Sensei Biotherapeutics Reports Second Quarter 2023 Financial Results and Recent Business Highlights

August 3, 2023

Phase 1/2 clinical trial enrolling for lead investigational candidate SNS-101, a conditionally active VISTA-blocking antibody for the treatment of advanced solid tumors

A total of 6 patients in three dosing cohorts enrolled to date, with initiation of combination arm now planned for Q4 2023

Initial PK and safety data now expected by year-end 2023, and topline efficacy and biomarker data expected in 2024

Strong balance sheet with cash runway into the second half of 2025

BOSTON, Aug. 03, 2023 (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 second quarter ended June 30, 2023, and provided recent business updates.

“The second quarter of 2023 was momentous for Sensei as we moved expeditiously from the FDA’s clearance of our SNS-101 trial in April to the enrollment of six patients by the end of July. We’re encouraged by the rapid clinical enrollment activity we’ve observed so far, which suggests that we may be able to accelerate the start of the combination arm of this study,” said John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics. “We’re grateful for the efforts of the clinical investigators, patients, and families without whom this clinical trial would not be possible.”

Highlights and Milestones

SNS-101

Sensei’s lead investigational candidate is SNS-101, a conditionally active antibody targeting the immune checkpoint VISTA (V-domain Ig suppressor of T cell activation), which is implicated in numerous cancer indications and whose expression correlates with low survival rates.

Recent updates for SNS-101 include:

- An Investigational New Drug (IND) application for SNS-101 was cleared by the U.S. Food and Drug Administration (FDA) in April 2023. The cleared starting dose of 0.3 mg/kg was substantially higher than other anti-VISTA antibodies.
- On June 1, 2023, Sensei reported the first patient dosed in the dose escalation portion of the SNS-101 multi-center Phase 1/2 clinical trial. To date, Sensei has enrolled a total of 6 patients, clearing its first patient cohort at 0.3 mg/kg and its second patient cohort at 1.0 mg/kg, and is currently dosing patients in its third cohort at 3.0 mg/kg.
- As a result of the pace of enrollment to date, Sensei expects to dose the first patient in combination with Regeneron’s PD-1 inhibitor Libtayo® (cemiplimab) in Q4 2023.
- Sensei now expects to report initial pharmacokinetic (PK) and safety data by year-end 2023, and topline monotherapy data and initial combination data for the Phase 1/2 clinical trial in 2024.
- On June 27, 2023, Sensei provided an overview of SNS-101 and its Phase 1/2 clinical trial in a virtual KOL event entitled “A New VISTA for Cancer Care: Exploring SNS-101’s Potential as a Transformative Treatment Option for Patients with Solid Tumors.” A link to the event recording can be accessed on the Sensei website. For this event, Sensei welcomed James Gulley, M.D., Ph.D., Co-Director of the Center for Immuno-Oncology, and Clinical Director at the National Cancer Institute (NCI), part of the National Institutes of Health, to provide an overview of today’s immuno-oncology treatment landscape and discuss NCI’s Cooperative Research & Development Agreement (CRADA) with Sensei, which includes ongoing research to further elucidate the role of VISTA in immune checkpoint resistance, research to expand the potential of SNS-101 as a combination therapy beyond anti-PD-1, and NCI serving as a clinical site for the SNS-101 Phase 1/2 clinical trial.

Other TMAb™ Platform Updates

Through its Tumor Microenvironment Activated biologics (TMAb) platform, Sensei is advancing several conditionally active antibody programs,

including SNS-102 targeting VSIG4 (V-Set and Immunoglobulin Domain Containing 4), SNS-103 targeting ENTPDase1 (ecto-nucleoside triphosphate diphosphohydrolase-1, also known as CD39) and a recently initiated bispecific antibody program.

Recent updates include:

- Sensei has completed lead optimization for its programs SNS-102 (targeting VSIG4) and SNS-103 (targeting CD-39) and is currently characterizing potential lead antibodies for each program. Sensei remains on track to select product candidates for both SNS-102 and SNS-103 in 2023.
- Sensei's early discovery bispecific antibody program has generated an initial set of conditionally active bispecific antibodies that are currently being characterized.
- Upon successful candidate selection, Sensei expects to advance one product candidate to IND-enabling studies.

Additional Updates

Robert Schreiber, Ph.D., Professor of Pathology & Immunology and Director of the Center for Human Immunology and Immunotherapy Programs at Washington University, has been appointed Chair of Sensei's Immuno-Oncology Advisory Board. Dr. Schreiber was largely responsible for defining the concept of cancer immunoediting and his research focuses on elucidating the biochemistry and molecular cell biology of immune responses to developing and established tumors. He is an expert on VISTA, the target of Sensei's lead program SNS-101, and his laboratory at Washington University in St. Louis, MO has partnered with Sensei to support the continued clinical development of SNS-101.

Second Quarter 2023 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were $78.8 million as of June 30, 2023, as compared to $107.1 million as of December 31, 2022. The decrease is due to cash used to fund operations and $7.8 million relating to shares repurchased within the period. Sensei expects its current cash balance to fund operations into the second half of 2025.

Research and Development (R&D) Expenses: R&D expenses were $4.8 million for the quarter ended June 30, 2023, compared to $6.4 million for the quarter ended June 30, 2022. The decrease in R&D expenses was primarily attributable to lower personnel costs due to the Company's December 2022 restructuring, lower expense relating to lab supply purchases and lower manufacturing-related expenses, partially offset by increased expense relating to outside research fees and higher expense associated with clinical trials.

General and Administrative (G&A) Expenses: G&A expenses were $5.4 million for the quarter ended June 30, 2023, compared to $4.3 million for the quarter ended June 30, 2022. The increase in G&A expense was primarily attributable to external professional services, including $1.56 million of non-recurring expenses associated with stockholder activism related to our 2023 annual meeting of stockholders, partially offset by lower recruiting expense.

Net Loss: Net loss was $9.4 million for the quarter ended June 30, 2023, compared to $10.5 million for the quarter ended June 30, 2022.

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 investigational 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 conditional binding monoclonal antibody targeting V-Set and Immunoglobulin Domain Containing 4 (VSIG-4), as well as SNS-103, also a conditionally active monoclonal antibody targeting ecto-nucleoside triphosphate diphosphohydrolase-1 (ENTPDase1), also known as CD39. For more information, please visit www.senseibio.com, and follow the company on Twitter @SenseiBio and LinkedIn.

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

	Three Months Ended June 30,	
	2023	**2022**
Operating expenses:		
Research and development	$ 4,784	$ 6,393
General and administrative	5,393	4,319
Total operating expenses	10,177	10,712
Loss from operations	(10,177)	(10,712)
Total other income	791	177
Net loss	(9,386)	(10,535)
Net loss per share, basic and diluted	$ (0.31)	$ (0.34)
Weighted-average common shares outstanding, basic and diluted	30,507,018	30,701,758

Selected Condensed Balance Sheet Data
(Unaudited, in thousands)

	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 10,226	$ 17,795
Marketable securities	68,614	89,321
Total assets	89,580	118,375
Total liabilities	10,379	14,968
Total stockholders' equity	79,201	103,407

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 selection of product candidates, and its belief that its existing cash and cash equivalents will be sufficient to fund its operations at least into the second half 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 we anticipate; risks associated with Sensei's dependence on third-party suppliers and manufacturers, including sole source suppliers, over which we may not always have full control; risks regarding the accuracy of our 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 or about August 3, 2023 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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