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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 7, 2019**

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**Infinity Pharmaceuticals, Inc.**

(Exact name of registrant as specified in charter)

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**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**

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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.

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## **Forward Looking Statements**

This Form 8-K and the exhibits 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, 2018 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 5, 2018, 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, 2018, the Company announced on January 7, 2019 that it expects to report that it had approximately \$58.6 million in cash and investments (unaudited) as of December 31, 2018.

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, 2018 and its results of operations for the three months and year ended December 31, 2018. The audit of the Company’s consolidated financial statements for the year ended December 31, 2018 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 7, 2019, the Company issued a press release announcing its 2019 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:

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	<a href="#">Press Release dated January 7, 2019</a>

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**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 7, 2019

By: /s/ Seth A. Tasker

Seth A. Tasker

Vice President, General Counsel



[www.infi.com](http://www.infi.com)

**Infinity Pharmaceuticals Provides 2019 Goals and Financial Guidance**

**-IPI-549 Safety and Clinical Activity Support Initiation of Studies in Earlier Lines of Cancer Therapy with Double and Triple Combination Regimens-**

*-MARIO-275: Global, Randomized Study of IPI-549 and Opdivo in I/O Naïve Urothelial Cancer-*

*-Phase 1b Study of Novel Triple Combination Therapy in Advanced TNBC with Arcus-*

*-Phase 1b Study of IPI-549 Combination in Front-Line Advanced Cancer-*

**- Company to Present at 37<sup>th</sup> Annual J.P. Morgan Healthcare Conference on January 10<sup>th</sup> at 9:30 a.m. PT (12:30 p.m. ET) –**

**Cambridge, MA – January 7, 2019** – Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) today announced anticipated 2019 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 and provided financial guidance for 2019.

“In the year ahead, we are excited to be moving into earlier lines of therapy, new indications, and novel, potentially transformative immuno-oncology combinations to execute on our strategy to expand the depth and breadth of the development of IPI-549,” said Adelene Perkins, Chief Executive Officer of Infinity Pharmaceuticals. “Importantly, we have a cash runway into the second half of 2020, which enables us to advance IPI-549 development in several innovative studies in 2019. We also have the support of tremendous collaborators BMS and Arcus for two of these potentially transformative studies.”

“The IPI-549 safety and clinical activity from the MARIO-1 Phase 1b study continues to inform our strategy to expand the depth and breadth of IPI-549 development for cancer patients,” said Dr. Sam Agresta, Chief Medical Officer of Infinity. “MARIO-275 is our first global, randomized study of IPI-549 in combination with Opdivo compared to Opdivo monotherapy. This study, in collaboration with BMS, is designed to address an unmet medical need for patients with advanced urothelial cancer and is an important step in advancing IPI-549 development beyond the checkpoint inhibitor refractory setting. In addition, the safety, clinical activity and mechanism of action of IPI-549 allows us to expand the breadth of the program by moving into novel combinations, including in previously treated, advanced triple negative breast cancer patients, with a novel triple therapy study in collaboration with Arcus. And I am particularly excited to initiate our first IPI-549 study in the front-line setting in 2019.”

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Infinity plans to initiate MARIO-275, a combination study of IPI-549 with Opdivo® in I/O naïve urothelial cancer (UC) patients, in the first half of 2019. Opdivo was approved for use by the FDA as a single agent in advanced urothelial cancer based on durable response associated with treatment in CheckMate-275, a Phase 2 single arm clinical trial of Opdivo in subjects with metastatic or unresectable urothelial cancer who have progressed or recurred following treatment with a platinum agent<sup>1</sup>. Retrospective analyses of this study showed that patients with higher levels of myeloid derived suppressor cells, or MDSCs, had poor outcomes<sup>2</sup>. IPI-549 has been shown to reduce MDSCs as both a monotherapy and in combination with Opdivo in MARIO-13-6. MARIO-275 is intended to evaluate the benefit of adding IPI-549 to Opdivo in cisplatin-refractory, I/O-naïve urothelial cancer patients. Clinical benefit will be assessed in the overall population as well as in subsets of patients with different baseline levels of MDSCs.

Infinity will also be advancing novel triple combination therapies with Arcus, initially evaluating IPI-549 in combination with AB928, Arcus's dual adenosine receptor antagonist, and chemotherapy in patients with previously treated, advanced triple negative breast cancer, or TNBC. As both macrophages and high adenosine levels are believed to play critical roles in creating a highly immune-suppressive tumor microenvironment in cancer after chemotherapy, the novel immuno-oncology combination being evaluated in this setting represent a potentially promising approach to treating TNBC.

Infinity's chair and chief executive officer, Adelene Perkins, will discuss the company's continued execution on its corporate strategy and 2019 priorities as part of a podium presentation at the 37th Annual J.P. Morgan Healthcare Conference on Thursday, January 10, at 9:30 a.m. PST (12:30 p.m. EST). The presentation will be webcast live on Infinity's website, [www.infi.com](http://www.infi.com), and an archived version of the webcast will be available on Infinity's website for 30 days.

### **Anticipated Milestones in 2019: Expanding Depth and Breadth of IPI-549 Development**

#### **1H2019**

- Advance into Immuno-Oncology (I/O) Naïve Indications in Combination with Opdivo: Initiate MARIO-275 in I/O naïve UC patients with BMS
- Advance into Novel Triple Combinations Beyond CPIs: Initiate Triple Therapy Combination (IPI-549+AB928+Chemo) in previously treated advanced TNBC with Arcus

#### **2H2019**

- Initiate the first IPI-549 combination study in front-line advanced cancer patients
- Complete enrollment of MARIO-1 seven combination expansion cohorts including:
  - o Augmented melanoma expansion cohort (n=40)
  - o TNBC expansion cohort (n=29)

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## 2019 Financial Guidance

Infinity ended 2018 with approximately \$58.6 million in cash and investments (unaudited) and plans to report its fourth quarter and full-year 2018 financial results in March. The company is providing the following financial guidance today:

- Net loss: \$30 million to \$40 million
- Year-end cash: \$20 million to \$30 million
- Cash runway: Into 2H 2020

Infinity's 2019 financial guidance is based on its current operating plans, excludes additional financing or business development activities, and includes a \$2 million milestone 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.

*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](http://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, adenosine receptor antagonists, including AB928, and chemotherapies; timing of company presentations; clinical trial plans regarding IPI-549; 2019 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. 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; 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

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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 5, 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.

**Contact:**

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<sup>1</sup> <https://www.fda.gov/drugs/informationondrugs/approveddrugs/ucm539646.htm>

<sup>2</sup> Sharma et al. AACR Annual Meeting 2018

<sup>3</sup> [www.clinicaltrials.gov](http://www.clinicaltrials.gov), NCT02637531.

<sup>4</sup> Hong et al, SITC 2017

<sup>5</sup> Sullivan et al., ASCO 2018

<sup>6</sup> Chmielowski et al, SITC 2018

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