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): November 2, 2021

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 November 2, 2021, Infinity Pharmaceuticals, Inc. (the "Company") issued a press release announcing its results for the quarter ended September 30, 2021 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.

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Forward-Looking Statements

This Current Report on Form 8-K and the exhibits attached hereto contain forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. 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 the Company's annual and quarterly reports filed with the Securities and Exchange Commission ("SEC"), and its other filings with the SEC, available through the Company's website at www.infi.com. Any forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated November 2, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 2, 2021

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

Infinity Pharmaceuticals Reports Third Quarter 2021 Financial Results and Provides Company Update

– Encouraging data for eganelisib in both PD-L1(-) and PD-L1(+) mTNBC patients, with meaningful prolongation of PFS over IMpassion130 reference benchmark –

– Updated mTNBC data to be presented at San Antonio Breast Cancer Symposium –

– Encouraging data for eganelisib in mUC patients, with a 7.5 month extension of overall survival versus control arm –

– Strengthened leadership team with Chief Scientific Officer, Chief Medical Officer and Board appointments –

CAMBRIDGE, Mass., November 2, 2021 /Business Wire/ -- Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) ("Infinity" or the "Company") today announced its third quarter 2021 financial results and provided a corporate update on eganelisib, its potentially first-in-class, oral, immuno-oncology macrophage reprogramming therapeutic.

"Infinity had a very successful 3rd quarter reaching major clinical milestones with eganelisib and welcoming two outstanding R&D executives to our management team," said Adelene Perkins, Chief Executive Officer and Chair, Infinity Pharmaceuticals. "In particular, data presented in July from MARIO-3 and MARIO-275 show that eganelisib, with its unique role in reprogramming macrophages, increases the effectiveness of current checkpoint inhibitors and improves patient outcomes across multiple indications and treatment settings. These data show that eganelisib has the potential to drive the next generation of cancer immuno-therapy."

"The data on prolonged progression-free survival in metastatic triple negative breast cancer, increased overall survival in metastatic urothelial cancer, and translational evidence of modulation of the tumor microenvironment highlight the broad potential of eganelisib to improve immune checkpoint inhibitor-based treatments for patients regardless of PD-L1 status. This is particularly meaningful for PD-L1 negative 1L mTNBC patients for whom no checkpoint inhibitors have been approved and for PD-L1 negative mUC patients for whom checkpoint inhibitors are less effective," said Dr. Robert Ilaria, Chief Medical Officer, Infinity Pharmaceuticals. "We look forward to presenting a TNBC update at SABCS in December for which we are especially interested in seeing if the encouraging PFS data presented this summer is maintained in the maturing data set and to providing an update on eganelisib in UC in our January 5th guidance for 2022."

Recent Updates:

MARIO-3: Updated data was presented from 43 patients (43 patients evaluable for safety and 38 patients evaluable for efficacy) were presented on July 27, 2021, from the Company's ongoing Phase 2 study evaluating eganelisib in a novel triple combination with Tecentriq® (atezolizumab) and Abraxane® (nab-paclitaxel) in unresectable locally advanced or metastatic triple negative breast cancer (TNBC). Updated safety and efficacy data will be presented at the San Antonio Breast Cancer Symposium (SABCS) Annual Meeting, December 7-10, 2021.

- Encouraging efficacy data presented on July 27, 2021, suggest the addition of eganelisib to Tecentriq and Abraxane has the potential to extend progression-free survival regardless of PD-L1 status.
- 86.8% (33/38) of evaluable patients demonstrated tumor reduction, with the majority of patients still on treatment.
- The addition of eganelisib appears to extend progression-free survival (PFS) in both PD-L1(+) and PD-L1(-) patients relative to the Tecentriq and Abraxane combination from the benchmark IMpassion130 study.
    - In PD-L1(-) patients, median PFS was 7.3 months (3.5, NA) in MARIO-3, compared to median PFS of 5.6 months for Tecentriq and Abraxane in IMpassion130. There are currently no approved checkpoint inhibitor regimens, including the combination of Tecentriq and Abraxane, for PD-L1 (-) 1L mTNBC patients.
    - In PD-L1(+) patients, median PFS was 11.2 months (5.3, 11.2) in MARIO-3 compared to 7.5 months for Tecentriq and Abraxane in IMpassion130. The Tecentriq and Abraxane combination is approved in PD-L1(+) 1L mTNBC patients in over 70 countries.

