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): December 10, 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

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 8.01. Other Events.

On December 10, 2021, Infinity Pharmaceuticals, Inc. (the "Company") issued a press release announcing data from MARIO-3 (MAcrophage Reprogramming in Immune Oncology), the Company's Phase 2 clinical trial evaluating eganelisib in a triple combination in the front-line setting with Tecentriq® (atezolizumab) and Abraxane® (nab-paclitaxel) in patients with unresectable locally advanced or metastatic triple negative breast cancer.

A copy 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 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 December 10, 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: December 10, 2021

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

Encouraging Updated Data from Phase 2 MARIO-3 TNBC Trial Presented at 2021 San Antonio Breast Cancer Symposium

— 88.6% of Evaluable 1L TNBC Patients Achieved Tumor Reduction —

— Disease Control Rate of 92.8% and 81.4% of Evaluable Patients with PD-L1 Positive and PD-L1 Negative Tumors, Respectively —

— Median PFS Improvement of 47% and 30% Compared to IMpassion130 Benchmark for Patients with PD-L1 Positive and PD-L1 Negative Tumors, Respectively —

— Safety Consistent with Expectations for the Three Component Drugs with No New Safety Signals —

— Investor Event with KOL Scheduled for Today, December 10, 9:30am ET —

CAMBRIDGE, Mass., December 10, 2021 /Business Wire/ -- Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) a clinical-stage biotechnology company developing eganelisib, a first-in-class, oral, immuno-oncology macrophage reprogramming therapeutic, today presented updated data from the ongoing MARIO-3 clinical study during the 2021 San Antonio Breast Cancer Symposium (SABCS). MARIO-3 is the Company's ongoing Phase 2 study evaluating eganelisib in combination with atezolizumab (Tecentriq®) and nab-paclitaxel (Abraxane®) in frontline metastatic triple negative breast cancer (TNBC).

"These promising updated data suggest that the addition of eganelisib to atezolizumab and nab-paclitaxel has the potential to provide improved patient outcomes over benchmark IMpassion130 data in front-line metastatic TNBC," said Hatem Soliman, M.D., MARIO-3 Investigator and Medical Director, Clinical Trials Office at the Moffitt Cancer Center. "Tumor reductions in 88.6% of evaluable patients were associated with a disease control rate of 81.4% in patients with PD-L1 negative tumors who are among the most challenging to treat. Importantly, we see that this impressive disease control rate is translating into durable clinical benefit, regardless of PD-L1 status, with encouraging mPFS compared to the IMpassion130 benchmark study. These compelling findings, combined with eganelisib's safety and tolerability profile, indicate that eganelisib has the potential to become an important new treatment option for advanced TNBC patients."

Adelene Perkins, Chief Executive Officer and Chair, Infinity Pharmaceuticals, said, "With a median duration of follow-up of almost 10 months, the durable clinical benefit seen with the eganelisib combination reinforces our vision of bringing better therapies to frontline TNBC patients. When compared to the IMpassion130 benchmark data, a 47% improvement in median PFS for patients with PD-L1 positive tumors and a 30% improvement in median PFS for patients with PD-L1 negative tumors provides consistent and compelling evidence of eganelisib's potential to improve outcomes for these patients."

MARIO-3 Key Data Updates:

- This data update includes 50 patients enrolled and 44 evaluable as of the October 2, 2021 data cutoff date, with a median duration of follow up of 9.9 months.
- Of evaluable patients, tumor reduction was observed in 92.8% of patients with PD-L1 positive tumors (13/14) and 85.2% of patients with PD-L1 negative tumors (22/27).
- Disease control rate (DCR)
    - 92.8% (13/14) DCR in patients with PD-L1 positive tumors: CR 14.3% (2/14), PR 57.1% (8/14), SD 21.4% (3/14)
    - 81.4% (22/27) DCR in patients with PD-L1 negative tumors: complete response (CR) 0% (0/27), partial response (PR) 48.1% (13/27), stable disease (SD) 33.3% (9/27)
- Progression free survival (PFS)
    - In patients with PD-L1(+) tumors, median PFS in MARIO-3 was 11.0 months, a 47% improvement in mPFS compared to the 7.5 months reported for atezolizumab and nab-paclitaxel alone in IMpassion130

    - In patients with PD-L1(-) tumors, median PFS in MARIO-3 was 7.3 months, a 30% improvement compared to the 5.6 months reported for atezolizumab and nab-paclitaxel alone in IMpassion130
    - 72% of the 32 PD-L1 (+) and PD-L1(-) patients treated since the June 26, 2021 data cut remain on treatment
    - 67% of the PD-L1(-) patients who reached the median PFS of 7.3 months remain on treatment
- Safety
    - MARIO-3 did not demonstrate any new safety signals compared to benchmark trials, and its safety profile was consistent with expectations for the three component drugs. The most common Grade 3 or higher treatment-related TEAEs were hepatic AEs (18%); neutropenia AEs (16%); skin AEs (12%); fatigue, diarrhea and peripheral sensory neuropathy (6% each); and vomiting and weight decreased (2% each). Seven patients (14%) discontinued treatment for treatment-related TEAEs and nine patients (18%) had treatment-related SAEs.
- Quantification across 11 paired tumor biopsies shows increased immune activation and decreased immune suppression including an increase in CD8+ T cells, activated T cells, and anti-tumor M1 macrophages and a decrease in tumor cells and pro-tumor M2 macrophages resulting in an increase in the M1:M2 ratio.
- Paired tumor biopsy data show 5 of 8 patients with PD-L1(-) tumors converting to PD-L1(+) two months after treatment utilizing the same 1% PD-L1 cutoff standard used in the benchmark IMpassion130 study. PD-L1 expression also increased in the three patients with PD-L1(+) tumors who started the study above the 1% cutoff. None of the patients converting to PD-L1(+) or patients with PD-L1(+) tumors who experienced increased PD-L1 expression had disease progression.

KOL Event Information

Infinity will host a KOL event today, December 10, 2021, at 9:30AM ET with Hatem Soliman, M.D., MARIO-3 Investigator and Medical Director, Clinical Trials Office at the Moffitt Cancer Center, to review the MARIO-3 data presented at SABCS.

To register for the webinar, please click here.

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 addresses 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® (nivolumab) in I/O naïve urothelial cancer. 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 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, including potential clinical benefit and potential to become an important treatment option; plans to present data; 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.

Tecentriq® is a registered trademark of Genentech, Inc.
Abraxane® is a registered trademark of Abraxis BioScience, LLC.
Opdivo® is a registered trademark of Bristol Myers Squibb.
Avastin® is a registered trademark of Genentech, Inc.
Doxil® is a registered trademark of Baxter Healthcare Corporation.

Contact:
Irina Koffler
LifeSci Advisors, LLC
646-970-4681
ikoffler@lifesciadvisors.com