

**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 10, 2022

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.)

451 D Street, Suite 710
Boston, MA
(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

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 10, 2022, Sensei Biotherapeutics, Inc. issued a press release announcing its financial results for the full year ended December 31, 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	<u>Exhibit Description</u>
99.1	Press Release of Sensei Biotherapeutics, Inc., dated March 10, 2022
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: March 10, 2022

Sensei Biotherapeutics, Inc.

/s/ John Celebi

John Celebi

President and Chief Executive Officer



Sensei Biotherapeutics Reports Full Year 2021 Financial Results and Business Highlights

- Reported preclinical proof of concept data from TMAb platform demonstrating potent and selective pH-dependent binding to “active” VISTA -
- Initiated 2 new therapeutic programs and IND-enabling studies with SNS-101, a tumor-selective anti-VISTA antibody product candidate from TMAb platform -
- Strengthened management team and Board of Directors with key appointments -
- Ended fourth quarter 2021 with strong cash, cash equivalents and marketable securities position of \$147.6 million; company reiterated cash runway at least into first half of 2024

BOSTON, MA – March 10, 2022 – 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 2021 and provided recent corporate updates.

“In 2021, we established important proof points for our SNS-101 program, which is designed to block the VISTA immune checkpoint,” said John Celebi, president and chief executive officer of Sensei Biotherapeutics. “VISTA is widely expressed on myeloid cells, presenting a challenge for drug development, yet plays a decisive role in suppressing the immune system in a broad set of tumor types. SNS-101 is a potent and pH-selective fully human anti-VISTA antibody that is designed to be highly selective for tumors and therefore has potential to overcome historical challenges associated with targeting VISTA.”

Mr. Celebi continued, “More broadly, our TMAb platform represents a fundamental advance for a number of important immune targets that are expressed in both normal tissues and tumors, avoiding potential pharmacokinetic sinks and on-target, off-tumor toxicities. Importantly, we are well funded with more than \$147 million as of December 31, 2021 to advance our programs.”

2021 Highlights and Milestones:

Pipeline

SNS-101 is a monoclonal antibody targeting the immune checkpoint VISTA and is currently in IND-enabling studies. **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 2021, Sensei achieved the following milestones for this program:

- In August, Sensei announced it had identified SNS-101, a potent pH-dependent product candidate that selectively blocks the interaction of VISTA with its receptor, PSGL-1, which occurs at low pH, as seen in the 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 November, Sensei presented a poster for SNS-101 at the Society for Immunotherapy of Cancer's (SITC) Annual Meeting being held in Washington, D.C. Data highlighted in the poster were the first preclinical data to be presented by Sensei in a scientific forum and highlighted the potency, selectivity, and mechanism of action of SNS-101.
- In November, Sensei hosted a virtual science symposium to discuss the potential of the VISTA checkpoint inhibitor to address current limitations of immune checkpoint therapy.
- Sensei entered into an agreement with a high-quality CDMO for the manufacture of GMP-grade material to advance toward clinical studies.
- 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. Sensei expects to receive pharmacokinetic and toxicology data from its single dose non-human primate studies in mid-2022 and submit an IND in the first half of 2023.

SNS-102 is a monoclonal antibody targeting **VSIG4 (V-Set and Immunoglobulin Domain Containing 4)**, a B7-family related protein that is frequently overexpressed on tumor-associated macrophages. VSIG4 is a potent inhibitor of T-cell activity and potential driver of immunosuppressive macrophage polarization. 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 TMAb antibody discovery campaign aimed at developing an inhibitory antibody with high selectivity for VSIG4 in the TME versus normal tissue environments.
- Sensei plans to select a product candidate and initiate IND-enabling studies in 2023.

SNS-103 is a monoclonal antibody targeting **ENTPDase1 (ecto-nucleoside triphosphate diphosphohydrolase-1), also known as CD39**. ENTPDase1 is the upstream, rate-limiting enzyme, leading to the breakdown of extracellular ATP. Extracellular ATP represents a potent immunologic "danger signal", which drives immune activation. The ultimate downstream product of this pathway, adenosine, has potent immunosuppressive activity through binding to adenosine receptors. Upregulation of ENTPDase1 by tumors is common and leads to a diminished anti-tumor immune response.



- Sensei has initiated a TMAb antibody campaign aimed at developing an inhibitory antibody with high selectivity for ENTPDase1 in the TME versus normal tissue environments.
- Sensei expects to select a product candidate in 2023.

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. Sensei plans to conduct 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

- Sensei completed an upsized initial public offering of its common stock in February 2021. The gross proceeds to Sensei, before deducting underwriting discounts and commissions and other offering expenses payable by Sensei, were approximately \$152.6 million.
- Sensei Biotherapeutics completed the move of its corporate headquarters to the Seaport Innovation District in Boston, MA. The new space more than doubles the size of the company's current research and development footprint. The company's manufacturing operations remain in Rockville, MD.
- Sensei strengthened its board of directors with the appointments of Deneen Vojta, Kristian Humer, and Jessie English.
- In January 2022, Sensei announced the promotions of Erin Colgan as Chief Financial Officer and Robert Pierce, M.D., as Chief R&D Officer.
- On March 9, 2022, Sensei announced the appointment William Ringo as the Chair of the Board of Directors.

Year End 2021 Financial Results

Cash Position – Cash, cash equivalents and marketable securities were \$147.6 million as of December 31, 2021, as compared to \$16.6 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 \$21.7 million for the year ended December 31, 2021, compared to \$11.9 million for the year ended December 31, 2020, including Alvaxa IPR+D. 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 \$15.8 million for the year ended December 31, 2021, compared to \$7.5 million for the year ended December 31, 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 \$36.8 million, for the year ended December 31, 2021, compared to \$20.1 million for the year ended December 31, 2020.

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

	Year Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 21,662	\$ 11,185
General and administrative	15,820	7,528
Alvaxa IPR&D	—	738
Total operating expenses	37,482	19,451
Loss from operations	(37,482)	(19,451)
Total other income (expense)	688	(649)
Net loss	(36,794)	(20,100)
Cumulative dividends on convertible preferred stock	—	(104)
Net loss attributable to common stockholders	(36,794)	(20,204)
Net loss per share, basic and diluted	<u>\$ (1.33)</u>	<u>\$ (12.53)</u>
Weighted-average common shares outstanding, basic and diluted	<u>27,710,686</u>	<u>1,612,140</u>

Selected Condensed Balance Sheet Data
(Unaudited, in thousands)

	December 31,	December 31,
	2021	2020
Cash and cash equivalents	\$ 7,159	\$ 16,596
Marketable Securities	140,462	—
Total assets	153,225	21,428
Total liabilities	6,712	5,535
Convertible preferred stock (Series AA)	—	61,411
Convertible preferred stock (Series BB)	—	10,925
Total stockholders’ equity (deficit)	146,513	(56,443)



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 is developing 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, the timing of selection of product candidates, the timing of IND submissions to the FDA, 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.



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