- Overall safety in MARIO-3 was consistent with the safety profile of eganelisib and the published safety profile of the marketed products Tecentriq and Abraxane, and no new safety signals were observed. The most common ≥GR3 treatment-related adverse events (AEs) were hepatic AEs (18%); neutropenia AEs (16%); skin AEs (12%); fatigue (6%); peripheral sensory neuropathy (6%); and diarrhea (6%).

MARIO-275: Updated data on 49 patients were presented on July 27, 2021, from the Company's randomized, placebo-controlled Phase 2 study evaluating the efficacy and safety of eganelisib in combination with Opdivo® (nivolumab) in platinum-refractory, I/O naïve patients with locally advanced or metastatic urothelial cancer (UC).

- Median overall survival (mOS) in the intent to treat population was 15.4 months (6.2, NE) on the eganelisib plus Opdivo arm compared to 7.9 months (2.3, NE) on the Opdivo control arm (hazard ratio of 0.62 (0.28, 1.36)), reflecting a 38% lower probability of death.
    - Median overall survival was equally strong in PD-L1(-) patients with a hazard ratio of 0.60 (0.21, 1.71), reflecting a 40% lower probability of death.
- The most common ≥Grade 3 treatment-related adverse events (AEs) were, across all doses, all causality, anemia (12.1%), and hepatic AEs including hepatotoxicity (15.2%), increased ALT (12.1%) and increased AST (12.1%) with no Hy's Law. No Grade 5 hepatic AEs were reported.

Corporate:

- Appointed Stéphane Peluso, Ph.D., as Chief Scientific Officer, joining Infinity from Ipsen.
- Appointed Robert Ilaria, Jr., M.D. as Chief Medical Officer, joining Infinity from Bristol Myers Squibb/Celgene.
- Appointed Brian Schwartz, M.D., to Board of Directors, transitioning from consulting Chief Physician to the Board.

Third Quarter 2021 Financial Results:

- At September 30, 2021, Infinity had total cash, cash equivalents and available-for-sale securities of $90.1 million, compared to $97.3 million at June 30, 2021.
- Research and development expense for the third quarter of 2021 was $7.1 million, compared to $6.1 million in the same period in 2020. The increase is primarily related to an increase in compensation related expenses and clinical development expenses to support continued development of eganelisib.
- General and administrative expense was $3.8 million for the third quarter of 2021, compared to $2.9 million for the same period in 2020. The increase in G&A expense is primarily due to an increase in consulting expenses, professional services and stock compensation.
- Net loss for the third quarter of 2021 was $10.7 million, or a basic and diluted loss per common share of $0.12, compared to a net loss of $9.5 million, or a basic and diluted loss per common share of $0.16 in the same period in 2020.

Financial Outlook: Infinity's 2021 financial guidance remains as follows:

- Net Loss: Infinity expects net loss for 2021 to range from $40 million to $50 million.
- Cash and Investments: Infinity expects to end 2021 with a year-end-cash, cash equivalents and available for sale securities balance ranging from $70 million to $80 million. Infinity's financial guidance does not include additional funding or business development activities.

Conference Call Information

Infinity will host a conference call today, November 2, 2021, at 4:30 PM 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 2938945. An archived version of the webcast will be available on Infinity's website for 30 days.

