
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): October 30, 2019

Infinity Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-31141
(Commission File Number)

33-0655706
(IRS Employer
Identification No.)

1100 Massachusetts Avenue, Floor 4, Cambridge,
MA
(Address of principal executive offices)

02138
(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 October 30, 2019, the Company issued a press release announcing its results for the quarter ended September 30, 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 October 30, 2019 |

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.

Date: October 30, 2019

INFINITY PHARMACEUTICALS, INC.

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

Infinity Pharmaceuticals Provides Company Update and Third Quarter 2019 Financial Results**-- MARIO-1 Enrollment Completion Expected in 2019 and Data Presentation Expected in 2020 --****-- MARIO-3 Enrollment Completion and Data Presentation Expected in 2020 --****-- MARIO-275 Enrollment Completion Expected in 2020 --**

CAMBRIDGE, Mass., October 30, 2019 /Business Wire/ -- Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) today announced its third quarter 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.

“It is an exciting and important time for Infinity as we anticipate completing enrollment in MARIO-1 by the end of this year and presenting data from our MARIO-1 and MARIO-3 trials in 2020. During 2020 we also expect to complete enrollment in MARIO-275, our randomized, controlled Phase 2 trial in patients with bladder cancer,” said Adelene Perkins, Chief Executive Officer and Chair of Infinity Pharmaceuticals. “As we advance multiple studies designed to produce compelling data across a wide range of indications in innovative combinations, we are witnessing surging recognition of the importance of tumor macrophage-directed immuno-oncology therapies among the medical and scientific communities. With additional clinical and translational data expected from IPI-549 studies starting in 2020, Infinity is positioned to become the leader in macrophage-targeted immunotherapy.”

Updated IPI-549 Clinical Program Guidance

- **MARIO-1 enrollment completion expected by year end with data presentation expected in 2020.** MARIO-1 is 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.
- **MARIO-3 enrollment completion and data presentation expected in 2020.** MARIO-3 is 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).
- **MARIO-275 enrollment completion expected during 2020.** MARIO-275 is the company’s global, randomized 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 (bladder) cancer.
- **Arcus Biosciences Collaboration Study Initiated:** This Phase 1 trial, being conducted by Arcus, is evaluating a checkpoint-inhibitor free, novel triple-combination regimen of IPI-549 + AB928 (dual adenosine receptor antagonist) + Doxil® in advanced TNBC patients.

Third Quarter 2019 Financial Results

- At September 30, 2019, Infinity had total cash, cash equivalents and available-for-sale securities of \$52.0 million, compared to \$63.0 million at June 30, 2019.
 - Research and development expense for the third quarter of 2019 was \$7.1 million, compared to \$5.4 million for the same period in 2018. The increase in R&D expense was primarily due to an increase in clinical and development activities for IPI-549.
 - General and administrative expense was \$3.6 million for the third quarter of 2019, compared to \$3.4 million for the same period in 2018.
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- Net loss for the third quarter of 2019 was \$11.4 million, or a basic and diluted loss per common share of \$0.20, compared to net income of \$13.4 million, or a basic and diluted earnings per common share of \$0.23 for the same period in 2018. In the third quarter of 2018, we recognized \$22.0 million in revenue related to a one-time payment due from Verastem for the approval by the U.S. Food and Drug Administration of Copiktra®, which Infinity licensed to Verastem in 2016.

2019 Financial Guidance

- **Net Loss:** Infinity expects net loss for 2019 to range from \$40 million to \$50 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.
- **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 for at least the next 12 months. Infinity's financial guidance excludes additional funding or business development activities.

Conference Call Information

Infinity will host a conference call today, October 30, 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 2612978. 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; 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 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.

Opdivo® is a registered trademark of Bristol-Myers Squibb.

Tecentriq® and Avastin® are registered trademarks of Roche.

Abraxane® is a registered trademark of Celgene.

Doxil® is a registered trademark of Janssen Products.

Copiktra® is a registered trademark of Verastem, Inc.

INFINITY PHARMACEUTICALS, INC.**Condensed Consolidated Balance Sheets****(in thousands)****(unaudited)**

| | September 30, 2019 | December 31, 2018 |
|--|---------------------------|--------------------------|
| Cash, cash equivalents and available-for-sale securities | \$ 51,989 | \$ 58,591 |
| Other current assets | 2,395 | 1,227 |
| Property and equipment, net | 2,274 | 28 |
| Other long-term assets | 2,450 | 369 |
| Total assets | \$ 59,108 | \$ 60,215 |
| | | |
| Accounts payable and accrued expenses | \$ 8,749 | \$ 7,718 |
| Liability related to sale of future royalties, net | 29,751 | — |
| Operating lease liability, less current portion | 1,955 | — |
| Long-term liabilities | 38 | 38 |
| Total stockholders' equity | 18,615 | 52,459 |
| Total liabilities and stockholders' equity | \$ 59,108 | \$ 60,215 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|----------------------------------|------------|---------------------------------|------------|
| | 2019 | 2018 | 2019 | 2018 |
| Collaboration revenue | \$ — | \$ 22,000 | \$ 2,000 | \$ 22,000 |
| Royalty revenue | 343 | — | 741 | — |
| Total revenues | 343 | 22,000 | 2,741 | 22,000 |
| Operating expenses: | | | | |
| Research and development | 7,076 | 5,379 | 18,918 | 15,039 |
| General and administrative | 3,641 | 3,442 | 10,810 | 10,435 |
| Royalty expense | 207 | — | 7,123 | — |
| Total operating expenses | 10,924 | 8,821 | 36,851 | 25,474 |
| Income (loss) from operations | (10,581) | 13,179 | (34,110) | (3,474) |
| Other income (expense): | | | | |
| Investment and other income | 299 | 202 | 906 | 534 |
| Interest expense ¹ | (1,135) | — | (2,525) | (93) |
| Total other income (expense) | (836) | 202 | (1,619) | 441 |
| Income (loss) before income taxes | (11,417) | 13,381 | (35,729) | (3,033) |
| Income taxes benefit | — | — | 54 | — |
| Net income (loss) | \$ (11,417) | \$ 13,381 | \$ (35,675) | \$ (3,033) |
| Earnings (loss) per common share: | | | | |
| Basic | \$ (0.20) | \$ 0.23 | \$ (0.63) | \$ (0.06) |
| Diluted | \$ (0.20) | \$ 0.23 | \$ (0.63) | \$ (0.06) |
| Weighted average number of common shares outstanding: | | | | |
| Basic | 57,028,970 | 56,851,811 | 56,965,711 | 54,918,963 |
| Diluted | 57,028,970 | 57,638,660 | 56,965,711 | 54,918,963 |

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 third quarter of 2019, non-cash interest expense was \$1.1 million.

Contact

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