

**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): May 12, 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 May 12, 2021, Sensei Biotherapeutics, Inc. issued a press release announcing its financial results for the three months ended March 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	Description
99.1	Press Release of Sensei Biotherapeutics, Inc., dated May 12, 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: May 12, 2021

Sensei Biotherapeutics, Inc.

/s/ John Celebi
John Celebi
President and Chief Executive Officer



Sensei Biotherapeutics Reports First Quarter 2021 Results and Provides Business Update

- ImmunoPhage™ platform programs and the VISTA program continue to advance -

- New safety and efficacy data from ongoing Phase 1/2 combination study of SNS-301 in squamous cell carcinoma of the head and neck accepted for presentation at ASCO 2021—

- Patient dosing underway in second cohort of Phase 1/2 combination study of SNS-301 in patients with no prior treatment with PD-1 blockade -

- Ended quarter with a strong cash position of \$169.4 million, runway at least into second half of 2023 -

BOSTON, MA and ROCKVILLE, MD – May 12, 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 first quarter ended March 31, 2021 and provided a business update.

“The first quarter was a productive time for Sensei with the successful execution of our IPO, continued progress with our pipeline, and expansion of our headcount to support anticipated growth,” said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. “As we approach several near-term events, we continue to believe in the strength of our proprietary ImmunoPhage platform to potentially generate multiple immune activating therapeutics and our monoclonal antibody and nanobody platform targeted to key immune pathways. We are looking forward to the presentation of more mature data from the Phase 1/2 clinical trial of SNS-301 at ASCO, and to further explore the potential breadth and depth of our programs in collaboration with leading researchers. With the proceeds raised from our recent IPO, we are well capitalized to advance our current programs and our drug discovery operations.”

Sensei Biotherapeutics is developing a pipeline of medicines designed to fulfill the substantial potential of the immune system to defeat cancer and other diseases. The company has developed two unique approaches – the ImmunoPhage™ platform, which leverages its proprietary knowledge and expertise in bacteriophage (widespread viruses that infect bacteria but not mammalian cells) immunology, and its monoclonal antibody and nanobody platform, which are comprised of unique human monoclonal antibodies and alpaca-derived nanobodies that are selectively active in the tumor microenvironment. Together, these platforms are designed to create a new class of personalized immuno-oncology medicines.

First Quarter and Recent Highlights:

- **Strengthened Immuno-Oncology Advisory Board and Board of Directors** – In May 2021, Sensei announced that it appointed Maura Gillison, M.D., Ph.D., Professor of Medicine, Thoracic/Head and Neck Medical Oncology at MD Anderson Cancer Center, and Richard Ulevitch, Ph.D., Professor of Immunology and Chairman Emeritus at The Scripps Research Institute to its Immuno-Oncology Advisory Board. In April 2021, Sensei appointed Jessie M. English, Ph.D. to its Board of Directors.



- **Completed Upsized Initial Public Offering (IPO)**– 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 were \$152.6 million.

Anticipated Pipeline Milestones and Events:

ImmunoPhage™ Platform Updates

SNS-301: a first-in-class, bacteriophage-based immune activating agent targeting human aspartate β^2 -hydroxylase (ASPH), a tumor associated antigen overexpressed in multiple tumor types – SNS-301 is being evaluated in a signal-seeking Phase 1/2 study in combination with pembrolizumab. The study is designed to have two cohorts and enroll 60 patients with locally advanced unresectable or metastatic SCCHN who did not achieve a response to prior treatment with PD-1 blockade or patients who did not receive prior therapy with PD-1 blockade. The company expects to add a third cohort by the end of 2021 to evaluate SNS-301 with HPV-specific E6/E7 ImmunoPhage.

- *American Society for Clinical Oncology (ASCO) 2021 conference:* An abstract titled: “Update on Safety and Efficacy of a Phase 1/2 Study of SNS-301 and Pembrolizumab in Patients with Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)” has been accepted for poster presentation at the 2021 ASCO Annual Meeting taking place virtually from June 4-8, 2021.
- *Phase 1/2 Topline Data Readout on Track:* Sensei remains on track to report a substantial subset of data from the Phase 1/2 study by the end of 2021.
- *Enrollment Ongoing in Frontline Therapy Trial:* Sensei announced that patient dosing has been initiated in the second cohort of the Phase 1/2 study evaluating SNS-301 as a first-line therapy in combination with pembrolizumab. The company continues to evaluate early enrollment trends in this cohort and the impact of COVID-19 on this clinical program.
- *Evaluation of New Opportunities for SNS-301 in the Neoadjuvant Setting:* Sensei’s current Phase 1/2 studies in head and neck cancer are focusing only on SNS-301 in combination with pembrolizumab (Keytruda®). Sensei has concluded its clinical trial collaboration with AstraZeneca for durvalumab (Imfinzi®). Sensei is currently evaluating additional opportunities to study SNS-301 in the neoadjuvant setting following the results in February from AstraZeneca’s Phase 3 KESTREL trial of durvalumab for the treatment of first line recurrent or metastatic head and neck squamous cell carcinoma.

