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): March 14, 2019

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 March 14, 2019, we issued a press release announcing our results for the year ended December 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:

Exhibit No.	Description
99.1	Press release dated March 14, 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: March 14, 2019

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

Exhibit 99.1

www.infi.com

Infinity Pharmaceuticals Reports Full Year 2018 Financial Results and Provides Company Update

— Copiktra™ Royalty Monetization for $30M in Gross Proceeds —

— Roche/Genentech Clinical Collaboration on MARIO-3 in Front-Line Triple Negative Breast Cancer and Renal Cell Cancer —

— BMS Clinical Collaboration on MARIO-275, a Randomized Study of IPI-549 and Opdivo® (nivolumab) in I/O Naïve Urothelial Cancer to be Initiated in 2Q19 —

Cambridge, Mass. – March 14, 2019 – Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) today announced its full year 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 targeting immune-suppressive tumor-associated myeloid cells through selective phosphoinositide-3-kinase-gamma (PI3K-gamma) inhibition. Today, Infinity also announced MARIO-3, a Phase 2 study in collaboration with Roche, which will evaluate IPI-549 in combination with Tecentriq® and Abraxane® (nab-paclitaxel) in front-line triple negative breast cancer (TNBC) and IPI-549 in combination with Tecentriq and Avastin® (bevacizumab) in front-line renal cell cancer (RCC). Roche will provide Tecentriq for MARIO-3, which is anticipated to initiate in the second half of 2019.

"We are thrilled to be collaborating with the Roche/Genentech team in adding IPI-549 to emerging front-line therapy regimens for patients with TNBC and RCC. Last Friday, the FDA granted accelerated approval for the combination of Tecentriq and Abraxane in treating front-line PD-L1 positive TNBC patients, the first immuno-oncology regimen approved in TNBC, based on results of the IMpassion130 study, and this combination is widely expected to become a new standard of care," said Adelene Perkins, Chief Executive Officer and Chair of Infinity Pharmaceuticals. "Based on the IMpassion 130 approval, the safety and efficacy we have seen with IPI-549 and checkpoint inhibition in patients with relapsed/refractory TNBC in MARIO-1 and the complementary mechanisms, we hope that the triple therapy of IPI-549 with Tecentriq and Abraxane could lead to a truly transformative therapy for front-line patients with TNBC. Our goal in adding IPI-549 to the newly approved regimen is to increase the complete response rate and the durability of the responses seen in IMpassion130. We are equally enthusiastic about the potential for mechanistic synergy in combining IPI-549 to Tecentriq and Avastin in front-line patients with renal cell carcinoma. Importantly, the proceeds of the Copiktra royalty monetization enables this significant expansion of the clinical development of IPI-549 while maintaining our cash runway into the second half of 2020."

"MARIO-3 represents a key step in moving IPI-549 to front line therapy with emerging and potentially transformative treatment regimens and complements MARIO-275, our randomized study in immuno-oncology naïve patients with urothelial cancer. MARIO-275 leverages our findings from MARIO-1 in which the majority of patients had a decrease in levels of myeloid derived suppressor cells (MDSCs) following treatment with IPI-549. High levels of MDSCs were associated with poorer outcomes in urothelial cancer patients treated with Opdivo monotherapy in BMS's approval study, Checkmate 275. Our hope is that by driving down MDSC levels with IPI-549 in urothelial cancer, the combination of IPI-549 and Opdivo will lead to better outcomes for patients," said Samuel Agresta, M.D., M.P.H., Chief Medical Officer of Infinity Pharmaceuticals. "MARIO-1 demonstrated proof of concept for IPI-549 in an extremely high-bar anti-PD-1 refractory clinical setting, which has enabled us to rapidly advance IPI-549 to the I/O naïve and front-line settings in collaboration with BMS and Roche/Genentech. With the addition of MARIO-3 and MARIO-275 to the ongoing MARIO-1 study, Infinity will be evaluating IPI-549 in a total of approximately 500 patients, exploring potentially transformative double and triple combinations in new indications, earlier lines of treatment and later stages of clinical development."

