

**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): November 7, 2023

Sensei Biotherapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39980
(Commission
File Number)

83-1863385
(IRS Employer
Identification No.)

1405 Research Blvd, Suite 125
Rockville, MD
(Address of Principal Executive Offices)

20850
(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 November 7, 2023, Sensei Biotherapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2023. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 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	Press Release of Sensei Biotherapeutics, Inc., dated November 7, 2023
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.

Date: November 7, 2023

Sensei Biotherapeutics, Inc.

/s/ Christopher W. Gerry

Christopher W. Gerry

General Counsel and Secretary

Sensei Biotherapeutics Reports Third Quarter 2023 Financial Results and Recent Business Highlights

- SNS-101 initial Phase 1 clinical data presented at SITC demonstrate potential best-in-class safety and pharmacokinetic profile, with no cytokine release syndrome or dose-limiting toxicities reported -

- Phase 1/2 trial of SNS-101 continues to enroll ahead of schedule, with new clinical data milestones anticipated throughout 2024 -

- Strong balance sheet with cash runway into the second half of 2025 -

BOSTON, MA – November 7, 2023 – 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 third quarter ended September 30, 2023, and provided recent business updates.

“The third quarter of 2023 was marked by significant progress, culminating in the presentation of favorable clinical data supporting our belief that our lead investigational candidate SNS-101 is a potentially transformative treatment in the oncology space with a best-in-class safety and pharmacokinetic profile,” said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. “Clinical data to-date support our capability to execute on the promise and development of conditionally active antibodies, and we believe we are well-capitalized to advance SNS-101 clinically toward our near-term business and scientific milestones.”

Highlights and MilestonesSNS-101

SNS-101 is a conditionally active antibody targeting the immune checkpoint VISTA (V-domain Ig suppressor of T cell activation), which is implicated in numerous cancer indications and whose 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:

- Enrollment as of November 6, 2023:
 - A total of 17 patients have been treated with SNS-101 across various dose levels, with 14 patients in the monotherapy arm and three patients in the combination arm.
 - In the monotherapy dose escalation arm, patients are enrolling at a dose level of 15 mg/kg after clearing dose levels of 0.3, 1, 3, and 10 mg/kg.
 - In the combination dose escalation arm, three patients have been enrolled in the first cohort which has cleared a dose level of 3.0 mg/kg SNS-101 + Libtayo.

- 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, including, as of the safety cutoff date of October 3, 2023:
 - Safety, cytokine expression and pharmacokinetic data were presented for seven patients from the first three monotherapy cohorts, all of which have cleared the dose-limiting toxicity assessment period.
 - A total of 11 adverse events (including one serious adverse event not considered related to SNS-101) were reported in five patients, with no dose-limiting toxicities observed. Only one adverse event (Grade 2 dermatitis acneiform) was considered related to SNS-101.
 - There were no instances of cytokine release syndrome and no significant changes in key inflammatory cytokines over time, consistent with preclinical studies.
 - Pharmacokinetic data demonstrate dose-proportional exposure consistent with lack of target mediated drug disposition, no notable accumulation with repeat dosing, and linear elimination kinetics of SNS-101, in concordance with preclinical data.
- 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).

Anticipated milestones for the SNS-101 Phase 1/2 clinical trial include:

- Initial safety and pharmacokinetic data for the combination dose escalation arm of SNS-101 and Libtayo in Q1 2024
- Topline data for the SNS-101 monotherapy dose escalation arm in Q2 2024
- Topline data for the combination dose escalation arm of SNS-101 and Libtayo in 2024

Additional TMAb™ Pipeline and Platform Updates

Through its Tumor Microenvironment Activated biologics (TMAb) platform, Sensei is advancing several conditionally active antibody programs, including SNS-102 targeting VSIG4 (V-Set and Immunoglobulin Domain Containing 4), SNS-103 targeting ENTPDase1 (ecto-nucleoside triphosphate diphosphohydrolase-1, also known as CD39) and SNS-201, a VISTAxCD28 bispecific antibody.

Recent updates:

- Sensei has selected a lead candidate for SNS-201, a conditionally active VISTAxCD28 bispecific antibody, supporting a mechanism focused on conditional activation of CD28 within low pH environments, such as the tumor microenvironment. CD28 is a major costimulatory pathway for T cells. Based on preclinical data of SNS-201 and a prototype molecule, Sensei believes SNS-201 has the potential to conditionally activate CD28 under low pH conditions, such as those found in the tumor microenvironment, leading to stimulation of T cell activation in the tumor while minimizing off-tumor toxicity.

- Sensei has selected a lead candidate for SNS-102, a conditionally active antibody that potently blocks the interaction of VSIG4 with its novel counter-receptor and is 585-fold more selective for VSIG4 at low pH conditions. A counter-receptor has been provisionally identified and confirmation is in progress.
- Sensei is continuing to evaluate two potential antibodies as potential lead candidates for SNS-103 (targeting CD39).
- Upon successful candidate selection, Sensei expects to advance one product candidate toward early manufacturing activities and single-dose toxicology studies.
- 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.

Corporate Updates

- On November 1, 2023, Sensei announced the appointment of Stephanie Krebs, MS, MBA, as Chief Business Officer.

Upcoming Events

- Sensei will participate in the Jefferies London Healthcare Conference in London, UK from November 14-16, 2023.
- Sensei will present at the Protein & Antibody Engineering Summit (PEGS-EU) in Lisbon, Portugal on Tuesday, November 14, 2023, at 5:00 p.m. CET.

Third Quarter 2023 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were \$72.0 million as of September 30, 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 nine months ended September 30, 2023. Sensei expects its current cash balance to fund operations into the second half of 2025.

Research and Development (R&D) Expenses: R&D expenses were \$3.8 million for the quarter ended September 30, 2023, compared to \$9.2 million for the quarter ended September 30, 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 \$3.9 million for the quarter ended September 30, 2023, compared to \$4.8 million for the quarter ended September 30, 2022. The decrease in G&A expense was primarily attributable to decreased personnel costs due to the Company’s December 2022 restructuring and lower expense related to directors and officers insurance.

Net Loss: Net loss was \$7.1 million for the quarter ended September 30, 2023, compared to \$13.4 million for the quarter ended September 30, 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 Twitter @SenseiBio and [LinkedIn](#).

Condensed Statements of Operations (Unaudited, in thousands except share and per share data)

	Three Months Ended September 30,	
	2023	2022
Operating expenses:		
Research and development	\$ 3,818	\$ 9,190
General and administrative	3,919	4,751
Total operating expenses	7,737	13,941
Loss from operations	(7,737)	(13,941)
Total other income	613	525
Net loss	(7,124)	(13,416)
Net loss per share, basic and diluted	\$ (0.28)	\$ (0.44)
Weighted-average common shares outstanding, basic and diluted	25,514,115	30,720,291

Selected Condensed Balance Sheet Data (Unaudited, in thousands)

	September 30, 2023	December 31, 2022
Cash and cash equivalents	\$ 11,343	\$ 17,795
Marketable securities	60,670	89,321
Total assets	81,658	118,375
Total liabilities	10,658	14,968
Total stockholders' equity	71,000	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 selection of product candidates, and its belief that its existing cash and cash equivalents will be sufficient to fund its operations at least into the second half 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 Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) on or about November 7, 2023 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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