

**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 9, 2021

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

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 9, 2021, Sensei Biotherapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2021. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 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 9, 2021
104	Cover Page Interactive Data file (embedded within the Inline XBRL document)

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 9, 2021

Sensei Biotherapeutics, Inc.

/s/ John Celebi

John Celebi

President and Chief Executive Officer



Sensei Biotherapeutics Reports Third Quarter 2021 Results and Recent Business Highlights

- SNS-101 identified as a tumor-selective anti-VISTA antibody product candidate from TMAb platform -

- SNS-101 preclinical data accepted for presentation at the Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting; abstract available online in the Journal for Immunotherapy of Cancer -

- VISTA science symposium to be webcast Tuesday, November 16 at 4:00 p.m. ET -

- Ended third quarter 2021 with cash, cash equivalents and marketable securities of 156.7 million; company reiterated cash runway at least into first half 2024 -

BOSTON, MA – November 9, 2021 – Sensei Biotherapeutics, Inc. (NASDAQ: SNSE), an immunotherapy company focused on the discovery and development of next generation therapeutics for cancer, today reported financial results for the third quarter ended September 30, 2021 and provided recent corporate updates.

“In the third quarter, we witnessed rapid preclinical progress with our TMAb platform, which is designed to address the challenge of resistance to checkpoint blockade. The global PD-1/PD-L1 checkpoint inhibitor market in 2020 was valued at greater than \$30 billion¹, yet approximately only 20-30 percent of people respond to treatment²,” said John Celebi, president and chief executive officer of Sensei Biotherapeutics. “VISTA is an immune checkpoint that is widely expressed on myeloid cells within the tumor microenvironment, a hub of immunosuppressive activity, and is implicated in resistance to checkpoint blockade. VISTA has been historically difficult to address therapeutically due to the presence of a pharmacokinetic sink in the blood and unique pH-dependent biology where the pH of the tumor is more acidic than the rest of the body. We have identified a promising first product candidate, SNS-101, by characterizing a robust set of pH-selective fully human anti-VISTA antibodies. Later this week at SITC, we plan to present preclinical data demonstrating how we rationally designed SNS-101 to block VISTA at low pH within the tumor microenvironment and present initial *in vivo* data with SNS-101.”

Mr. Celebi continued, “We also continue to advance our ImmunoPhage platform to generate new tumor-specific T-cells and are looking forward to providing more updates when we finalize the genetic design of the new ImmunoPhage backbone. Importantly, we are well funded with more than \$156 million to advance our two platforms.”

¹ PD-1 and PD-L1 Inhibitors Market Size In 2021 - MarketWatch, 360Research.

² Jin-Yu Sun, Resistance to PD-1/PD-L1 blockade cancer immunotherapy: mechanisms, predictive factors, and future perspectives, volume 8, Biomarker Research, 2020.

Third Quarter Highlights and Pipeline Milestones:

TMAb™ (Tumor Microenvironment Activated Biologics) Platform

VISTA (V-domain Ig suppressor of T cell activation) is an immune checkpoint that is implicated in resistance to PD-1/PD-L1 and correlates with poor survival across numerous cancers. In the third quarter, Sensei achieved the following milestones for this program:

- In August, Sensei announced it had selected SNS-101, a potent pH-dependent product candidate that selectively blocks the interaction of VISTA with its receptor, PSGL-1, in the low pH tumor microenvironment. The identification of SNS-101 was partly based on nonclinical data from a human VISTA knock-in mouse model, which showed that TMAb antibodies significantly enhanced anti-tumor responses in combination with PD-1 blockade compared to treatment with PD-1 blockade alone.
- In July, Sensei selected a CDMO for the manufacture of GMP-grade material to advance its SNS-VISTA program toward clinical studies.
- In September, Sensei announced that an abstract for SNS-101 was accepted for poster presentation at the Society for Immunotherapy of Cancer's (SITC) Annual Meeting being held in Washington, D.C. from November 10—14, 2021. Data highlighted in the poster are the first preclinical data to be presented by Sensei Bio in a scientific forum from the company's TMAb platform.
- Sensei will host a virtual science symposium on Tuesday, November 16, 2021, at 4:00 p.m. Eastern Time to discuss the potential of the VISTA checkpoint inhibitor to address current limitations of immune checkpoint therapy. The event will be hosted by Sensei's management team and will include a presentation on VISTA biology by Robert Schreiber, Ph.D., the Andrew M. Bursky and Jane M. Bursky Distinguished Professor of Pathology and Immunology, Professor of Molecular Microbiology and co-leader of the tumor immunology program at the Siteman Comprehensive Cancer Center and Founding Director of the Center for Human Immunology and Immunotherapy Programs at the Washington University School of Medicine. A live webcast of the symposium will be available under "Events & Presentations" in the Investors section of the company's website at www.senseibio.com. An archived replay will be available for approximately 90 days following the event.
- Sensei has initiated IND-enabling studies for SNS-101. Key nonclinical studies include the generation of a broader set of *in vivo* efficacy data from Sensei's human VISTA knock-in mouse models, nonclinical pharmacokinetic data, and nonclinical safety data.

VSIG4 (V-Set and Immunoglobulin Domain Containing 4) is a B7-family related protein and a potent inhibitor of T-cell activity, frequently overexpressed on tumor-associated macrophages and a potential driver of immunosuppressive macrophage polarization. VSIG4 is implicated in resistance to checkpoint blockade. Expression of VSIG4 is also found within normal tissues, presenting potential safety challenges, making VSIG4 an ideal candidate for Sensei's TMAb platform.



- Sensei has initiated its antibody discovery campaign.
- Sensei plans to select a product candidate from this program in 2023.

