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): February 27, 2020

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

Delaware	**000-31141**	**33-0655706**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
1100 Massachusetts Avenue, Floor 4, Cambridge, MA		**02138**
(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))

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**

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 3, 2020, Infinity Pharmaceuticals, Inc. (the "Company") issued a press release announcing its results for the year ended December 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b) On February 27, 2020, Jeffery Kutok, M.D., Ph.D., Chief Scientific Officer and a named executive officer of the Company, notified the Company of his decision to resign effective March 31, 2020.

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 3, 2020

SIGNATURES

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 3, 2020

By: /s/ Seth A. Tasker
Seth A. Tasker
Chief Business Officer

www.infi.com

Infinity Pharmaceuticals Reports Full Year 2019 Financial Results and Provides Company Update

-- Enrollment Completion for MARIO-275, Infinity's Global, Randomized Phase 2 Study in Patients with Urothelial Cancer, Expected in 2020 with Data Expected in 2021 --

-- Initial Data from Phase 2 MARIO-3 Trial and Updated Data from Ongoing Phase 1b MARIO-1 Trial Expected in 2020 --

-- Cash Runway into 2H 2021 Through Data Readouts from All Current IPI-549 Studies --

CAMBRIDGE, Mass., March 3, 2020 /Business Wire/ -- Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) today announced its full year 2019 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.

"2019 was a year of great execution at Infinity with tremendous progress in building a data-driven clinical program designed to clearly elucidate the activity of IPI-549 across a range of indications and innovative combination treatment regimens," said Adelene Perkins, Chief Executive Officer and Chair of Infinity Pharmaceuticals. "This progress in 2019 included the initiation of Phase 2 MARIO-275 and MARIO-3 studies as well as the clinical collaboration with Arcus Biosciences. These new studies were informed by MARIO-1, our Phase 1 study that provided important early clinical and translational data demonstrating anti-cancer activity of IPI-549, on target reduction of myeloid derived suppressor cells, or MDSCs, and an excellent tolerability profile. These data laid the foundation for our upcoming milestone rich 2020 which will include enrollment completion for MARIO-275 in bladder cancer, and enrollment completion and initial data from MARIO-3 in front-line renal cell carcinoma and triple negative breast cancer. Importantly, our cash runway funds our trials through key data readouts, encompassing over 500 patients. We look forward to continued momentum as we establish MDSC and tumor macrophage-directed immunotherapies as important new options for patients currently unresponsive or refractory to available treatments."

Key 2019 Accomplishments and IPI-549 Program Guidance:

Financial:

- In January 2020, completed a $20 million non-dilutive asset-backed financing with BVF Partners L.P. with sole recourse in potential royalty payments due on future sales of patidegib, a hedgehog pathway inhibitor discovered by Infinity and licensed to PellePharm in 2013. In addition, Infinity is eligible to receive from BVF an additional $5 million payment upon positive data from PellePharm's Phase 3 trial in patients with Gorlin Syndrome. PellePharm completed enrollment of its Phase 3 trial in 2019.
- Completed a royalty monetization with HealthCare Royalty Partners (HCR) for the right to receive certain royalty payments based on worldwide annual net sales of COPIKTRA® (duvelisib), payable by Verastem. Under the agreement, HCR paid Infinity a $30 million upfront payment.
- Extended cash runway with approximately $62 million cash at January 8, 2020 to fund all current IPI-549 trials to key data readouts in over 500 patients throughout 2020 and into mid-2021.

Clinical:

- Initiated MARIO-275, the company's ongoing global, randomized, controlled Phase 2 study in collaboration with Bristol-Myers Squibb, to evaluate IPI-549 in combination with Opdivo® in platinum-refractory, I/O naïve patients with advanced urothelial cancer. Completion of enrollment is expected in 2020 with data mid-2021.

