

**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): March 28, 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)

**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		The Nasdaq Stock Market LLC
Purchase Rights		

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 March 28, 2023, Sensei Biotherapeutics, Inc. issued a press release announcing its financial results for the full year ended December 31, 2022. 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

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Press Release of Sensei Biotherapeutics, Inc., dated March 28, 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: March 28, 2023

Sensei Biotherapeutics, Inc.

/s/ Christopher W. Gerry

Christopher W. Gerry
General Counsel

Sensei Biotherapeutics Reports Full Year 2022 Financial Results and Recent Business Highlights

- Investigational New Drug (IND) application submitted for lead candidate SNS-101, a conditionally active VISTA-blocking antibody -

- New collaborations with Regeneron, the National Cancer Institute and Washington University in St. Louis will support development of SNS-101 -

- Company anticipates advancing a second TMAb™ program to IND-enabling studies following successful candidate selection -

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

BOSTON, MA – March 28, 2023 – Sensei Biotherapeutics, Inc. (Nasdaq: SNSE), an immuno-oncology company focused on the discovery and development of next-generation therapeutics for cancer patients, today reported financial results for full-year 2022 and provided recent business updates.

“Over the last year the team has worked with urgency to test the biological rationale for our lead product candidate, SNS-101, as a potentially transformative therapeutic option for patients with solid tumors,” said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. “We remain committed to the belief that VISTA has tremendous potential as an immune checkpoint target and continue to take steps to prioritize the advancement of SNS-101. We are pleased that, despite industry headwinds, our work has culminated in the recent submission of an IND to begin a Phase 1/2 clinical trial with the support of our partners. We’re also excited about the overall progress of programs generated through our TMAb™ platform, including SNS-102 and SNS-103, and look forward to advancing other conditionally active antibodies that ignite and deploy the immune system’s full potential to fight cancer.”

Added Mr. Celebi, “Following the streamlining and realignment of the Company’s resources to support its key indications and programs, including reductions in operating expenses, employee-related costs and occupancy costs, our programs are supported by a healthy cash position that provides runway into the second half of 2025. We are confident in our strategy and expect to continue achieving critical near-term milestones across our pipeline.”

Highlights and Milestones

SNS-101

Sensei continues to advance SNS-101, a conditionally active antibody targeting the immune checkpoint VISTA (V-domain Ig suppressor of T cell activation), which is implicated in resistance to PD-1/PD-L1 therapy and whose expression correlates with poor survival across numerous cancers. Recent updates for SNS-101 include:

- In March 2023, Sensei submitted an IND application to the U.S. Food and Drug Administration for the planned Phase 1/2 clinical trial of SNS-101 in patients with solid tumors.

- In November 2022, Sensei presented preclinical data on SNS-101 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, highlighting the antibody's potentially improved safety, pharmacokinetic and efficacy profile over non-conditionally active VISTA-blocking antibodies. Presented data showed a significantly lower risk of inducing cytokine release syndrome (CRS), linear elimination kinetics and avoidance of target-mediated drug disposition and significant enhancement of anti-tumor effects in combination with anti-PD-1 antibodies.
- Additional preclinical data presented at the Keystone Symposia on Next-Generation Antibody Therapeutics in February 2023 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.
- New preclinical efficacy data support a rationale for SNS-101 both as monotherapy and in combination with PD-1 blockade for patients with solid tumors.

Key Collaborations Supporting SNS-101

Sensei recently announced three collaborations key to the development of SNS-101 and the planned Phase 1/2 clinical trial in solid tumors:

- 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.
- 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).
- In November 2022, Sensei announced a Sponsored Research Agreement with Washington University in St. Louis to support research into the underlying molecular mechanisms that enable SNS-101 to overcome myeloid cell-driven immunosuppression within the tumor microenvironment.

Additional TMAb Platform Updates

Through its proprietary Tumor Microenvironment Activated biologics (TMAb) platform, Sensei is also advancing several pH-sensitive antibodies, including SNS-102 targeting VSIG4 (V-Set and Immunoglobulin Domain Containing 4) and SNS-103 targeting ENTPDase1 (ecto-nucleoside triphosphate diphosphohydrolase-1, also known as CD39).

