

**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 25, 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 March 25, 2021, Sensei Biotherapeutics, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the year ended December 31, 2020. This press release has been furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

Exhibit Number	Exhibit Description
99.1	Press Release, dated March 25, 2021

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 25, 2021

Sensei Biotherapeutics, Inc.

/s/ John Celebi

John Celebi

President and Chief Executive Officer

Sensei Biotherapeutics Reports Full Year 2020 Results and Provides Business Update

-Successfully completed upsized IPO in February 2021 raising approximately \$152.6 million in gross proceeds –

-Large subset of data expected from ongoing Phase 1/2 study of SNS-301 in combination with pembrolizumab for the treatment of locally advanced unresectable or metastatic squamous cell carcinoma of the head and neck (SCCHN) by year-end -

BOSTON, MA and ROCKVILLE, MD. – **March 25, 2021** – Sensei Biotherapeutics, Inc. (NASDAQ: SNSE), a clinical-stage immunotherapy company focused on the discovery and development of next generation therapeutics for cancer, today reported financial results for the full year ended 2020 and provided an update on recent business progress.

“With a strong foundation built in 2020, Sensei has already achieved significant milestones in 2021, highlighted by our upsized initial public offering completed in February. Throughout 2020, we have worked diligently and efficiently to broaden our in-house R&D capabilities to deliver our novel and versatile ImmunoPhage platform and Phortress™ library to patients,” said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. “Looking ahead, we have a well-capitalized foundation on which to further advance our pipeline of immunotherapies based on our proprietary ImmunoPhage platform for the treatment of cancer. We expect to report a large additional subset of data from our ongoing Phase 1/2 study of SNS-301 in SCCHN by year-end, as well as progressing our other personalized, off-the-shelf product candidates.”

Recent Business Highlights

- **Addition to Russell 2000 Index:** On March 22, 2021, Sensei was added to the Russell 2000® Index as part of its quarterly IPO additions. The Russell 2000® Index is a subset of the Russell 3000® Index, which measures the performance of the small-cap segment of the U.S. equity market.
- **Completed Upsized Initial Public Offering** – In February 2021, Sensei completed its initial public offering of 8,030,295 shares of common stock, inclusive of the exercise by the underwriters of their option to purchase 1,030,243 shares, at a public offering price of \$19.00 per share. Gross proceeds from the IPO were \$152.6 million.
- **Completed Private Financing to Support Pipeline Advancement** - In January 2021, Sensei announced a private financing round, co-led by Apeiron Investment Group and Catalio Capital Management, which was subsequently upsized for gross proceeds of \$34.5 million.
- **Presented Data from Ongoing Phase 1/2 Study of SNS-301 in Combination with Pembrolizumab for the Treatment of Locally Advanced Unresectable or Metastatic SCCHN** –At the Society for Immunotherapy of Cancer’s (SITC) 35th Anniversary Annual Meeting in November 2020, Sensei presented new data demonstrating that one patient with PD-L1 negative disease achieved a partial response (PR) with a tumor reduction of 43% at week 12 and

was confirmed at week 18. Additionally, one patient achieved a stable disease (SD) for more than 4 months following progressive disease (PD) after 10 months of PD-1 blockade treatment prior to study entry, and two patients achieved SD for more than 36 weeks. These data were supportive of earlier data presented at the European Society for Medical Oncology (ESMO) Virtual Congress in September 2020. Further, immunohistochemical staining of paired pre- and on-treatment biopsies (12 weeks) from the responding patient's tumor demonstrated a conversion from a PD-L1-negative, poorly inflamed phenotype into an inflamed, PD-L1-positive tumor, characterized by tumor necrosis, and abundant infiltrating immune cells, including CD4, CD8 T cells and macrophages. SNS-301 was well tolerated with no dose-limiting toxicities and observed adverse events (AEs) have primarily been either Grade 1 or 2 and mostly unrelated to treatment.

- **Advanced the ongoing SNS-301 Phase 1/2 study**—Enrollment in Stage 2 of the ongoing Phase 1/2 clinical trial commenced in the first half of 2021, including the initiation of enrollment of the newly opened PD-1 naïve cohort of the study.
- **Strengthened ImmunoPhage™ Platform with the Acquisition of Alvaxa Biosciences** – In May 2020, Sensei announced the acquisition of Alvaxa Biosciences and its existing camelid nanobody libraries, expertise in nanobody discovery, as well as its partnership with Hope Farms, LLC, a United States Department of Agriculture (USDA) licensed Alpaca farm, for the generation of future alpaca-derived nanobodies, or camelid antibodies that are small, highly-specific antigen-binding domains with high-affinity binding. Nanaobodies are a core component of Sensei's proprietary ImmunoPhage platform, enabling both precision APC targeting and the delivery of immunomodulatory payloads.
- **Expanded Executive Team and Board of Directors with Multiple Appointments** – Sensei grew its executive management team with the appointments of Anu Hoey as chief business officer, Marie-Louise Fjaellskog, M.D., Ph.D. as chief medical officer, and Robert Pierce, M.D. as chief scientific officer. In addition, Sensei added Deneen Vojta, M.D. to its board of directors.

