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): May 23, 2024

Sensei Biotherapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-39980**	**83-1863385**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1405 Research Blvd, Suite 125
Rockville, MD **20850**
(Address of Principal Executive Offices) **(Zip Code)**

Registrant's telephone number, including area code: (240) 243-8000

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 Securities Exchange Act of 1934:

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common Stock	SNSE	The Nasdaq Stock Market LLC
Series A Preferred Stock Purchase Rights		The Nasdaq Stock Market LLC

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 7.01 Regulation FD Disclosure.

On May 23, 2024, Sensei Biotherapeutics, Inc. (the "Company") issued a press release titled "Sensei Biotherapeutics Presents Promising Clinical Data from Phase 1 Dose Escalation Study of SNS-101." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 and the exhibit attached hereto are being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, whether filed before or after the date hereof and regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Sensei Biotherapeutics, Inc. press release, dated May 23, 2024
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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.

Sensei Biotherapeutics, Inc.

Date: May 23, 2024

/s/ Christopher W. Gerry
Christopher W. Gerry
General Counsel and Secretary

Exhibit 99.1

Sensei Biotherapeutics Presents Promising Clinical Data from Phase 1 Dose Escalation Study of SNS-101

- Once every 3-week dosing of SNS-101 demonstrates initial signs of promising clinical activity -

- Pharmacokinetic and safety profile validate conditionally active approach -

- Investor webcast to be held on Monday, June 3 at 8:00 a.m. ET -

BOSTON, MA – May 23, 2024– Sensei Biotherapeutics, Inc. (Nasdaq: SNSE), a clinical stage immuno-oncology company focused on the discovery and development of next-generation therapeutics for cancer patients, today reported encouraging clinical data from the dose escalation portion of its Phase 1/2 trial of SNS-101, a conditionally active, human monoclonal antibody targeting the immune checkpoint VISTA (V-domain Ig suppressor of T cell activation).

“I am pleased that SNS-101 has been well-tolerated in the study, reaching its highest planned dose level with no dose limiting toxicities and demonstrating its potential to successfully overcome the prior challenges of VISTA-targeted programs,” said Dr. Shiraj Sen, Medical Oncologist and Director of Clinical Research at NEXT Oncology, Dallas, and a principal investigator for the SNS-101 study. “The data show encouraging signs of clinical activity in a heterogeneous population of patients with advanced solid tumors, where you typically wouldn’t expect to see clinical responses, especially in microsatellite stable colorectal and endometrial tumors. There is a continued unmet need for patient populations that have become resistant or don’t respond to current immunotherapy treatment options. I look forward to continuing to evaluate its progress.”

Dose escalation portion of the Phase 1/2 clinical trial

The dose escalation portion of the Phase 1/2 clinical trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of SNS-101. This study assesses SNS-101 both as monotherapy and in combination with Regeneron’s PD-1 inhibitor Libtayo® (cemiplimab, 350 mg), in patients with advanced solid tumors with primary (unfavorable candidates for immunotherapy) or acquired PD-1 therapy resistance (progressed on prior anti-PD-1 therapy).

A total of 34 patients received SNS-101 once every 3 weeks, with 16 patients in the monotherapy arm and 18 patients in the combination arm. The majority of patients (85%) had a tumor type that is typically unresponsive to PD-1 monotherapy (“cold” tumors).

As of the April 30, 2024 data cutoff, SNS-101 demonstrated preliminary evidence of promising clinical activity in multiple tumor types, including:

- One microsatellite stable (MSS) endometrial cancer patient that received SNS-101 plus cemiplimab had a confirmed partial response (59% decrease) and remains on study at 30+ weeks. MSS endometrial cancer has been previously shown to have a low response rate to monotherapy immunotherapy treatments.
- One MSS colorectal cancer (CRC) patient that received SNS-101 plus cemiplimab remained on study for 18 weeks and had tumor regression of 27%. MSS CRC has been previously shown to be unresponsive to PD-1 treatments.

- One pembrolizumab-resistant renal cell carcinoma patient that received SNS-101 plus cemiplimab remained on study for 12 weeks and had tumor regression of 18%.
- One pembrolizumab-resistant human papillomavirus (HPV)+ head and neck cancer patient that received SNS-101 as monotherapy remained on study for 12 weeks and had tumor regression of 17%.

These clinical data are consistent with preclinical studies suggesting therapeutically relevant clinical doses of SNS-101 at 3mg/kg or higher. Additionally, preliminary flow-based pharmacodynamic analysis showed dose-dependent changes in specific T-cell populations suggesting SNS-101 may be having a pharmacological effect on T-cell subsets.

SNS-101 demonstrated a potentially best-in-class pharmacokinetic (PK) profile with linear elimination kinetics and dose-proportional increases in exposure, supporting once every three week dosing. The data are consistent with lack of target-mediated drug disposition (TMDD), which has been observed in non-conditionally active anti-VISTA antibodies.