- Initiated MARIO-3, the company's ongoing Phase 2 study in collaboration with Roche/Genentech to evaluate IPI-549 in novel triple combination front-line therapies with Tecentriq® and Abraxane® in triple negative breast cancer (TNBC) and with Tecentriq and Avastin® in renal cell cancer (RCC). Enrollment completion and initial data are expected in 2020.
- Initiated a Phase 1b collaboration study with Arcus Biosciences, which is being conducted by Arcus, evaluating a checkpoint-inhibitor free, novel triple-combination regimen of IPI-549 + AB928 (dual adenosine receptor antagonist) + Doxil® in advanced TNBC patients. Enrollment in the expansion cohort of up to 40 patients is ongoing.
- Completed enrollment in MARIO-1, the company's ongoing Phase 1/1b study of IPI-549 as a monotherapy and in combination with Opdivo in patients with advanced solid tumors. Additional data are expected in 2020.

Corporate:

- Established Clinical Advisory Board with the following initial members:
    - Chair: Sam Agresta, MD, Infinity Board Member and Chief Medical Officer of Foghorn Therapeutics. Previously Dr. Agresta was responsible for the development and approval of several important drugs including of TIBSOVO® and IDHIFA® for patients with IDH1 and IDH2 mutation positive AML while at Agios and, while at Genentech, he played a key role in the global development of KADCYLA®, which is approved for HER2 positive breast cancer. Dr. Agresta also played a key role in designing the Infinity trials now underway and is actively engaged with the company in advancing these trials.
    - Padmanee (Pam) Sharma, MD, PhD, co-leader of the MD Anderson Cancer Center's immunotherapy platform and T.C. and Jeanette Hsu Endowed Chair in Cell Biology, Department of Genitourinary Medical Oncology. Dr. Sharma was the principal investigator on the BMS Checkmate 275 study that first demonstrated the association of high MDSCs to significantly lower overall survival in patients with UC and which provided the inspiration for our MARIO-275 study to which Dr Sharma will bring unique insight.
    - Toni Choueiri, MD, Director of the Lank Center for Genitourinary Oncology at Dana-Farber Cancer Institute/Brigham and Women's Hospital and the Jerome and Nancy Kohlberg Chair and Professor of Medicine at Harvard Medical School and a recognized thought leader in the GU field who has done extensive work in the development of better treatments for patients with RCC and will bring great insight to the interpretation of our data from MARIO-3 in RCC and the development of next steps.
    - Michael Postow, MD, Co-Lead Melanoma Disease Management Team at Memorial Sloan Kettering Cancer Center and assistant professor of medicine at Weill Cornell Medical College. Dr. Postow treats patients with advanced melanoma and was the principal investigator of a clinical trial which led to FDA approval of the nivolumab + ipilimumab immunotherapy combination to treat melanoma. He is currently leading clinical trials testing new immunotherapy combinations in patients with advanced melanoma and will bring tremendous insight to potential future paths for IPI-549 in melanoma.
- Jeff Kutok, MD, PhD, will be stepping down as Chief Scientific Officer at the end of March to lead drug discovery at another life science company and will assume the role as Chair of Infinity's Scientific Advisory Board.
- Seth Tasker, J.D. was promoted from General Counsel to Chief Business Officer.

Full Year 2019 Financial Results:

- At December 31, 2019, Infinity had total cash, cash equivalents and available-for-sale securities of $42.4 million, compared to $58.6 million at December 31, 2018 and approximately $62 million at January 8, 2020.

