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): February 28, 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** **(Address of Principal Executive Offices)**	**20850** **(Zip Code)**
451 D Street, Suite 710 **Boston, MA** **(Former Address of Principal Executive Offices)**	**02210** **(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 2.02 Results of Operations and Financial Condition.

On February 28, 2024, Sensei Biotherapeutics, Inc. issued a press release announcing its financial results for the full year ended December 31, 2023. A copy of the press release is attached hereto as Exhibit 99.1.

The information in Item 2.02 and the exhibit attached hereto is 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	Press Release of Sensei Biotherapeutics, Inc., dated February 28, 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: February 28, 2024

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

Exhibit 99.1

Sensei Biotherapeutics Reports Full Year 2023 Financial Results and Recent Business Highlights

- Updated dose escalation data from SNS-101 clinical study supports favorable and potentially best-in-class safety and PK profile both as monotherapy and in combination with PD-1 blockade -

- Topline efficacy and biomarker data for both monotherapy and combination arms of dose escalation study now expected in Q2 2024, ahead of previous guidance -

- Strong balance sheet with cash runway into fourth quarter of 2025 -

BOSTON, MA – February 28, 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 financial results for the full year 2023, and provided corporate updates.

"2023 saw the entry of our differentiated anti-VISTA antibody, SNS-101, into clinical development," said John Celebi, President and Chief Executive Officer. "Initial data revealed in November, and updated today, support a favorable and potentially best-in-class clinical safety and PK profile, consistent with preclinical studies, thus overcoming major hurdles associated with prior efforts to drug VISTA. We believe SNS-101 is now the first anti-VISTA therapy to reach pharmacologically relevant dose levels in a clinical study, and we are looking forward to an exciting year for Sensei. Based on the rapid pace of enrollment, we now plan to share topline efficacy and biomarker data for both monotherapy and combination arms in the second quarter of 2024, which is ahead of previous guidance. Looking ahead, part of management's attention in 2024 will be directed toward preparations for an end-of-Phase 1 meeting with FDA in the fourth quarter of 2024 and defining the paths we intend to follow over the next several years to maximize the value of SNS-101 and our additional novel product candidates."

Highlights and Milestones

SNS-101

SNS-101 is a conditionally active antibody harnessing the acidic tumor microenvironment to target the immune checkpoint VISTA (V-domain Ig suppressor of T cell activation). VISTA is implicated in numerous cancer indications and its expression correlates with low survival rates. Sensei is conducting a multi-center Phase 1/2 clinical trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of SNS-101 as both a monotherapy and in combination with Regeneron's PD-1 inhibitor Libtayo® (cemiplimab) in patients with advanced solid tumors. Recent updates include:

- As of February 23, 2024:
    - A total of 33 patients have been treated with SNS-101 +/- Libtayo in the dose escalation phase of this study.
        - In the monotherapy dose escalation arm, 16 patients have been enrolled and cleared all planned dosing cohorts of 0.3, 1, 3, 10, and 15 mg/kg.
        - In the combination dose escalation arm, 17 patients have been enrolled and cleared the first two planned dosing cohorts of 3 and 10 mg/kg + Libtayo. The third cohort at a dose level of 15.0 mg/kg of SNS-101 plus Libtayo is enrolling.

- Patient enrollment has started for the recently announced monotherapy dose expansion arm in patients with microsatellite stable (MSS) colorectal cancer (CRC) at a dose level of 15 mg/kg.
- The combination dose expansion arm will commence once the safety monitoring committee reviews the third combination dose escalation cohort.
- SNS-101 +/- Libtayo has been well tolerated in both the monotherapy and combination dose escalation cohorts with no dose-limiting toxicities observed.
    - In the monotherapy dose escalation arm, 13/16 patients (81%) experienced at least one treatment-emergent adverse event (TEAE), with the majority of adverse events (AEs) Grade 1 or 2.
    - In the combination dose escalation arm, 10/17 patients (59%) experienced at least one TEAE, with the majority of AEs Grade 1 or 2.
- SNS-101 has demonstrated potentially best-in-class pharmacokinetics, with linear elimination kinetics and dose-proportional increases in exposure across monotherapy and combination cohorts. There was no notable difference in pharmacokinetics between monotherapy and combination dosing. The pharmacokinetic data support once every 3-week dosing for SNS-101.
- As a result of rapid enrollment, Sensei now expects to report both topline monotherapy and combination dose escalation data in Q2 2024.
- Initial data for the SNS-101 dose expansion cohorts is expected by the end of 2024.

- In January 2024, Sensei announced plans to enroll up to 40 additional patients in both monotherapy and in combination with Libtayo in specific tumor types to further optimize the design of the Phase 2 trial.
    - In the monotherapy dose expansion arm, Sensei plans to enroll up to 10 patients with MSS CRC at a dose level of 15 mg/kg.
    - In the combination dose expansion arm, Sensei plans to enroll up to 30 patients with MSS CRC, head and neck cancer (H&N), non-small cell lung cancer (NSCLC), and melanoma.
    - The initially selected solid tumor types are focused on a basket of more commonly occurring histologies, including both “hot” (NSCLC, H&N, Melanoma) and “cold” (CRC) tumors. All patients with “hot” tumors enrolling into the expansion arm are expected to have been previously treated with a PD-1/L1 checkpoint inhibitor. Additional tumor types and doses may be considered for both the monotherapy and combination expansion arms.
- Sensei presented supporting SNS-101 data at numerous medical meetings throughout 2023:
    - On November 3, 2023, Sensei reported initial data from the monotherapy dose-escalation portion of the Phase 1/2 clinical trial for SNS-101 in a late-breaker poster presentation at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting, showing that SNS-101 has a potential best-in-class safety and pharmacokinetic profile.
    - On October 23, 2023, Sensei presented a trial-in-progress poster from the Phase 1/2 clinical trial for SNS-101 at the European Society for Medical Oncology Congress (ESMO) 2023.
    - On September 21, 2023, Sensei presented new preclinical data reinforcing SNS-101’s pharmacokinetic profile, safety characteristics, and mechanism of action at the Seventh Annual CRI-ENCI-AACR International Cancer Immunotherapy Conference: Translating Science into Survival (CICON).

