Sensei Biotherapeutics Reports First Quarter 2024 Financial Results and Recent Business Highlights

May 9, 2024

- Completed SNS-101 monotherapy and combination dose escalation through 15mg/kg with no dose limiting toxicities -

- Company to present topline clinical data from the SNS-101 Phase 1 dose escalation study at the 2024 ASCO Annual Meeting -

- Enrollment in the dose expansion portion of the clinical study advancing -

- Strong balance sheet with cash runway into fourth quarter of 2025 -

BOSTON, May 09, 2024 (GLOBE NEWSWIRE) -- Sensei Biotherapeutics, Inc. (Nasdaq: SNSE), a clinical stage immuno-oncology company focused on the discovery and development of next-generation therapeutics for cancer patients, today reported financial results for the first quarter ended March 31, 2024, and provided corporate updates.

“Building upon our initial data for SNS-101, which we believe support a favorable and potentially best-in-class clinical safety and PK profile, we now look forward to sharing topline dose escalation data at ASCO in June and initial dose expansion data in the fourth quarter of this year,” said John Celebi, President and Chief Executive Officer. “Looking ahead, we are squarely focused on advancing patient enrollment in the dose expansion cohorts, which are intended to generate additional supportive data and optimize the Phase 2 trial design for SNS-101. With cash runway into the fourth quarter of 2025, we believe we are in a strong position to build on both our clinical momentum on behalf of the patients we aim to serve and our scientific advances, as illustrated by our recent publication in *Nature Communications*.”

Highlights and Milestones

SNS-101

SNS-101 is a conditionally active antibody harnessing the acidic tumor microenvironment to selectively target the immune checkpoint VISTA (V-domain Ig suppressor of T cell activation). VISTA is implicated in numerous cancer indications and its expression correlates with low survival rates. Sensei is conducting a multi-center Phase 1/2 clinical trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of SNS-101 as both a monotherapy and in combination with Regeneron’s PD-1 inhibitor Libtayo® (cemiplimab) in patients with advanced solid tumors. Recent updates include:

- Sensei has completed enrollment in the dose escalation portion of the Phase 1/2 clinical trial of SNS-101, enrolling 16 patients in the monotherapy arm and 18 patients in the combination arm.
  - In the monotherapy dose escalation arm, patients have cleared all planned dosing cohorts of 0.3, 1, 3, 10, and 15 mg/kg.
  - In the combination dose escalation arm, patients have cleared all planned dosing cohorts of 3, 10, and 15 mg/kg of SNS-101 plus Libtayo.
  - There have been no dose limiting toxicities (DLT) observed across both the monotherapy and the combination arms.
  - Sensei will present topline clinical data from the monotherapy and combination dose escalation portion of its Phase 1/2 trial of SNS-101 in a poster presentation at the upcoming 2024 American Society of Clinical Oncology (ASCO) Annual Meeting taking place in Chicago, IL, from May 31 – June 4, 2024.
    - **Title:** Initial results from a first-in-human phase 1 study of SNS-101 (pH-selective anti-VISTA antibody) alone or in combination with cemiplimab in patients with advanced solid tumors
    - **Presenter:** Dr. Shiraj Sen
    - **Session Type:** Poster Session
    - **Session Title:** Developmental Therapeutics—Immunotherapy
    - **Date and Time:** Saturday, June 1, 2024, at 9:00 a.m. – 12:00 p.m. CDT
    - **Abstract Number:** 2600
- Patient enrollment is ongoing for both the monotherapy and combination dose expansion arms.
  - In the monotherapy dose expansion arm, Sensei is enrolling patients with microsatellite stable (MSS) colorectal

cancer (CRC) at a dose level of 15 mg/kg.
    - In the combination dose expansion arm, Sensei is enrolling patients with MSS CRC, Head and Neck (H&N) cancer, non-small cell lung cancer (NSCLC), and melanoma at a dose level of 15 mg/kg plus Libtayo.
    - The solid tumor types were selected to focus the cancer indications on a basket of more commonly occurring histologies, including both “hot” (NSCLC, H&N, Melanoma) and “cold” (CRC) tumors where the company believes SNS-101 has potential to provide clinical benefit based on VISTA biology and supporting preclinical data. Additional tumor types and doses may be considered for both the monotherapy and combination expansion arms.
    - The Company expects to report initial data from the dose expansion cohorts and hold an end-of-Phase 1 meeting with the FDA by the end of 2024.
- In April 2024, Sensei published a peer-reviewed research paper in *Nature Communications* describing the mechanism of action of SNS-101 selectively targeting the active form of VISTA within the tumor microenvironment.
- In March 2024, the company presented SNS-101 data at Keystone Symposia’s Cancer Immunotherapy: Beyond Immune Checkpoint Blockade and Overcoming Resistance.
- In February, Sensei presented at the 10th Annual Immuno-Oncology 360 Conference (IO360).