- Revenue during 2019 was $3.0 million, which primarily relates to the achievement of a $2.0 million milestone from PellePharm. Revenue during 2018 was $22.1 million, related to the amount received from Verastem for the approval by the FDA of COPIKTRA.
- Research and development expense for 2019 was $27.1 million, compared to $19.8 million in 2018. The increase in R&D expense in 2019 compared to 2018 was primarily due to higher clinical development expenses for IPI-549.
- General and administrative expense was $14.3 million for 2019, compared to $14.2 million for 2018.
- Royalty expense for 2019 was $7.3 million, which primarily reflects Takeda's share of the $30 million gross proceeds received from HCR for the monetization of COPIKTRA royalties in 2019, which was recognized as a liability in accordance with relevant accounting guidance. While recognized as a liability, the company is not obligated to repay the $30 million from HCR.
- Net loss for 2019 was $47.1 million, or a basic and diluted loss per common share of $0.83, compared to a net loss of $11.3 million, or a basic and diluted loss per common share of $0.20 for 2018. The increase in net loss was mostly driven by the $22 million milestone received from Verastem in 2018 for the approval of COPIKTRA and the $7.3 million royalty expense to Takeda in 2019 for their share of the COPIKTRA royalty monetization with HCR.

Financial Outlook:

Infinity's 2020 financial guidance remains unchanged:

- Net Loss: Infinity expects net loss for 2020 to range from $40 million to $50 million.
- Cash and Investments: Infinity expects to end 2020 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, including the $20.0 million received from BVF in January 2020, will be adequate to satisfy the company's capital needs into 2H 2021. Infinity's financial guidance does not include additional funding or business development activities or a potential $5 million milestone payment from BVF for positive patidegib Phase 3 data and any milestones from, or the sale of the company's equity interest in, PellePharm.

Conference Call Information

Infinity will host a conference call today, March 3, 2020, 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 (877) 316-5293 (domestic) and (631) 291-4526 (international) five minutes prior to start time. The conference ID number is 6177179. 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. MARIO-275 and MARIO-3 have recently initiated. MARIO-275 is a global, randomized, combination study of IPI-549 combined with Opdivo in I/O naïve urothelial cancer patients. MARIO-3 is the first IPI-549 combination study in front-line advanced cancer patients and is evaluating 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 enrollment and data presentation timelines; 2020 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: 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 and quarterly reports filed with the Securities and Exchange Commission (SEC), and in other filings that Infinity makes with the SEC, available through the company’s website at www.infi.com. 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, 2019	December 31, 2018
Cash, cash equivalents and available-for-sale securities	$ 42,444	$ 58,591
Other current assets	2,137	1,227
Property and equipment, net	2,186	28
Other long-term assets	2,247	369
Total assets	$ 49,014	$ 60,215
Accounts payable and accrued expenses	$ 9,698	$ 7,718
Liability related to sale of future royalties, net	29,626	—
Operating lease liability, less current portion	1,926	—
Long-term liabilities	38	38
Total stockholders' equity	7,726	52,459
Total liabilities and stockholders' equity	$ 49,014	$ 60,215

INFINITY PHARMACEUTICALS, INC.

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

	Year Ended December 31,	
	2019	**2018**
Collaboration revenue	$ 2,000	$ 22,000
Royalty revenue	1,049	146
Total revenues	3,049	22,146
Operating expenses:		
Research and development	27,116	19,758
General and administrative	14,289	14,248
Royalty expense	7,308	69
Total operating expenses	48,713	34,075
Income (loss) from operations	(45,664)	(11,929)
Other income (expense):		
Investment and other income	1,116	769
Interest expense[1]	(2,563)	(93)
Total other income (expense)	(1,447)	676
Income (loss) before income taxes	(47,111)	(11,253)
Income taxes benefit	54	—
Net income (loss)	$ (47,057)	$ (11,253)
Basic and diluted loss per common share	$ (0.83)	$ (0.20)
Basic and diluted weighted average number of common shares outstanding	56,983,652	55,411,370

[1] In the first quarter of 2019, Infinity recognized $30.0 million in gross cash proceeds received from the Copiktra® royalty monetization as a liability on the balance sheet in accordance with accounting guidance for royalty monetization. The company is amortizing the liability to non-cash interest expense on a quarterly basis. For the year ended 2019, non-cash interest expense was $2.6 million.

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