- In February 2023, preclinical data presented at the Keystone Symposia on Next-Generation Antibody Therapeutics included crystal structure analysis further elucidating SNS-101's mechanism of action, showing that the antibody directly blocks the pH-dependent interaction between VISTA and PSGL-1.

- In February 2024, Sensei co-authored a publication discussing the development of a preclinical *in vivo* model to assess cytokine release syndrome (CRS).
- In August 2023, Sensei published a review article describing its pH-sensitive antibody engineering efforts, entitled "Conditionally Active, pH-Sensitive Immunoregulatory Antibodies Targeting VISTA and CTLA-4 Lead an Emerging Class of Cancer Therapeutics," in Antibodies, an international, peer-reviewed journal.
- In June 2023, Sensei hosted a KOL event featuring James Gulley, M.D., Ph.D., Co-Director of the Center for Immuno-Oncology at the National Cancer Institute (NCI) entitled "A New Vista for Cancer Care: Exploring SNS-101's Potential as a Transformative Treatment Option for Patients with Solid Tumors".
- Sensei announced two collaborations key to the development of SNS-101 and the Phase 1/2 clinical trial:
    - A Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), executed in February 2023, is designed to further demonstrate the role of VISTA in checkpoint resistance and will enable Sensei to explore SNS-101's potential as a combination therapy beyond anti-PD-1. The NCI will also participate as a clinical site in the Phase 1/2 clinical trial.
    - In January 2023, the Company signed a clinical supply agreement with Regeneron that will enable Sensei to evaluate SNS-101 in combination with the anti-PD1 therapy Libtayo® (cemiplimab).

Corporate Updates

- On January 4, 2024, Sensei announced the appointment of Ron Weitzman, M.D., F.A.C.P., as part-time Chief Medical Officer.
- On November 1, 2023, Sensei announced the appointment of Stephanie Krebs, MS, MBA, as Chief Business Officer.
- In January 2024, Sensei announced a realignment of its resources to fully support the Phase 1/2 clinical trial of SNS-101. As a result, Sensei has paused IND-enabling work on its preclinical-stage TMAb programs, including SNS-102 (VSIG4), SNS-103 (CD39) and SNS-201 (VISTAxCD28). Preclinical work to characterize selected lead antibodies, including their mechanisms of action, and target biology is expected to continue throughout 2024.
- As a result of this realignment of resources Sensei's cash runway now extends into the fourth quarter of 2025.

Year End 2023 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were $65.8 million as of December 31, 2023, as compared to $107.1 million as of December 31, 2022. The decrease is due to cash used to fund operations and $9.8 million relating to shares repurchased during the year ended December 31, 2023. Sensei expects its current cash balance to fund operations into the fourth quarter of 2025.

Research and Development (R&D) Expenses: R&D expenses were $18.3 million for the year ended December 31, 2023, compared to $30.4 million for the year ended December 31, 2022. The decrease in R&D expenses was primarily attributable to lower manufacturing-related expenses, lower personnel costs due to the Company's December 2022 restructuring and lower expense relating to lab supply purchases, partially offset by higher expense associated with clinical trials.

General and Administrative (G&A) Expenses: G&A expenses were $18.8 million for the year ended December 31, 2023, compared to $19.8 million for the year ended December 31, 2022. The decrease in G&A expense was primarily attributable to lower expense related to director and officer insurance and decreased personnel costs due to the Company's December 2022 restructuring.

Net Loss: Net loss was $34.1 million for the year ended December 31, 2023, compared to $48.6 million for the year ended December 31, 2022.

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 to unleash T cells against tumors. 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.

Condensed Statements of Operations

(Unaudited, in thousands except share and per share data)

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 18,299	$ 30,.383
General and administrative	18,765	19,805
Total operating expenses	37,064	50,188
Loss from operations	(37,064)	(50,188)
Total other income	2,963	1,600
Net loss	(34,101)	(48,588)
Net loss per share, basic and diluted	$ (1.22)	$ (1.58)
Weighted-average common shares outstanding, basic and diluted	27,952,857	30,703,295

Selected Condensed Balance Sheet Data

(Unaudited, in thousands)

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 13,011	$ 17,795
Marketable securities	52,746	89,321
Total assets	74,374	118,375
Total liabilities	9,479	14,968
Total stockholders' equity	64,895	103,407

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 and potential therapeutic benefits of Sensei's product candidates, the timing of Sensei's Phase 1/2 clinical trial of SNS-101, including reporting of data therefrom, the timing of preclinical R&D activities, and its belief that its existing cash and cash equivalents will be sufficient to fund its operations at least into the fourth quarter of 2025. 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 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on or about February 29, 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.

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