
**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): August 9, 2022

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 August 9, 2022, Infinity Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its results for the quarter ended June 30, 2022 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.

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

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press release dated August 9, 2022
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104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
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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: August 9, 2022

INFINITY PHARMACEUTICALS, INC.

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



Infinity Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Business Update

- Positive eganelisib data from two-year landmark analysis demonstrate durable survival benefit in urothelial cancer (UC) patients from MARIO-275 –
- MARIO-3 triple negative breast cancer (TNBC) data update on track by year end –
- Further eganelisib clinical development stage gated on potential partnership –
- Increased 2022 year-end cash guidance with runway extended into 2024 –
- Investor conference call to be held today at 4:30 PM EDT –

CAMBRIDGE, Mass.--(BUSINESS WIRE)—August 9, 2022-- Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) (“Infinity” or the “Company”), a clinical-stage biotechnology company developing eganelisib, a first-in-class, oral, immuno-oncology macrophage reprogramming therapeutic, today announced its second quarter 2022 financial results, unveiled new positive data from the Phase 2 MARIO-275 clinical trial, and provided a business update.

“Today, we are pleased to announce positive survival data that shows approximately a doubling of patient survival at the two-year landmark analysis, a durable benefit for urothelial cancer patients being treated with eganelisib plus nivolumab versus standard-of-care nivolumab monotherapy. This impressive magnitude of benefit is particularly meaningful given this is a second line patient population whose cancer has progressed following treatment with a platinum-based chemotherapy,” said Robert Ilaria, Jr., MD, Chief Medical Officer of Infinity.

“Based on the positive eganelisib data generated to-date in several indications and settings, we remain in discussions with multiple parties regarding potential partnerships to further advance the development of eganelisib,” said Adelene Perkins, Chief Executive Officer and Chair of Infinity. “At this stage in eganelisib’s clinical development, and given the current market environment, we have decided to prioritize establishing potential partnerships before beginning new efficacy studies, including MARIO-4 in TNBC and the MARIO-P platform study. Infinity has a track record of fiscal discipline, and this approach allows us to focus our current resources on ongoing clinical trials, extend our cash runway into 2024, and provide the flexibility to accommodate potential partners’ input on the prioritization and design of our next studies. These initiatives support our commitment to advancing development of eganelisib across multiple oncology indications to maximize value for patients and shareholders.”

Positive MARIO-275 Clinical Trial Results in Second Line Urothelial Cancer:

- At two-year landmark survival analysis of MARIO-275 as of July 29, 2022, 45% of patients in the eganelisib plus nivolumab arm are alive compared to 24% of patients in the nivolumab control arm, a near doubling of survival benefit.
- Durable survival benefit was also seen in the PD-L1-negative subgroup, with 38% of patients alive at two years in the eganelisib plus nivolumab arm versus 17% in the control group, over a doubling of survival in this patient population underserved by checkpoint inhibitors alone.
- No new safety signals were observed during the extended period on treatment.

Second Quarter 2022 Financial Results:

- At June 30, 2022, Infinity had total cash, cash equivalents and available-for-sale securities of \$56.6 million, compared to \$80.7 million at December 31, 2021.
- Research and development expenses for the second quarter of 2022 were \$8.8 million, compared to \$8.0 million in the same period in 2021. The increase is primarily related to an increase in compensation expense due primarily to new hires during the period and an increase in consulting expense, partially offset by a decrease in clinical development expenses.

- General and administrative expenses were \$3.5 million for the second quarter of 2022 as well as for the second quarter of 2021.
- Net loss for the second quarter of 2022 was \$12.0 million, or a basic and diluted loss per common share of \$0.13, compared to a net loss of \$11.3 million, or a basic and diluted loss per common share of \$0.13 in the same period in 2021.
- 2022 Financial Outlook: Net Loss: Infinity expects net loss for 2022 to range from \$40 million to \$50 million.
- Cash and Investments: Infinity expects to end 2022 with a cash, cash equivalents and available for sale securities balance ranging from \$35 million to \$45 million, which provides a cash runway into 2024. Infinity's financial guidance does not include additional funding or business development activities.

Conference Call Information

Infinity will host a conference call today, August 9, 2022, at 4:30 PM EDT to discuss these financial results and business 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 (800) 715-9871 (domestic) and (646) 307-1963 (international) five minutes prior to start time. The conference ID number is 3032412. 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 first-in-class, oral, immuno-oncology macrophage reprogramming therapeutic which is designed to address a fundamental biologic mechanism of immune suppression in cancer in multiple clinical studies. 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. MARIO-275 is a randomized, controlled combination study of eganelisib combined with Opdivo® in I/O naïve urothelial cancer. 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 the Company's guidance with respect to net loss, cash and cash equivalents and cash runway; plans to evaluate and establish potential partnerships; 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 or will be successful in establishing a strategic partnership to further the development of eganelisib. 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.

Opdivo® is a registered trademark of Bristol Myers Squibb.

Tecentriq® is a registered trademark of Genentech, Inc.

Abraxane® is a registered trademark of Abraxis BioScience, LLC., a wholly owned subsidiary of Bristol Myers Squibb Company.

Avastin® is a registered trademark of Genentech, Inc.

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents and available-for-sale securities	\$ 56,575	\$ 80,726
Other current assets	3,035	1,542
Property and equipment, net	1,017	1,241
Other long-term assets	1,230	1,276
Total assets	\$ 61,857	\$ 84,785
Accounts payable and accrued expenses	\$ 14,339	\$ 13,300
Liabilities related to sale of future royalties, net ¹	47,955	48,727
Operating lease liability, less current portion	633	917
Long-term liabilities	37	270
Total stockholders' (deficit) equity	(1,107)	21,571
Total liabilities and stockholders' (deficit) equity	\$ 61,857	\$ 84,785

¹ The company is not obligated to repay any of 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Royalty revenue	\$ 686	\$ 512	\$ 1,338	\$ 979
Operating expenses:				
Research and development	8,795	7,957	17,785	16,158
General and administrative	3,495	3,498	7,171	7,064
Royalty expense	414	308	807	590
Total operating expenses	12,704	11,763	25,763	23,812
Loss from operations	(12,018)	(11,251)	(24,425)	(22,833)
Other income (expense):				
Investment and other income	77	27	93	25
Non-cash interest expense ¹	(45)	(45)	(90)	(90)
Total other expense	32	(18)	3	(65)
Net loss	\$ (11,986)	\$ (11,269)	\$ (24,422)	\$ (22,898)
Basic and diluted loss per common share:	\$ (0.13)	\$ (0.13)	\$ (0.27)	\$ (0.28)
Basic and diluted weighted average number of common shares outstanding:	89,161,777	88,661,934	89,158,562	82,230,784

¹ The liabilities related to sale of future royalties will be amortized using the effective interest method over the life of the arrangements.

Investor Relations:

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