Multiple Upcoming Anticipated Milestones for 2021 and 2022 Across Pipeline:

- Sensei expects to announce multiple updates from its SNS-301 program, a first-in-class cancer immunotherapy designed to overcome immune tolerance and induce robust and durable antigen-specific humoral and cellular responses including:
 - Initiation of a Phase 2 study in the neoadjuvant setting in combination with durvalumab
 - Commencement of an additional cohort of the ongoing Phase 1/2 study of HPV-specific E6/E7 ImmunoPhage in combination with SNS-301 and pembrolizumab
 - Announcement of a large subset of data from the Phase 1/2 study in combination with pembrolizumab for the treatment of locally advanced unresectable or metastatic SCCHN
- Sensei expects to submit an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) for its SNS-401 program, a personalized ImmunoPhage™ cocktail for the treatment of Merkel Cell Carcinoma in the first half of 2022.
- Sensei expects to initiate IND-enabling studies for its SNS-VISTA, antibody-based therapeutic targeting V-domain Ig suppressor of T cell activation (VISTA) program by year end 2021.



Full Year 2021 Financial Results

- **Cash Position** – Cash and cash equivalents were \$16.6 million as of December 31, 2020, as compared to \$0.3 million as of December 31, 2019. Total cash and cash equivalents at December 31, 2020 does not include net proceeds of approximately \$138.5 million from the company’s upsized IPO in February 2021 or the closing of the company’s final private round of financing in January 2021. Sensei expects the current cash balance to fund operations at least into the second half of 2023.
- **Research and Development (R&D) Expenses** – R&D expenses were \$11.9 million for the year ended December 31, 2020, compared to \$8.4 million for the year ended December 31, 2019 including costs related to the Alvaxa acquisition. The increase in expenses is primarily attributable to investments being made in early research and development activities and the clinical and preclinical development of SNS-301, SNS-401 and SNS-VISTA.
- **General and Administrative (G&A) Expenses** – G&A expenses were \$7.5 million for the year ended December 31, 2020, compared to \$4.1 million for the year ended December 31, 2019. The increase is mainly driven by strategic external consulting, legal and recruiting costs, as well as stock compensation.
- **Net Loss** – Net loss was \$20.1 million, for the year ended December 31, 2020, compared to \$16.7 million for the year ended December 31, 2019.

About Sensei Biotherapeutics

Sensei Biotherapeutics is a clinical-stage biopharmaceutical company focused on the discovery, development and delivery of next generation immunotherapies for the treatment of cancer and infectious diseases. The company has developed a proprietary bacteriophage-based platform, ImmunoPhage™, that enables the rapid generation of immune activating therapeutic agents that fully engage the immune system. Using the ImmunoPhage™ platform, Sensei is developing a library of ImmunoPhage, called Phortress™, to target multiple tumor-associated antigens to create a personalized yet off-the-shelf cocktail approach for treating cancer patients. The platform enables efficient, scalable and cost-effective manufacturing to support all of Sensei’s clinical programs. The company’s most advanced immunotherapy, SNS-301, a first-in-class ImmunoPhage™ targeting the tumor antigen Aspartyl beta Hydroxylase (ASPH), is currently in a Phase 1/2 clinical trial in patients with advanced Squamous Cell Carcinoma of the Head and Neck. Earlier stage programs include SNS-401, a ImmunoPhage™ cocktail for the treatment of Merkel Cell Carcinoma, and SNS-VISTA, 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).

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 potential clinical development of Sensei’s product candidates, the availability of data from Sensei’s clinical trials and the timing of regulatory filings. 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 conduct of clinical trials, 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 prospectus filed with the U.S. Securities and Exchange Commission (SEC) pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, on February 4, 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 Statements of Operations
(Unaudited, in thousands except share and per share data)

	<u>Year Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Operating expenses:		
Research and development	\$ 11,185	\$ 8,350
General and administrative	7,528	4,085
Alvaxa IPR&D	738	—
Total operating expenses	19,451	12,435
Loss from operations	(19,451)	(12,435)
Total other expense	(649)	(4,305)
Net loss	(20,100)	(16,740)
Cumulative dividends on convertible preferred stock	(104)	(3,804)
Net loss attributable to common stockholders	<u>\$ (20,204)</u>	<u>\$ (20,544)</u>
Net loss per share, basic and diluted	<u>\$ (12.53)</u>	<u>\$ (55.92)</u>
Weighted-average common shares outstanding, basic and diluted	<u>1,612,140</u>	<u>367,359</u>

Selected Condensed Balance Sheet Data
(Unaudited, in thousands)

	<u>Year Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Cash and cash equivalents	\$ 16,596	\$ 251
Total assets	21,428	1,217
Total liabilities	5,535	22,334
Convertible preferred stock	72,336	47,545
Total stockholders' deficit	(56,443)	(68,662)



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