

**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 14, 2024

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 14, 2024, Sensei Biotherapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2024. 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 14, 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.

Date: November 14, 2024

Sensei Biotherapeutics, Inc.

/s/ Christopher W. Gerry

Christopher W. Gerry

General Counsel and Secretary

Sensei Biotherapeutics Reports Third Quarter 2024 Financial Results and Recent Business Highlights

- SNS-101 Phase 1/2 dose expansion clinical data expected in the first half of 2025 -

- Organizational restructuring to focus resources on advancing the clinical development of SNS-101 -

- Cash runway extended into the second quarter of 2026 -

BOSTON, MA – November 14, 2024 – Sensei Biotherapeutics, Inc. (Nasdaq: SNSE), a clinical stage biotechnology 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, 2024, and provided corporate updates.

“The third quarter of 2024 saw significant progress in advancing patient enrollment in the dose expansion portion of the Phase 1 study for SNS-101 across dose levels and patients with primary and acquired resistance to PD-1 inhibitors. Looking ahead, management has focused its attention on preparing for Phase 2 studies,” said John Celebi, President and Chief Executive Officer. “We believe SNS-101 has disruptive potential for the treatment of a multitude of cancer indications and for this reason we are making the difficult decision to reduce our headcount to focus our resources on advancing the clinical development of SNS-101. We anticipate that these changes will extend our cash runway into the second quarter of 2026. We look forward to sharing a clinical update focused primarily on the activity profile of SNS-101 and additional details about the design of Phase 2 studies. I want to express my gratitude to all our affected employees for the contributions they have made to the Company.”

Clinical Highlights and Milestones**SNS-101**

SNS-101 is a conditionally active antibody designed to selectively target the immune checkpoint VISTA (V-domain Ig suppressor of T cell activation) within the tumor microenvironment. 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.

- Patient enrollment is advancing in the dose expansion portion of the Phase 1/2 study, with approximately half of the dose expansion study enrolled. To further the Company’s objective of generating clinical data that informs both the optimal dose and patient population for Phase 2 studies, including comprehensive data from patients with both primary and acquired resistance to PD-1 inhibitors, the Company expects to report clinical data across two dose levels in multiple tumor types in the first half of 2025.

- Sensei received preliminary guidance from the FDA on the dose optimization strategy for SNS-101. The Company plans to re-engage with the agency following additional data from the dose expansion portion of the Phase 1/2 clinical trial.
- SNS-101 continues to be well tolerated with a best-in-class pharmacological profile among anti-VISTA antibodies.
- In November, Sensei presented an overview of SNS-101 at PEGS Europe: Protein and Antibody Engineering Summit.
- In November, the Company presented data on spatial proteomic profiling of VISTA and PSGL-1 interactions across cancer indications in a poster presentation at the Society of Immunotherapy Cancer (SITC) 39th Annual Meeting.

Corporate Updates

- Sensei is announcing an organizational restructuring to streamline operations and focus resources on advancing the clinical development of SNS-101. The Company will close its research site in Rockville, Maryland and reduce its workforce by approximately 46 percent, with most of the headcount reductions in the Company's preclinical research and development group. These changes are anticipated to extend cash runway into the second quarter of 2026.
- In July, the Company announced the appointment of Josiah Craver as Senior Vice President, Finance. In September, Josiah was appointed as the Company's principal financial officer and principal accounting officer.

Third Quarter 2024 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were \$47.0 million as of September 30, 2024. Sensei expects its current cash balance to fund operations into the second quarter of 2026.

Research and Development (R&D) Expenses: R&D expenses were \$4.6 million for the quarter ended September 30, 2024, compared to \$3.8 million for the quarter ended September 30, 2023. The increase in R&D expenses was primarily attributable to higher expense associated with clinical trials, personnel costs and manufacturing related expense partially offset by lower costs for preclinical research and lower consulting fees.

General and Administrative (G&A) Expenses: G&A expenses were \$3.2 million for the quarter ended September 30, 2024, compared to \$3.9 million for the quarter ended September 30, 2023. The decrease in G&A expense was primarily attributable to decreased costs associated with insurance premiums as well as lower outside services expense, personnel costs and license fees.

Net Loss: Net loss was \$7.3 million for the quarter ended September 30, 2024, compared to \$7.1 million for the quarter ended September 30, 2023.

About Sensei Biotherapeutics

Sensei Biotherapeutics (Nasdaq: SNSE) is a clinical stage biotechnology 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 product 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. 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)

	Three Months Ended September 30,	
	2024	2023
Operating expenses:		
Research and development	\$ 4,637	\$ 3,818
General and administrative	3,186	3,919
Total operating expenses	7,823	7,737
Loss from operations	(7,823)	(7,737)
Total other income	570	613
Net loss	(7,253)	(7,124)
Net loss attributable to common stockholders	(7,253)	(7,124)
Net loss per share, basic and diluted	\$ (0.29)	\$ (0.28)
Weighted-average common shares outstanding, basic and diluted	25,147,999	25,514,115

Selected Condensed Balance Sheet Data (Unaudited, in thousands)

	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 19,131	\$ 13,011
Marketable securities	27,870	52,746
Total assets	53,254	74,374
Total liabilities	7,475	9,479
Total stockholders' equity	45,779	64,895

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, and its belief that its existing cash and cash equivalents will be sufficient to fund its operations into the second quarter of 2026. 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 November 14, 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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