SNS-401: a first-in-class personalized ImmunoPhage cocktail being developed in collaboration with the University of Washington – SNS-401 is in preclinical development for the treatment of Merkel Cell Carcinoma, an aggressive form of skin cancer commonly caused by the Merkel Cell Carcinoma Polyoma Virus.



- *IND submission planned for first half of 2022:* Sensei plans to submit an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) for its SNS-401 program in the first half of 2022.

ImmunoPhage Platform and Phortress™ Library – Phortress is Sensei’s proprietary library of ImmunoPhages, derived from antigens found across multiple patient populations and tumor types. Sensei has manufactured more than 25 ImmunoPhages and continues to add inventory to this “off-the-shelf” library as well as drive technologic innovations to the ImmunoPhage platform itself.

Monoclonal Antibody Platform Update

VISTA (V-domain Ig suppressor of T cell activation) is an immune checkpoint that inhibits anti-tumor immune responses – SNS-VISTA is in preclinical development in collaboration with Adimab LLC.

- *IND-Enabling Studies on Track:* Sensei announced it is on track to initiate IND-enabling studies for its SNS-VISTA program by year-end 2021.

Corporate Update

Sensei Biotherapeutics announced that it will move 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 will remain in Rockville, MD.

First Quarter 2021 Financial Results

Cash Position – Cash and cash equivalents were \$169.4 million as of March 31, 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 second half of 2023.

Research and Development (R&D) Expenses – R&D expenses were \$3.4 million for the quarter ended March 31, 2021, compared to \$2.2 million for the quarter ended March 31, 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 \$4.6 million for the quarter ended March 31, 2021, compared to \$1.9 million for the quarter ended March 31, 2020. The increase was primarily attributable to higher personnel costs, including stock-based compensation expense, to support Sensei’s business.

Net Loss – Net loss was \$8.0 million, for the quarter ended March 31, 2021, compared to \$4.7 million for the quarter ended March 31, 2020.

KEYTRUDA® is a registered trademark of Merck, and IMFINZI® is a registered trademark of the AstraZeneca group of companies.



About Sensei Biotherapeutics

Sensei Biotherapeutics is a clinical-stage 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 ImmunoPhage platform that leverages bacteriophage to fully engage the immune system, and its monoclonal antibody (mAb) and nanobody platform, which is comprised of unique human monoclonal antibodies and alpaca derived nanobodies that are selectively active in the tumor microenvironment. 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. Additional ImmunoPhage program is SNS-401, an ImmunoPhage cocktail in preclinical development for the treatment of Merkel Cell Carcinoma. Using its mAb platform, the company has developed SNS-VISTA, an antibody-based therapeutic in lead generation targeting an immune checkpoint gene that inhibits anti-tumor immune responses called V-domain Ig suppressor of T cell activation (VISTA). 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 potential clinical development of Sensei's product candidates, the availability of data from Sensei's clinical trials and the timing of regulatory filings, and its belief that its existing cash and cash equivalents will be sufficient to fund its operations at least into the second half of 2023. 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 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 Consolidated Statements of Operations
(Unaudited, in thousands except share and per share data)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 3,365	\$ 2,195
General and administrative	4,604	1,908
Total operating expenses	7,969	4,103
Loss from operations	(7,969)	(4,103)
Total other expense	(3)	(589)
Net loss	(7,972)	(4,692)
Cumulative dividends on convertible preferred stock	—	(104)
Net loss attributable to common stockholders	\$ (7,972)	\$ (4,796)
Net loss per share, basic and diluted	\$ (0.42)	\$ (4.00)
Weighted-average common shares outstanding, basic and diluted	18,904,853	1,199,550

Selected Condensed Consolidated Balance Sheet Data
(Unaudited, in thousands)

	March 31,	December 31,
	2021	2020
Cash and cash equivalents	\$169,418	\$ 16,596
Total assets	174,476	21,428
Total liabilities	3,224	5,535
Convertible preferred stock	—	72,336
Total stockholders' equity (deficit)	171,252	(56,443)

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