About Infinity and Eganelisib

Infinity Pharmaceuticals, Inc. (“Infinity” or the “Company”), is a clinical-stage biotechnology company developing eganelisib (IPI-549), a potentially first-in-class, oral, immuno-oncology macrophage reprogramming therapeutic which addresses a fundamental biologic mechanism of immune suppression in cancer in multiple clinical studies. MARIO-275 is a randomized, controlled combination study of eganelisib combined with Opdivo® in I/O naïve urothelial cancer. MARIO-3 is the first eganelisib combination study in front-line advanced cancer patients and is evaluating eganelisib in combination with Tecentriq® and Abraxane® in front-line TNBC and in combination with Tecentriq and Avastin® in front-line RCC. In collaboration with Arcus Biosciences, Infinity is evaluating a checkpoint inhibitor-free, novel combination regimen of eganelisib plus etrumadenant (AB928, a dual adenosine receptor antagonist) plus Doxil® in advanced TNBC and ovarian cancer patients. In 2019, Infinity completed enrollment in MARIO-1, a Phase 1/1b study evaluating eganelisib as a monotherapy and in combination with Opdivo (nivolumab) in patients with advanced solid tumors including patients refractory to checkpoint inhibitor therapy. With these studies Infinity is evaluating eganelisib 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 eganelisib; plans to present data; registrational trial planning; the Company’s guidance with respect to net loss, cash and cash equivalents and cash runway; 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 eganelisib 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 cost, timing and results of clinical trials and other development activities that may be delayed or disrupted by the COVID-19 pandemic or otherwise; 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; unplanned cash requirements and expenditures; development of agents by Infinity's competitors for diseases in which Infinity is currently developing or intends to develop eganelisib; and Infinity's ability to obtain, maintain and enforce patent and other intellectual property protection for eganelisib. 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 does not undertake and 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)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and available-for-sale securities	$ 90,088	$ 34,108
Other current assets	1,838	1,912
Property and equipment, net	1,361	1,710
Other long-term assets	1,328	1,589
Total assets	$ 94,615	$ 39,319
Accounts payable and accrued expenses	$ 12,351	$ 11,047
Liability related to sale of future royalties, net[1]	48,909	28,021
Liability related to sale of future royalties to a related party, net[1]	—	21,559
Operating lease liability, less current portion	1,054	1,436
Long-term liabilities	157	245
Total stockholders' equity (deficit)	32,144	(22,989)
Total liabilities and stockholders' equity	$ 94,615	$ 39,319

[1] The company is not obligated to repay the liabilities related to sale of future royalties but these are recorded as a liability on the balance sheet in accordance with accounting guidance for royalty monetization. During the first quarter of 2021, the liability related to sale of future royalties to a related party was reclassified to liability related to sale of future royalties since the Biotechnology Value Fund, L.P. (BVF) is no longer considered a related party.

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,	
	2021	2020	2021	2020
Royalty revenue	$ 428	$ 496	$ 1,407	$ 1,283
Operating expenses:				
Research and development	7,073	6,112	23,231	19,582
General and administrative	3,847	2,930	10,911	9,191
Royalty expense	258	299	848	774
Total operating expenses	11,178	9,341	34,990	29,547
Loss from operations	(10,750)	(8,845)	(33,583)	(28,264)
Other income (expense):				
Investment and other income (expense)	82	(63)	107	173
Non-cash interest expense[1]	(45)	(38)	(135)	(115)
Non-cash related party interest expense[1]	—	(588)	—	(1,687)
Total other income (expense)	37	(689)	(28)	(1,629)
Net loss	$ (10,713)	$ (9,534)	$ (33,611)	$ (29,839)
Basic and diluted loss per common share:	$ (0.12)	$ (0.16)	$ (0.40)	$ (0.51)
Basic and diluted weighted average number of common shares outstanding:	88,766,912	60,506,373	84,433,435	58,438,343

[1] The liabilities related to sale of future royalties will be amortized using the effective interest method over the life of the arrangements. During the first quarter of 2021, the non-cash related party interest expense was reclassified to non-cash interest expense since BVF is no longer considered a related party.

Investor Relations:
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