Corporate Updates

- In January 2024, Sensei announced the appointment of Ron Weitzman, M.D., F.A.C.P., as part-time Chief Medical Officer.
- In January 2024, Sensei announced a realignment of its resources to fully support the Phase 1/2 clinical trial of SNS-101. As a result, Sensei has paused IND-enabling work on its preclinical-stage TMAb programs, including SNS-102 (VSIG4), SNS-103 (CD39) and SNS-201 (VISTAxCD28). Preclinical work to characterize selected lead antibodies, including their mechanisms of action, and target biology is expected to continue throughout 2024.
- As a result of this realignment of resources Sensei’s cash runway now extends into the fourth quarter of 2025.

First Quarter 2024 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were $58.1 million as of March 31, 2024, as compared to $65.8 million as of December 31, 2023. The decrease is due to cash used to fund operations. Sensei expects its current cash balance to fund operations into the fourth quarter of 2025.

Research and Development (R&D) Expenses: R&D expenses were $4.9 million for the quarter ended March 31, 2024, compared to $5.2 million for the quarter ended March 31, 2023. The decrease in R&D expenses was primarily attributable to lower manufacturing-related expenses and lower costs related to preclinical research, primarily offset by higher expenses associated with clinical trials.

General and Administrative (G&A) Expenses: G&A expenses were $3.8 million for the quarter ended March 31, 2024, compared to $5.8 million for the quarter ended March 31, 2023. The decrease in G&A expense was primarily attributable to decreased cost for external professional services.

Net Loss: Net loss was $8.0 million for the quarter ended March 31, 2024, compared to $10.2 million for the quarter ended March 31, 2023.

About Sensei Biotherapeutics
Sensei Biotherapeutics (Nasdaq: SNSE) is a clinical stage immuno-oncology company focused on the discovery and development of next-generation therapeutics for cancer patients. Through its TMAb™ (Tumor Microenvironment Activated biologics) platform, Sensei develops conditionally active therapeutics designed to disable immunosuppressive signals or activate immunostimulatory signals selectively in the tumor microenvironment to unleash T cells against tumors. Sensei’s lead product candidate is SNS-101, a conditionally active antibody designed to block the V-domain Ig suppressor of T cell activation (VISTA) checkpoint selectively within the low pH tumor microenvironment, where VISTA acts as a suppressor of T cells by binding the receptor PSGL-1. The company is also developing SNS-102, a conditionally active monoclonal antibody targeting V-Set and Immunoglobulin Domain Containing 4 (VSIG-4); SNS-103, a conditionally active monoclonal antibody targeting ecto-nucleoside triphosphate diphosphohydrolase-1 (ENTPDase1), also known as CD39; and SNS-201, a conditionally active VISTAxCD28 bispecific antibody consisting of a CD28 agonist arm and a pH-sensitive anti-VISTA arm. For more information, please visit www.senseibio.com, and follow the company on X @SenseiBio and LinkedIn.

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

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 4,917	$ 5,204
General and administrative	3,813	5,804
Total operating expenses	8,730	11,008
Loss from operations	(8,730)	(11,008)
Total other income	738	831
Net loss	(7,992)	(10,177)
Net loss attributable to common stockholders	(7,992)	(10,177)
Net loss per share, basic and diluted	$ (0.32)	$ (0.33)

Weighted-average common shares outstanding, basic and diluted	25,049,111	30,866,087

Selected Condensed Balance Sheet Data
(Unaudited, in thousands)

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 10,956	$ 13,011
Marketable securities	47,125	52,746
Total assets	66,695	74,374
Total liabilities	8,221	9,479
Total stockholders' equity	58,474	64,895

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 and phrases such as "believe", "designed to," "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 and potential therapeutic benefits of Sensei's product candidates, the timing of Sensei's Phase 1/2 clinical trial of SNS-101, including reporting of data therefrom, the timing of preclinical R&D activities, and its belief that its existing cash and cash equivalents will be sufficient to fund its operations into the fourth quarter of 2025. 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 the risk that any one or more of Sensei's product candidates will not be successfully developed or commercialized; the risk of delay or cessation of any planned clinical trials of Sensei's product candidates; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Sensei's product candidates; the risk that Sensei's product candidates or procedures in connection with the administration thereof will not have the safety or efficacy profile that Sensei anticipates; risks associated with Sensei's dependence on third-party suppliers and manufacturers, including sole source suppliers, over which Sensei may not always have full control; risks regarding the accuracy of Sensei's estimates of expenses, capital requirements and needs for additional financing; and other risks and uncertainties that are described in Sensei's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) on May 9, 2024 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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