ImmunoPhage™ Platform

SNS-401-NG is a potential first-in-class, multi-antigenic personalized ImmunoPhage candidate being developed in collaboration with the University of Washington designed to treat a broad range of cancers. The first proof-of concept clinical application is directed to the treatment of Merkel Cell Carcinoma (MCC), an aggressive form of skin cancer commonly driven by the Merkel Cell Polyoma Virus. Once clinical proof of concept is achieved, Sensei plans to evaluate a broader study in patients with multiple tumor types, potentially including head and neck cancer, lung cancer, melanoma, and triple negative breast cancer based on the prevalence of Phortress antigens.

- Sensei is finalizing the genetic design of its next generation ImmunoPhage, which will serve as the backbone for delivery of anti-tumor antigens to the immune system.
- Sensei intends to initiate IND-enabling studies for this product candidate in the second half of 2022.

Corporate

- In August, Sensei strengthened its board of directors with the appointment of Kristian Humer as an independent director to its Board.
- In October, the company promoted Edward van der Horst, Ph.D. to Senior Vice President, TMAb Research. The company plans to hire additional team members to extend the capabilities of its TMAb and ImmunoPhage programs.

Third Quarter 2021 Financial Results

Cash Position – Cash, cash equivalents and marketable securities were \$156.7 million as of September 30, 2021, as compared to \$16.6 million as of December 31, 2020. Sensei expects the current cash balance to fund operations at least into the first half of 2024.

Research and Development (R&D) Expenses – R&D expenses were \$6.4 million for the quarter ended September 30, 2021, compared to \$3.6 million for the quarter ended September 30, 2020.



The increase in R&D expenses was primarily attributable to increased headcount to support Sensei's research, development, and manufacturing activities.

General and Administrative (G&A) Expenses – G&A expenses were \$3.9 million for the quarter ended September 30, 2021, compared to \$1.8 million for the quarter ended September 30, 2020. The increase in G&A expenses was primarily attributable to higher personnel costs, including stock-based compensation expense, and costs associated with operating as a public company.

Net Loss – Net loss was \$9.7 million, for the quarter ended September 30, 2021, compared to \$5.4 million for the quarter ended September 30, 2020.

About SNS-101

SNS-101 is a potent, pH-dependent fully human monoclonal antibody designed to block the interaction of VISTA, a novel immune checkpoint that is expressed primarily on myeloid cells, with its receptor, PSGL-1. Selectivity is achieved because SNS-101 targets the active (i.e., protonated) VISTA present in the low pH tumor microenvironment. SNS-101 was selected based on 1) the lack of significant binding to VISTA at physiologic pH (i.e., deprotonated VISTA in the blood), and 2) its high-affinity binding to active VISTA (pH 6.0), which yielded a > 600-fold selectivity. Based on the biochemical properties of SNS-101, we anticipate tumor microenvironment selective activity for this preclinical product candidate. VISTA has been shown to be expressed in numerous tumor types, including non-small cell lung cancer (NSCLC).

About Sensei Biotherapeutics

Sensei Biotherapeutics is a biopharmaceutical company engaged in discovery, development, and delivery of next generation immunotherapies with an initial focus on treatments for cancer. Sensei has developed two unique approaches – its TMAB™ (Tumor Microenvironment Activated biologics) platform, comprising unique human monoclonal antibodies and alpaca derived nanobodies that are selectively active in the tumor microenvironment, and its ImmunoPhage™ platform that leverages bacteriophage to drive the generation of tumor antigen-specific immune responses. Using its TMAB platform, the company has developed SNS-101, an antibody-based therapeutic targeting an immune checkpoint gene that inhibits anti-tumor immune responses called V-domain Ig suppressor of T cell activation (VISTA). Using the ImmunoPhage platform, Sensei is developing a library of ImmunoPhage, called Phortress™, with multiple tumor-associated antigens to create a personalized, yet off-the-shelf cocktail approach for treating cancer patients. The platform is designed to enable efficient, scalable and cost-effective manufacturing to support all of Sensei's clinical programs. SNS-401-NG is an ImmunoPhage cocktail in preclinical development for the treatment of Merkel Cell Carcinoma. 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 such as “believe”, “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 of Sensei’s product candidates and platforms, the availability of data from Sensei’s preclinical studies, and its belief that its existing cash and cash equivalents will be sufficient to fund its operations at least into the first half of 2024. 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 preclinical discovery and development, conduct of clinical trials and related regulatory requirements, Sensei’s reliance on third parties over which it may not always have full control, 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 March 30, 2021 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.



Condensed Statement of Operations
(unaudited, in thousands except share and per share data)

	Three Months Ended September 30,	
	2021	2020
Operating expenses:		
Research and development	\$ 6,443	\$ 3,576
General and administrative	3,873	1,788
Total operating expenses	10,316	5,364
Loss from operations	(10,316)	(5,364)
Total other income (expense)	631	(3)
Net loss	(9,685)	(5,367)
Cumulative dividends on convertible preferred stock	—	—
Net loss attributable to common stockholders	(9,685)	(5,367)
Net loss per share, basic and diluted	\$ (0.32)	\$ (3.00)
Weighted-average common shares outstanding, basic and diluted	30,588,495	1,787,124

Selected Condensed Balance Sheet Data
(Unaudited, in thousands)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 9,533	\$ 16,596
Marketable Securities	147,129	—
Total assets	161,249	21,428
Total liabilities	6,041	5,535
Convertible preferred stock (Series AA)	—	61,411
Convertible preferred stock (Series BB)	—	10,925
Total stockholders' equity (deficit)	155,208	(56,443)

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