
**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 7, 2019

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, \$0.001 par value	INFI	Nasdaq Global Select Market

Item 2.02. Results of Operations and Financial Condition.

On May 7, 2019, we issued a press release announcing our results for the quarter ended March 31, 2019 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 7, 2019

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 7, 2019

By: /s/ Seth A. Tasker

Seth A. Tasker
VP & General Counsel

www.infi.com

Infinity Pharmaceuticals Provides Company Update and First Quarter 2019 Financial Results

— **MARIO-275 Phase 2 Study in I/O Naïve Urothelial Cancer Patients on Track to Initiate in 2Q19** —

— **MARIO-3 Phase 2 Study in Front-Line Triple Negative Breast Cancer and Renal Cell Cancer Patients on Track to Initiate in 3Q19** —

— **Infinity Received Net Proceeds of \$22.9M in Non-Dilutive Capital from the Monetization of Copiktra™ Royalties and a Phase 3 Milestone from PellePharm** —

CAMBRIDGE, Mass., May 7, 2019 /PRNewswire/ — Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) today announced its first quarter 2019 financial results and provided an update on the company, including its progress in expanding the breadth and depth of the development of IPI-549 in over 500 patients. IPI-549 is a first-in-class oral immuno-oncology product candidate that targets immune-suppressive tumor-associated myeloid cells through selective phosphoinositide-3-kinase-gamma (PI3K-gamma) inhibition. In the first quarter of 2019, Infinity entered into a clinical collaboration with Roche/Genentech moving into front-line triple negative breast cancer (TNBC) and renal cell cancer (RCC) with MARIO-3. In the first quarter of 2019, Infinity also closed the Copiktra royalty monetization for \$20.9M in net proceeds and earned a \$2M milestone from PellePharm, providing non-dilutive capital to fund the expanded development of IPI-549, including MARIO-3.

“Shareholder value creation will be driven by the generation of compelling clinical data with IPI-549, funded with dilution-sensitive capital, and we are pleased to have made important progress on both of these fronts in the first quarter of this year. We continue to advance IPI-549 and remain focused on achieving our key clinical milestones for 2019,” said Adelene Perkins, Chief Executive Officer and Chair of Infinity Pharmaceuticals. “We are studying IPI-549 in earlier lines of therapy, new indications and novel, potentially transformative immuno-oncology combinations in 2019.”

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

2Q2019

- Initiate MARIO-275, a Phase 2 study of IPI-549 in combination with Opdivo[®], in second-line immuno-oncology (I/O) naïve urothelial cancer patients, in collaboration with BMS

2H2019

- Initiate MARIO-3, a Phase 2 study of novel triple combination front-line therapy, in clinical collaboration with Roche/Genentech:
 - IPI-549 in combination with Tecentriq[®] and Abraxane[®] in TNBC
 - IPI-549 in combination with Tecentriq and Avastin[®] in RCC
- Complete enrollment of MARIO-1 combination expansion cohorts including:
 - Augmented melanoma expansion cohort (n=40)
 - TNBC expansion cohort (n=29)
- Advance into novel triple combination therapies beyond checkpoint inhibitors: initiate triple therapy (IPI-549+AB928+Abraxane) in previously treated advanced TNBC in collaboration with Arcus Biosciences

First Quarter 2019 Financial Results

- At March 31, 2019, Infinity had total cash, cash equivalents and available-for-sale securities of \$70.5 million, compared to \$58.6 million at December 31, 2018.
- Infinity recognized the \$30 million gross proceeds from the Copiktra royalty monetization as a liability, net of transaction costs, as of March 31, 2019. We are amortizing the liability to non-cash interest expense, and we will continue to recognize the royalty revenue that Verastem pays to HealthCare Royalty Partners III, L.P. (HCR) as non-cash royalty revenue. We shared 25% of the proceeds, net of expenses, under the HCR agreement with Takeda. In addition, we will pay to Takeda 25% of royalties that, but for the HCR agreement, would have been payable to us by Verastem during the term of the HCR agreement.
- Revenue during the first quarter of 2019 was \$2.1 million, which primarily relates to the achievement of a \$2.0 million milestone from PellePharm for the initiation of a Phase 3 study investigating patidegib (a hedgehog pathway inhibitor) in patients with Gorlin Syndrome. We did not have any revenue for the same period in 2018.
- R&D expense for the first quarter of 2019 was \$5.8 million, compared to \$5.9 million for the same period in 2018.

