

**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): June 28, 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 7.01 Regulation FD Disclosure.

On June 28, 2021, Sensei Biotherapeutics, Inc. (the “**Company**”) issued a press release announcing the prioritization of its next-generation, multi-antigenic ImmunoPhage platform, monoclonal antibody and nanobody programs, as well as information regarding a conference call to discuss these company updates. The Company’s press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished pursuant to Item 7.01 and 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 liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this item of this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated June 28, 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: June 28, 2021

Sensei Biotherapeutics, Inc.

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



Sensei Biotherapeutics Announces Prioritization of Next-Generation Multi-Antigenic ImmunoPhage Platform, Monoclonal Antibody and Nanobody Programs

- Company to focus on development of next-generation phage product candidates from ImmunoPhage platform and monoclonal antibody and nanobody programs -

- Discontinuation of first-generation, single-antigen phage SNS-301 program upon analysis of clinical activity and antigen specific T-cell data -

- Cash runway extended into first half of 2024 -

- Conference call scheduled for today at 4:30 p.m. ET -

BOSTON, MA, June 28, 2021 – Sensei Biotherapeutics, an immunotherapy company focused on the discovery and development of next generation therapeutics for cancer, today announced that it is reprioritizing its pipeline programs to focus on its product candidates, including its multi-antigenic next generation ImmunoPhage candidate, now referred to as SNS-401-NG, and its monoclonal antibody SNS-VISTA (V-set Immunoglobulin Domain Suppressor of T cell Activation) candidate. With this reallocation of resources, Sensei expects its cash and cash equivalents will be sufficient to fund its operations into the first half of 2024.

“Sensei’s approach to drug development is deeply rooted in targeting key mechanisms of checkpoint resistance to induce a robust, focused and coordinated immune response to cancer. We believe our next generation, multi-antigenic ImmunoPhage product candidates have the potential to drive robust antigen-specific T cell responses that will translate into clinical benefit,” said John Celebi, president and chief executive officer of Sensei Biotherapeutics. “Given the totality of data generated to-date from the Phase 1/2 combination trial of first-generation SNS-301, we believe we have captured important insights into the power of our ImmunoPhage platform that will further advance development of our pipeline product candidates. Through SNS-301, we have gained important information on key product attributes that we believe contribute to the safety and immunogenicity of our ImmunoPhage platform as well as how to manufacture and scale our product candidates. Specifically, we have learned that the use of gpD fusion as an antigen display technology is suboptimal for use in an active cancer vaccine. We believe the incorporation of new antigen attachment technologies will ensure optimal immunogenicity. We are excited by our next generation programs, and we look forward to further advancing our two ongoing programs SNS-401-NG and SNS-VISTA into the clinic and completing discovery work for our VSIG4 antibody program.”

“I would like to express my gratitude to all of the patients and their families, investigators and collaborators who participated in the SNS-301 study,” said, Marie-Louise Fjaellskog, M.D., Ph.D. chief medical officer of Sensei Biotherapeutics. “Our data-driven decision-making process is at the forefront of our work, and we are well positioned and capitalized to further progress our next-generation pipeline programs, SNS-401-NG and SNS-VISTA, by utilizing our two unique drug discovery approaches – our ImmunoPhage platform and our monoclonal antibody and nanobody platform. We look forward to initiating IND-enabling studies for SNS-VISTA by the end of 2021 and for SNS-401-NG in second half of 2022.”

SNS-301 was developed as a first-generation, bio-engineered, inactivated bacteriophage virus expressing a fragment of the tumor-associated antigen, human aspartate β -hydroxylase (ASPH), as a fusion protein to the bacteriophage lambda capsid decoration protein, gpD, for patients with locally advanced unresectable or metastatic squamous cell head and neck cancer (SCCHN). To date, 25 patients were enrolled in the Phase 1/2 clinical study and received at least one dose of SNS-301 in combination with pembrolizumab; one patient had a deep and durable partial response (PR) and 8 patients had stable diseases. While encouraged by the safety profile of the SNS-301 single antigen approach, based upon the recent analysis of antigen specific T-cell activation which did not show a significant increase in ASPH-specific T cells, including the one patient who experienced a long-standing and deep PR, and an updated analysis of clinical data, Sensei has decided to reprioritize its pipeline and refocus resources. Sensei anticipates sharing full SNS-301 clinical data and the results of specific B and T cell response data at a future scientific conference.

Next-Generation Pipeline Highlights and Upcoming Milestones

Sensei is focused on progressing novel product candidates generated from both its ImmunoPhage platform and Phortress Library™, coupled with its human monoclonal antibody and nanobody platform. Sensei's Phortress Library of immunophages, derived from antigens found across multiple patient populations and tumor types, enables a personalized, yet off-the-shelf therapeutic option to patients.

- **SNS-401-NG** is a first-in-class, multi-antigenic personalized ImmunoPhage candidate being developed in collaboration with the University of Washington. Sensei has designed SNS-401-NG as a personalized product candidate composed of premanufactured Immunophage from Sensei's Phortress library on an improved and proprietary bacteriophage construct. Sensei intends to initiate IND-enabling studies for this product candidate in the second half of 2022. The first 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. If clinical proof of concept is achieved, Sensei plans to evaluate a broader basket study in patients with head and neck cancer, lung cancer, melanoma, and triple negative breast cancer based on the prevalence of Phortress antigens.
- **VISTA (V-domain Ig suppressor of T cell activation)** is an immune checkpoint that inhibits anti-tumor immune responses. VISTA is implicated in PD-1/PD-L1 resistance and therapeutic intervention. VISTA has the potential to be effective as a monotherapy and synergistic with PD-1/PD-L1 inhibition. Sensei has generated potent pH-dependent parental antibodies that block the interaction of VISTA with its receptor, PSGL1, expected to result in a favorable pharmacokinetic (PK) profile and selective activity in the acidic tumor microenvironment – a critical feature of this product candidate, and an important differentiator to other compounds in development targeting VISTA. Sensei plans to present preclinical data from the SNS-VISTA program at a scientific conference in 2021 and to initiate IND-enabling studies by the end of 2021.
- **VSIG4 (V-Set And Immunoglobulin Domain Containing 4)** is a potent inhibitor of T cell activity, often overexpressed on macrophages within the tumor microenvironment. Sensei believes that a tumor-selective blocking monoclonal antibody will have potent anti-tumor immune effects. Sensei is extending its approach to developing antibodies with enhanced tumor selective activity to other candidate immune checkpoint targets, and anticipates selecting a product candidate from this program in 2023.

Conference Call and Webcast Information

Sensei will host a live conference and webcast today, June 28, 2021, at 4:30 p.m. ET, to discuss these company updates. To access the conference call, please dial 833-362-0204 (domestic) or 914-987-7673 (international) and refer to conference ID number 7464477. The live webcast can be accessed under the “Events & Presentations” section of Sensei’s website at www.senseibio.com. The webcast will be archived and made available for replay on Sensei’s website approximately two hours after the call and will be available for 30 days.

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 ImmunoPhage platform that leverages bacteriophage to fully engage the immune system, and its monoclonal antibody (mAb) and nanobody platform, comprising 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 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. 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 preclinical and clinical development of Sensei’s product candidates and platforms, the availability of data from Sensei’s clinical trials, and its belief that its existing cash and cash equivalents will be sufficient to fund its operations 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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