Sionna Therapeutics Reports First Quarter 2025 Financial Results

May 12, 2025

Phase 1 dosing completed for NBD1 stabilizers SION-719 & SION-451; both compounds continue to be generally well tolerated

Phase 1 topline data anticipated this quarter

On track to initiate Phase 2a proof-of-concept trial and at least one dual combination MAD trial in the second half of 2025; topline data for both anticipated in mid-2026

Strong cash position following completed upsized IPO, with approximately $354.7 million in cash and cash equivalents, expected to fund operations into 2028

WALTHAM, Mass., May 12, 2025 (GLOBE NEWSWIRE) -- Sionna Therapeutics, Inc. (Nasdaq: SION), a clinical-stage biopharmaceutical company on a mission to revolutionize the current treatment paradigm for cystic fibrosis (CF) by developing novel medicines that normalize the function of the cystic fibrosis transmembrane conductance regulator (CFTR) protein, today reported financial results for the quarter ended March 31, 2025, and provided a business update.

"Following our upsized IPO in February, we are in a strong financial position to advance our mission to transform the treatment paradigm for patients with CF," said Mike Cloonan, President and Chief Executive Officer of Sionna. "We continue to execute across our pipeline and have completed dosing in our Phase 1 trials for both SION-719 and SION-451. We look forward to announcing topline data from these trials this quarter, and to initiating our Phase 2a POC trial and the combination MAD Phase 1 program later this year. With multiple meaningful milestones on the horizon, we are focused on execution and building on our strong momentum throughout 2025."

Pipeline Updates

NBD1 Stabilizers

- **Phase 1 Dosing Completed:** Sionna has completed dosing in the single ascending dose (SAD), multiple ascending dose (MAD), and food effect and tablet bioequivalence parts of the Phase 1 healthy volunteer trials of SION-719 and SION-451. Both compounds continue to be generally well tolerated, and their safety profiles remain consistent with prior disclosures. Full topline data are on schedule to be reported the second quarter of 2025. As previously reported in interim data, target exposures were achieved that have the potential, based on Sionna's preclinical cystic fibrosis human bronchial epithelial (CFHBE) model, to provide clinically meaningful benefit to patients if SION-719 or SION-451 were administered as part of a dual combination with one of Sionna's complementary modulators or as an add-on to the current standard of care (SOC).
- **Phase 2a Proof-of-Concept Trial:** Sionna remains on track to initiate a Phase 2a proof-of-concept (POC) trial in the second half of 2025, after completion of a drug-drug interaction trial, to evaluate an NBD1 stabilizer in combination with the current SOC in CF patients. Topline data from this trial are anticipated in mid-2026.
- **Dual Combination MAD Trials:** Sionna remains on track to initiate at least one combination MAD trial in the second half of 2025, evaluating a dual combination of an NBD1 stabilizer with a complementary modulator in healthy subjects. Topline data are expected in mid-2026.

Business Highlights

- **Completion of Upsized IPO:** In February 2025, Sionna completed its upsized initial public offering (IPO), raising approximately $219 million gross proceeds before deducting underwriting discounts and commissions and other expenses. Sionna issued 12,176,467 shares of its common stock at a public offering price of $18.00 per share, which included 1,588,234 shares issued upon the full exercise by the underwriters of their option to purchase additional shares of common stock in the offering. Shares began trading on the Nasdaq Global Market on February 7, 2025, under the symbol "SION."

Upcoming Events and Presentations

- **Presentation at 48th European Cystic Fibrosis Conference:** Preclinical data assessing combinations of Sionna's NBD1 stabilizers, SION-451 and SION-719, with complementary Sionna CFTR modulators, galifactor (SION-2222) and SION-109, will be featured in an oral presentation at the European Cystic Fibrosis Society's (ECFS) 48 th European Cystic Fibrosis Conference, being held June 4-7, 2025 in Milan, Italy. The abstract is entitled, "Stabilizers of CFTR NBD1 synergize with galicaftor (SION-2222) or SION-109 to enable full correction of ΔF508-CFTR."

Financial Results for the Quarter Ended March 31, 2025

Research and Development Expenses: Research and development expenses were $13.7 million for the first quarter of 2025, compared to $10.2 million for the first quarter of 2024. This increase was mainly driven by direct program spend to support

Sionna's clinical pipeline.

