this Form 8-K. The Company anticipates that subsequent events and development will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it has no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing the Company's views as of any date subsequent to the date of this Form 8-K.

Item 2.02 Results of Operations and Financial Condition.

Although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2017, the Company announced on January 8, 2018, that it expects to report that it had approximately $57.6 million in cash and investments (unaudited) as of December 31, 2017.

The information contained in Item 2.02 of this Form 8-K is unaudited and preliminary, and does not present all information necessary for an understanding of the Company's financial condition as of December 31, 2017 and its results of operations for the three months and year ended December 31, 2017. The audit of the Company's consolidated financial statements for the year ended December 31, 2017 is ongoing and could result in changes to the information set forth above.

The information in this Item 2.02 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On January 8, 2018, the Company issued a press release announcing its 2018 business goals and financial guidance. The full text of this press release is filed 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.

Item 9.01 Financial Statements and Exhibits.

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

Exhibit No.	Description
99.1	Press Release dated January 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: January 8, 2018

By: /s/ Seth A. Tasker
Seth A. Tasker
Vice President, General Counsel

Exhibit 99.1

www.infi.com

Infinity Provides Update on IPI-549 Phase 1/1b Study, 2018 Goals and Financial Guidance

– Monotherapy Expansion Fully Enrolled –

– Combination Dose Escalation Completed, and Six Combination Expansion Cohorts Initiated –

– Adding Seventh Combination Expansion Cohort of IPI-549 with Opdivo® to Include Cancer Patients with High Baseline Levels of Myeloid Derived Suppressor Cells –

– Clinical and Translational Data from Monotherapy Expansion, Combination Dose Escalation and Combination Expansion Anticipated Throughout 2018 –

– Company to Present at 36th Annual J.P. Morgan Healthcare Conference on January 11 at 9:30 a.m. PST (12:30 p.m. EST) –

CAMBRIDGE, MA., January 8, 2018 – Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) today announced the achievement of four development milestones for IPI-549, a 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. First, the Phase1/1b monotherapy expansion component of the study has been fully enrolled. Second, the combination dose escalation component of the study has been completed. Third, six disease-specific combination expansion cohorts are open to enrollment at the recommended phase 2 dose of 40mg daily of IPI-549 plus Opdivo® (nivolumab) at 240 mg every two weeks in patients with non-small cell lung cancer, melanoma, triple negative breast cancer, head and neck cancer, mesothelioma, and adrenocortical carcinoma. Fourth, the company announced today the expansion of its Phase 1/1b clinical trial of IPI-549 to include a combination cohort of IPI-549 plus Opdivo that will enroll patients with high baseline levels of myeloid derived suppressor cells (MDSCs). Studies have shown that poor response to checkpoint inhibitor therapy is correlated with the presence of high baseline levels of MDSCs in cancer patients.[1] [2] [3] In addition, preliminary translational data from Infinity's Phase 1/1b study demonstrated an association between high baseline levels of MDSCs and clinical responses. Enriching for patients with high MDSCs could lead to improved clinical activity for patients treated with the combination of IPI-549 and anti-PD1. Infinity expects to begin enrolling this combination expansion cohort in patients with high baseline levels of MDSCs in the first quarter of 2018.

Infinity also provided financial guidance for 2018 and outlined anticipated 2018 milestones for the development of IPI-549. During the year, the company expects to make substantial progress with the Phase 1/1b clinical study of IPI-549, which is designed to evaluate IPI-549 both as a monotherapy and in combination with Opdivo. Infinity plans to report data from the monotherapy expansion and combination dose escalation components and initial data from the combination expansion component of the Phase 1/1b study of IPI-549 with Opdivo in the second quarter of 2018. In the second half of 2018, Infinity expects to report more mature clinical data from the combination expansion component of the study including translational insights from paired tumor biopsies across multiple diseases.

“2018 will be a decisive year for both Infinity and IPI-549, as we look forward to reporting maturing data from the Phase 1/1b trial both in monotherapy and in combination with Opdivo at several medical meetings throughout the year, which will help to define our development and regulatory strategy for this first-in-class product candidate,” stated Adelene Perkins, Infinity’s chair and chief executive officer. “IPI-549 represents a unique approach to targeting tumors through its effects on myeloid cells within the tumor microenvironment, and we are very pleased with the data to date. There is a significant need for better treatment options for patients, especially for patients who do not respond to, or develop resistance to, existing immunotherapies, as well as for types of cancer where there is limited benefit from treatment with checkpoint inhibitors. We look forward to presenting updates throughout 2018 from our Phase 1/1b clinical trial.”