Summary of progress since 3Q18

Clinical Development:

- **Announced Plans to Initiate MARIO-3:** Today, Infinity announced a clinical collaboration with Roche on a Phase 2 study, which will evaluate IPI-549 in combination with Tecentriq and Abraxane in front-line TNBC and IPI-549 in combination with Tecentriq and Avastin in front-line RCC. Roche will provide Tecentriq for MARIO-3, which is anticipated to initiate in 2H19.
- **Announced Plans to Initiate MARIO-275**: In November, Infinity announced the expanded clinical collaboration with Bristol-Myers Squibb to evaluate IPI-549 in combination with Opdivo in MARIO-275, a randomized Phase 2 study in IO-naïve patients with advanced urothelial cancer. The study is expected to initiate in 2Q19.
- **Presented Clinical and Translational Data from Expansion Cohorts of MARIO-1 Study at SITC Annual Meeting:** In November, Infinity announced updated clinical and translational data from the MARIO-1 Phase 1/1b study in a late-breaking poster presentation at the SITC Annual Meeting 2018. These data established on-mechanism proof-of-concept for IPI-549 and demonstrated preliminary evidence that IPI-549 in combination with Opdivo is clinically active in indications not expected to respond to Opdivo alone. The data also demonstrated evidence of reversal of resistance to Opdivo in a patient with metastatic melanoma who progressed on immediate prior Opdivo therapy. IPI-549 plus Opdivo also demonstrated a 26% reduction of tumor target lesions in a patient with chemotherapy-resistant triple negative breast cancer and sustained partial responses in a patient with microsatellite stable gallbladder cancer and a patient with adrenocortical carcinoma.

Corporate Development:

- **Announced Copiktra Royalty Monetization for Gross Proceeds of $30 Million.** In March 2019 Infinity announced a $30 million royalty monetization with HealthCare Royalty Partners (HCR), in which HCR has agreed to pay Infinity a $30 million upfront payment and up to $20 million in potential milestone payments, $15 million of which have the potential to be earned based on Copiktra sales in 2019. After sharing with Takeda Pharmaceuticals, Infinity retains $22.5 million in gross proceeds (approximately $20 million in net proceeds).

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

2H2019

- Initiate MARIO-3 with novel triple combinations in front-line therapy in clinical collaboration with Roche
    - 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 beyond Checkpoint inhibitors: initiate triple therapy (IPI-549+AB928+Chemo) in previously treated advanced TNBC with Arcus Biosciences

Full Year 2018 Financial Results

- At December 31, 2018, Infinity had total cash, cash equivalents and available-for-sale securities of $58.6 million, compared to $57.6 million at December 31, 2017.
- Revenue during 2018 was $22.1 million, related to the amount received from Verastem for the approval by the FDA of duvelisib for the treatment of adult patients with relapsed

or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two prior therapies, as well as adult patients with relapsed or refractory follicular lymphoma after at least two prior systemic therapies and royalties on net sales of duvelisib following the FDA approval. Revenue during 2017 was $6.0 million related to the amount received from Verastem for the DUO study meeting the pre-specified criteria at completion.

- Research and development expense for 2018 was $19.8 million, compared to $20.8 million in 2017.
- General and administrative expense was $14.2 million for 2018, compared to $21.6 million for 2017. The decrease in general and administrative expense was primarily due to a reduction in bonus and stock compensation.
- Net loss for 2018 was $11.3 million, or a basic and diluted loss per common share of $0.20, compared to a net loss of $41.8 million, or a basic and diluted loss per common share of $0.83 for 2017.

Financial Outlook

Infinity's updated 2019 financial guidance is:

- **Net Loss:** Infinity expects net loss for 2019 to range from $30 million to $40 million.
- **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 includes 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.

Conference Call Information

Infinity will host a conference call today, March 14, 2019, at 8 a.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 3569646. 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 225 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. 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 annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 14, 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)

	December 31, 2018	December 31, 2017
Cash, cash equivalents and available-for-sale securities	$ 58,591	$ 57,609
Other current assets	1,227	777
Property and equipment, net	28	219
Other long-term assets	369	748
Total assets	$ 60,215	$ 59,353
Note payable	$ —	$ 6,000
Other current liabilities	7,718	5,595
Other long-term liabilities	38	28
Total stockholders' equity	52,459	47,730
Total liabilities and stockholders' equity	$ 60,215	$ 59,353

INFINITY PHARMACEUTICALS, INC.

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

	Years Ended December 31,	
	2018	**2017**
Revenue:		
Collaboration revenue	$ 22,000	$ 6,000
Royalty revenue	146	—
Total revenues	22,146	6,000
Operating expenses:		
Research and development	19,758	20,830
General and administrative	14,248	21,615
Royalty expense	69	—
Total operating expenses	34,075	42,445
Loss from operations	(11,929)	(36,445)
Other income (expense):		
Investment and other income	769	1,787
Interest expense	(93)	(1,010)
Other expense	—	(6,882)
Total other income (expense)	676	(6,105)
Loss before income taxes	(11,253)	(42,550)
Income taxes benefit	—	720
Net loss	$ (11,253)	$ (41,830)
Basic and diluted loss per common share	$ (0.20)	$ (0.83)
Basic and diluted weighted average number of common shares outstanding	55,411,370	50,560,195

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