General and Administrative Expenses: General and administrative expenses were $6.0 million for the first quarter of 2025, compared to $2.9 million for the first quarter of 2024. This increase was primarily due to personnel-related costs, including stock-based compensation, and professional fees.

Net Loss: Net loss was $16.5 million for the first quarter of 2025, compared to a net loss of $11.8 million for the first quarter of 2024.

Cash and Cash Equivalents: Cash, cash equivalents and marketable securities totaled $354.7 million as of March 31, 2025, which includes net proceeds from Sionna's IPO of $199.6 million, after deducting underwriting discounts and commissions and other offering costs. Sionna expects its current cash position to fund operations into 2028.

About Sionna Therapeutics
Sionna Therapeutics is a clinical-stage biopharmaceutical company on a mission to revolutionize the current treatment paradigm for CF by developing novel medicines that normalize the function of the CFTR protein. Sionna's goal is to deliver differentiated medicines for people living with CF that can restore their CFTR function to as close to normal as possible by directly stabilizing CFTR's nucleotide-binding domain 1 (NBD1), which Sionna believes is central to potentially unlocking dramatic improvements in clinical outcomes and quality of life for people with CF. Leveraging more than a decade of the co-founders' research on NBD1, Sionna is advancing a pipeline of small molecules engineered to correct the defects caused by the F508del genetic mutation, which resides in NBD1. Sionna is also developing a portfolio of complementary CFTR modulators that are designed to work synergistically with its NBD1 stabilizers to improve CFTR function. For information about Sionna, visit www.sionnatx.com.

Sionna intends to use its Investor Relations website as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor the Company's Investor Relations website, in addition to following the Company's press releases, SEC filings, public conference calls, presentations, and webcasts.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements about Sionna's beliefs and expectations regarding: the initiation, timing, progress and results of Sionna's research and development programs, preclinical studies and clinical trials, including the timing of Phase 1 topline data for SION-719 and SION-451, and the planned initiation of combination MAD trials and a Phase 2a POC trial and the timing of topline data from these trials; the ability of clinical trials to demonstrate safety and efficacy of Sionna's product candidates; the ability of Sionna's preclinical studies to predict later clinical trial results; financial projections and expectations regarding the time period in which Sionna's capital resources will be sufficient to fund its anticipated operations, including cash runway, use of capital, expenses and other financial results; and other statements that are not historical facts. In some cases, the forward-looking statements can be identified by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by the forward-looking statements contained in this press release. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties inherent in the development of product candidates, including uncertainties concerning the initiation, timing, progress, and results of our planned and future clinical trials and studies; our ability to replicate positive results from earlier preclinical studies or clinical trials in current or future clinical trials; our ability to demonstrate that our NBD1 stabilizers, complementary CFTR modulators, and any potential future product candidates are safe and effective for their proposed indications; regulatory developments in the United States and foreign countries; and general economic, industry and market conditions. These risks and uncertainties are described in the section entitled "Risk Factors" in Sionna's most recent Annual Report on Form 10-K as well as any subsequent filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. In addition, any forward-looking statements represent Sionna's views only as of today and should not be relied upon as representing its views as of any subsequent date. Sionna explicitly disclaims any obligation to update any forward-looking statements except as required by law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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Sionna Therapeutics, Inc.
Consolidated Statements of Operations
(In thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 13,668	$ 10,220
General and administrative	5,991	2,927
Total operating expenses	19,659	13,147
Loss from operations	(19,659)	(13,147)
Other income:		
Interest income	3,000	1,132
Other income	177	168
Total other income	3,177	1,300
Net loss	$ (16,482)	$ (11,847)
Net loss per share, basic and diluted	$ (0.62)	$ (3.84)
Weighted-average common shares outstanding, basic and diluted	26,596,059	3,082,635

Sionna Therapeutics, Inc.
Selected Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	March 31, 2025	**December 31, 2024**
Cash, cash equivalents, and marketable securities	$ 354,688	$ 168,043
Working capital[1]	264,153	140,573
Total assets	369,674	185,752
Total stockholders' equity (deficit)	351,769	(163,713)

[1]Sionna defines working capital as current assets minus current liabilities.