“As the majority of patients treated with IPI-549 monotherapy have advanced forms of cancer and received several therapies prior to enrollment in this study, it’s very encouraging to see single-agent activity, including a patient with a partial response who has remained on treatment for over a year and continues on study today,” said Dr. David Hong from MD Anderson Cancer Center, Deputy Chair of the Department of Investigational Cancer Therapeutic. “IPI-549 has also been well tolerated with a favorable safety profile.”

Infinity’s chair and chief executive officer, Adelene Perkins, will discuss the company’s continued execution on its corporate strategy and 2018 priorities as part of a podium presentation at the 36th Annual J.P. Morgan Healthcare Conference on Thursday, January 11, at 9:30 a.m. PST (12:30 p.m. EST). The presentation will be webcast on Infinity’s website, www.infi.com.

Anticipated Milestones in 2018

During 2018, Infinity expects to achieve the following IPI-549 data milestones:

- Report data from the monotherapy expansion component of the study in the second quarter of 2018
- Report data from the combination dose-escalation component of the study in the second quarter of 2018

- Report initial data from the combination expansion component of the study in the second quarter of 2018
- Report additional data from the combination expansion component, with more mature clinical and translational data, including insights from paired tumor biopsies, in the second half of 2018

2018 Financial Guidance

Infinity ended 2017 with approximately $57.6 million in cash and investments (unaudited) and plans to report its fourth quarter and full-year 2017 financial results in March. The company is providing the following financial guidance today:

- **Net Loss:** Infinity expects net loss for 2018 to range from $40 million to $50 million.
- **Cash and Investments:** Infinity expects to end 2018 with a year-end cash and investments balance ranging from $10 million to $20 million.
- Based on its current operational plans, Infinity expects that its existing cash, cash equivalents and available-for-sale securities at December 31, 2017, will be adequate to satisfy the company's capital needs into the first 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. Verastem has provided its expectation that it plans to submit a New Drug Application to the U.S. Food and Drug Administration for duvelisib in the first quarter of 2018.

About IPI-549

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 reprograms macrophages from a pro-tumor (M2), immune suppressive function, to an anti-tumor (M1) immune activating function and can enhance the activity of, and overcome resistance to, checkpoint inhibitors.[4] [5] 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.[6] The four-component study includes monotherapy and combination dose-escalation components, in addition to monotherapy expansion and combination expansion components. The monotherapy dose-escalation component is complete and the monotherapy expansion component has been fully enrolled. The combination dose-escalation component is also complete, and combination expansion cohorts are open to enrollment.

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 squamous cell carcinoma (HNSCC) 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 levels of MDSCs.

IPI-549 is an investigational compound, and its safety and efficacy have 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 medicines for people with cancer. Infinity is advancing IPI-549, an oral immuno-oncology development candidate that selectively inhibits 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 preclinical, clinical and translational data of IPI-549; unaudited year-end 2017 cash and investments balance, 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 clinical development phases or that Infinity will receive any of the benefits of the agreement with Verastem including the receipt of milestone and royalty payments. Further, there can be no guarantee that any positive developments in Infinity's product portfolio or any strategic options Infinity may pursue 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, including subsequent analysis of existing data and new data received from ongoing and future studies; 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 November 7, 2017, 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.

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1 Kitano et al. Myeloid Derived Suppressor Cell Quantity Prior to Treatment with Ipilimumab at 10mg/kg Predicts for Improved Overall Survival in Patients with Metastatic Melanoma. ASCO annual meeting #2518, 2013

2 Postow et al. Immunologic Correlates of the Abscopal Effect in a Patient with Melanoma. NEJM 2012, 366;10.

3 Kitano et al. Computational Algorithm-Driven Evaluation of Monocytic Myeloid-Derived Suppressor Cell Frequency For Prediction of Clinical Outcomes. Cancer Immunol Res. 2014, 2(8): 812

4 Kaneda, M., Messer, K., Ralainirina, N., Li, H., et al. PI3KÎ³ is a molecular switch that controls immune suppression. Nature, 2016 Nov;539:437–442.

5 De Henau, O., Rausch, M., Winkler, D., Campesato, L., et al. Overcoming resistance to checkpoint blockade therapy by targeting PI3KÎ³ in myeloid cells. Nature, 2016 Nov;539:443-447.

6 www.clinicaltrials.gov, NCT02637531.