- SNS-102: Eight parental pH-sensitive VSIG4 antibodies have been selected for lead optimization. Data on this program presented at SITC in November 2023 characterized endogenous expression patterns of VSIG4 in polarized macrophage populations and showed robust VSIG4-mediated suppression of primary human T-cells. Additionally, Sensei reported that a ligand receptor capture-trifunctional chemoproteomic (LRC-TriCEPS)-based proteomics strategy identified receptors on primary human T-cells that interact with recombinant VSIG4 protein.
- SNS-103: Sensei has identified eight parental pH-sensitive CD39 antibodies and begun further optimization on a lead antibody set.

Upcoming Milestones

- Sensei will present preclinical data on its SNS-103 program at the American Association for Cancer Research (AACR) Annual Meeting in a poster session on April 18, 2023.
- Sensei remains on track to select product candidates for both SNS-102 and SNS-103 in 2023. Upon successful candidate selection, Sensei expects to advance at least one product candidate to IND-enabling studies.
- The Company has initiated early discovery efforts for a fourth TMAb program.

Cost Savings

- Following the streamlining and realignment of the Company's resources to support its key indications and programs, including reductions in operating expenses, employee-related costs and occupancy costs, Sensei projects it has a cash runway into the second half of 2025.
- As a result of the Company's prudent fiscal strategy, Sensei expects significant cost savings while preserving the ability to fund development and continuation of programs for potential nearer-term data catalysts.

Corporate Updates

- In December 2022, Sensei promoted Edward van der Horst, Ph.D., to Chief Scientific Officer.

Year End 2022 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were \$107.1 million as of December 31, 2022, as compared to \$147.6 million as of December 31, 2021. 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 \$30.4 million for the year ended December 31, 2022, compared to \$21.7 million for the year ended December 31, 2021. The increase in R&D expenses was primarily attributable to increased manufacturing and early development activities for the Company's lead program SNS-101, partially offset by a decrease in clinical trial expenses.

General and Administrative (G&A) Expenses: G&A expenses were \$19.8 million for the year ended December 31, 2022, compared to \$15.8 million for the year ended December 31, 2021. The increase in G&A expense was primarily attributable to external professional services and personnel costs.

Net Loss: Net loss was \$48.6 million for the year ended December 31, 2022, compared to \$36.8 million for the year ended December 31, 2021.

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

	Twelve Months Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 30,383	\$ 21,662
General and administrative	19,805	15,820
Total operating expenses	50,188	37,482
Loss from operations	(50,188)	(37,482)
Total other income	1,600	688
Net loss	(48,588)	(36,794)
Net loss per share, basic and diluted	\$ (1.58)	\$ (1.33)
Weighted-average common shares outstanding, basic and diluted	30,703,295	27,710,686

Selected Condensed Balance Sheet Data
(Unaudited, in thousands)

	December 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 17,795	\$ 7,159
Marketable Securities	89,321	140,462
Total assets	118,375	153,225
Total liabilities	14,968	6,712
Total stockholders' equity (deficit)	103,407	146,513

About Sensei Biotherapeutics

Sensei Biotherapeutics (Nasdaq: SNSE) is an 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 conditional binding monoclonal antibody targeting V-Set and Immunoglobulin Domain Containing 4 (VSIG-4), as well as SNS-103, also a conditionally active monoclonal antibody targeting ecto-nucleoside triphosphate diphosphohydrolase-1 (ENTPDase1), also known as CD39. For more information, please visit www.senseibio.com, and follow the company on Twitter @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 and potential therapeutic benefits of Sensei’s product candidates, the expected safety profile of Sensei’s product candidates, the availability of data from Sensei’s preclinical studies, 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 first 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 we anticipate; risks associated with Sensei’s dependence on third-party suppliers and manufacturers, including sole source suppliers, over which we may not always have full control; risks regarding the accuracy of our 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 8, 2022 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:

Chris Railey
Ten Bridge Communications
chris@tenbridgecommunications.com