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): January 5, 2022

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

Not Applicable
(Former name or former address, if changed since last report)

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 Each Class	Trading Symbol	Name of Each 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.

Although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2021, on January 5, 2022, Infinity Pharmaceuticals, Inc. (the "Company") announced that it expects to report that it had approximately $81 million in cash and investments (unaudited) as of December 31, 2021.

The information contained in Item 2.02 of this Form 8-K is unaudited and preliminary and does not present all information necessary for an understanding of the Company's financial condition as of December 31, 2021 and its results of operations for the three months and year ended December 31, 2021. The audit of the Company's consolidated financial statements for the year ended December 31, 2021 is ongoing and could result in changes to the information set forth above.

The information in this Item 2.02 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 8.01. Other Events.

On January 5, 2022, the Company issued a press release announcing its 2022 business goals and financial guidance and providing an update regarding its clinical development strategy. The full text of this press release is filed 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.

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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 January 5, 2022
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: January 5, 2022

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

Infinity Pharmaceuticals Outlines Eganelisib Clinical Development Strategy and Provides 2022 Guidance

- MARIO-4 registration study in frontline metastatic triple negative breast cancer to be initiated by year end 2022 -

- MARIO-P platform study in multiple solid tumors to be initiated on a rolling basis in 3Q 2022 -

CAMBRIDGE, Mass. — (BUSINESS WIRE) — January 05, 2022 — Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) a clinical-stage biotechnology company developing eganelisib, a first-in-class, oral, immuno-oncology macrophage reprogramming therapeutic, today provided an update on eganelisib clinical development plans and 2022 guidance.

“Eganelisib is a unique drug for which we have presented positive results in multiple indications where checkpoint inhibitors have provided little to no patient benefit. Based on these strong data, we will be initiating a registration study in frontline TNBC in 2022 – due to the magnitude of the unmet need in this very large patient population and the magnitude of the eganelisib benefit. Eganelisb combination therapy has demonstrated tumor volume reductions of 92.8% and 85.2%, and disease control rates of 92.8% and 81.4%, in PD-L1(+) and PD-L1 (-) frontline TNBC patients, respectively, as well as improvements in progression free survival over standard of care benchmarks regardless of PD-L1 status,” said Adelene Perkins, Chief Executive Officer and Chair, Infinity Pharmaceuticals.

“We are aggressively advancing a registration focused study in TNBC with the goal of bringing eganelisib to patients in need as quickly as possible. We also continue to be encouraged by the overall survival benefit seen in patients with urothelial cancer, and to support the initiation of future registration trials in 2023 and beyond, we are also expanding the development of eganelisib in a platform study in additional indications where checkpoint inhibitors and other current therapies have offered little benefit,” said Robert Ilaria, Jr. M.D., Chief Medical Officer, Infinity Pharmaceuticals.

Program Updates and Guidance:

- The Company plans to initiate a frontline mTNBC randomized, double-blind, pivotal trial by the end of 2022 with progression free survival (PFS) and overall survival (OS) as endpoints. In the PD-L1 negative patients eganelisib will be evaluated in combination with chemotherapy and a checkpoint inhibitor (the eganelisib triplet) vs chemotherapy. In the PD-L1 positive patients the eganelisib triplet will be evaluated vs chemotherapy and a checkpoint inhibitor. Pending feedback from a MARIO-3 end-of-Phase 2 meeting with global regulatory authorities, Infinity will finalize the MARIO-4 trial design.
- Infinity also plans to initiate MARIO-P, a platform study to evaluate the clinical benefit of eganelisib to support the initiation of future registration focused studies across various solid tumor indications, on a rolling basis in 3Q 2022.
- The Company expects multiple data releases in 2H 2022:
    - MARIO-3 study in mTNBC patients
    - MARIO-3 study in renal cell carcinoma patients
    - MARIO-275 study in urothelial cancer patients
    - Window of Opportunity IST study in head and neck squamous cell carcinoma patients sponsored by Dr. Ezra Cohen

2022 Financial Guidance:

Infinity ended 2021 with approximately $81 million in cash and investments (unaudited) and plans to report its fourth quarter and full-year 2021 financial results in March 2022. The Company expects to end 2022 with between $25 million to $35 million in cash and investments based on its current operating plans, which excludes additional financing or business activities. The company expects net loss for 2022 to range between $45 million to $55 million.

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-4 is a frontline mTNBC randomized, double-blind, pivotal trial the Company expects to initiate by the end of 2022. MARIO-3 is the first eganelisib combination study in frontline advanced cancer patients and is evaluating eganelisib in combination with Tecentriq® and Abraxane® in frontline TNBC and in combination with Tecentriq and Avastin® in frontline RCC. MARIO-275 is a randomized, controlled combination study of eganelisib combined with Opdivo® (nivolumab) in I/O naïve urothelial cancer. MARIO-P is a platform study to evaluate eganelisib to support the initiation of future registration focused studies across various solid tumor indications, which the Company expects to initiate on a rolling basis in 3Q 2022. 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 initiate the MARIO-4 registration study and the MARIO-P platform study; design plans for MARIO-4; plans to release clinical data; the Company’s estimated year end 2021 cash balance; financial guidance; plans to release 2021 financial results; 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: results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; 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.

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