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- General and administrative expense was \$3.4 million for the first quarter 2019, compared to \$3.6 million for the same period in 2018.
 - Royalty expense for the first quarter of 2019 was \$6.8 million, which primarily relates to our payment to Takeda in relation to the monetization of Copiktra royalties.
 - Net loss for the first quarter of 2019 was \$13.7 million, or a basic and diluted loss per common share of \$0.24, compared to a net loss of \$9.5 million, or a basic and diluted loss per common share of \$0.18 for the same period in 2018.

2019 Updated Financial Guidance

- **Net Loss:** Infinity expects net loss for 2019 to range from \$40 million to \$50 million including the Copiktra royalty monetization.
- **Cash and Investments:** Infinity expects to end 2019 with a year-end cash, cash equivalents and available-for-sale securities balance ranging from \$40 million to \$50 million including the Copiktra royalty monetization.
- **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 2H 2020. Infinity's financial guidance excludes additional funding or business development activities and excludes the potential monetization of future milestones and/or royalties payments from PellePharm, a private company, to whom Infinity licensed patidegib in 2013.

Conference Call Information

Infinity will host a conference call today, May 7, 2019, 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) and 1-631-291-4526 (international) five minutes prior to start time. The conference ID number is 5779562. An archived version of the webcast will be available on Infinity's website for 30 days.

About Infinity and IPI-549

Infinity is an innovative biopharmaceutical company dedicated to advancing novel medicines for people with cancer. Infinity is advancing IPI-549, a first-in-class, oral immuno-oncology development candidate that selectively inhibits PI3K-gamma, in multiple clinical studies. MARIO-1 is an ongoing Phase 1/1b study evaluating IPI-549 as a monotherapy and in combination with Opdivo (nivolumab) in approximately 220 patients with advanced solid tumors including patients refractory to anti-PD-1 therapy. Infinity intends to initiate MARIO-275, a global, randomized, combination study of IPI-549 combined with Opdivo in I/O naïve urothelial

cancer patients in 2Q19, as well as to initiate MARIO-3, the first IPI-549 combination study in front-line advanced cancer patients in 2H19. MARIO-3 will evaluate IPI-549 in combination with Tecentriq and Abraxane in front-line TNBC and in combination with Tecentriq and Avastin in front-line RCC. With the addition of MARIO-275 and MARIO-3 to the ongoing MARIO-1 study, Infinity will be evaluating IPI-549 in the anti-PD-1 refractory, I/O-naïve and front-line settings in a total of ~500 patients. 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 other cancer therapies; clinical trial plans and progress; 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; 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 7, 2019, 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)

	<u>March 31, 2019</u>	<u>December 31, 2018</u>
Cash, cash equivalents and available-for-sale securities	\$ 70,531	\$ 58,591
Other current assets	3,641	1,227
Property and equipment, net	51	28
Other long-term assets	522	369
Total assets	<u>\$ 74,745</u>	<u>\$ 60,215</u>
Current liabilities	\$ 7,459	\$ 7,718
Liability related to sale of future royalties, net	27,846	—
Other long-term liabilities	35	38
Total stockholders' equity	39,405	52,459
Total liabilities and stockholders' equity	<u>\$ 74,745</u>	<u>\$ 60,215</u>

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

	Three Months Ended March 31,	
	2019	2018
Collaboration revenue	\$ 2,000	\$ —
Royalty revenue	142	—
Total revenues	2,142	—
Operating expenses:		
Research and development	5,766	5,911
General and administrative	3,398	3,606
Royalty expense	6,761	—
Total operating expenses	15,925	9,517
Loss from operations	(13,783)	(9,517)
Other income (expense):		
Investment and other income	289	159
Interest expense	(304)	(93)
Total other income (expense)	(15)	66
Loss before income taxes	(13,798)	(9,451)
Income taxes benefit	54	—
Net loss	\$ (13,744)	\$ (9,451)
Basic and diluted loss per common share:	\$ (0.24)	\$ (0.18)
Basic and diluted weighted average number of common shares outstanding:	56,924,914	51,883,570

Contact

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