SNS-101 was well tolerated alone and in combination with cemiplimab, with no dose-limiting toxicities observed. The majority of AEs were Grade 1 or 2 in severity. Two patients experienced Grade 1 cytokine release syndrome (CRS), one in monotherapy and one in combination, both at the highest dose of SNS-101. Both cases were mild and manageable, demonstrating that SNS-101 has the potential to overcome a key hurdle that hindered first-generation VISTA-targeting approaches. Four patients in the combination cohort experienced immune-mediated events. There were also no significant changes to key inflammatory cytokine levels, including interferon gamma, interleukin-6, interleukin-10, interleukin-8, TNF-alpha, and CCL5-RANTES, across cohorts.

“The dose escalation portion of the Phase 1/2 trial of SNS-101 answers the critical question of whether a pH-selective approach can overcome the previous hurdles associated with targeting VISTA, which included severe safety and PK issues. We believe the topline data presented today marks an important milestone and validates the mechanism of action by demonstrating the potentially best-in-class PK and a well-tolerated safety profile of SNS-101 at therapeutically relevant dose levels,” said Ron Weitzman, Chief Medical Officer of Sensei Bio. “We saw promising clinical activity primarily in tumor types that don’t typically respond to PD-1 monotherapy and look forward to progressing through the expansion phase of the study.”

Ongoing dose expansion portion of the Phase 1/2 clinical trial

Patient enrollment is advancing in the dose expansion portion of the Phase 1/2 study. The Company expects to report initial data from the dose expansion cohorts and to hold an end-of-Phase 1 meeting with the FDA by the end of 2024.

ASCO presentation

The data will be presented in a poster presentation entitled “Initial results from a first-in-human phase 1 study of SNS-101 (pH-selective anti-VISTA antibody) alone or in combination with cemiplimab in patients with advanced solid tumors,” on June 1, 2024, at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago, IL. The poster will be available on the Sensei website at the start of the poster presentation.

Investor webcast

Sensei will host a webcast on Monday, June 3, 2024, at 8:00 a.m. ET (7:00 a.m. CT) to discuss the data. Participating alongside Company management will be Dr. Shiraj Sen, M.D., Ph.D., Medical Oncologist and Director of Clinical Research at NEXT Oncology-Dallas. Dr. Sen is an investigator on the ongoing Phase 1/2 clinical trial for SNS-101, and lead author of the SNS-101 poster. The live event can be assessed here: https://lifescievents.com/event/sensei/ and can be accessed on the Investor page of Sensei's website at https://investors.senseibio.com/. A replay of the webcast will be available after the completion of the event.

About Sensei Biotherapeutics

Sensei Biotherapeutics (Nasdaq: SNSE) is a clinical stage immuno-oncology company focused on the discovery and development of next-generation therapeutics for cancer patients. Through its TMAb™ (Tumor Microenvironment Activated biologics) platform, Sensei develops conditionally active therapeutics designed to disable immunosuppressive signals or activate immunostimulatory signals selectively in the tumor microenvironment. Sensei's lead investigational candidate is SNS-101, a conditionally active antibody designed to block the V-domain Ig suppressor of T cell activation (VISTA) checkpoint selectively within the low pH tumor microenvironment, where VISTA acts as a suppressor of T cells by binding the receptor PSGL-1. The company is also developing SNS-102, a conditionally active monoclonal antibody targeting V-Set and Immunoglobulin Domain Containing 4 (VSIG-4); SNS-103, a conditionally active monoclonal antibody targeting ecto-nucleoside triphosphate diphosphohydrolase-1 (ENTPDase1), also known as CD39; and SNS-201, a conditionally active VISTAxCD28 bispecific antibody consisting of a CD28 agonist arm and a pH-sensitive anti-VISTA arm. For more information, please visit www.senseibio.com, and follow the company on X @SenseiBio and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words and phrases such as "believe", "designed to," "expect", "may", "plan", "potential", "will", and similar expressions, and are based on Sensei's current beliefs and expectations. These forward-looking statements include expectations regarding the development, potential therapeutic benefits and safety profile of Sensei's product candidates, including SNS-101, and the timing of reporting data from the Phase 1/2 study of SNS-101. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the development of therapeutic product candidates, such as the risk that any one or more of Sensei's product candidates will not be successfully developed or commercialized; the risk of delay or cessation of any planned clinical trials of Sensei's product candidates; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Sensei's product candidates; the risk that Sensei's product candidates or procedures in connection with the administration thereof will not have the safety or efficacy profile that Sensei anticipates; risks associated with Sensei's dependence on third-party suppliers and manufacturers, including sole source suppliers, over which Sensei may not always have full control; risks regarding the accuracy of Sensei's estimates of expenses, capital requirements and needs for additional financing; and other risks and uncertainties that are described in Sensei's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange

Commission (SEC) on May 9, 2024 and Sensei's other Periodic Reports filed with the SEC. Any forward-looking statements speak only as of the date of this press release and are based on information available to Sensei as of the date of this release, and Sensei assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contact:
Michael Biega
Senior Director, Investor Relations
Sensei Biotherapeutics
mbiega@senseibio.com

Media Contact:
Joyce Allaire
LifeSci Advisors
Jallaire@lifesciadvisors.com