Sionna Therapeutics Reports Second Quarter 2025 Financial Results

August 11, 2025

Announced positive Phase 1 data for SION-719 and SION-451 demonstrating both first-in-class NBD1 stabilizers were generally well tolerated and exceeded pharmacokinetic targets

Initiation of Phase 2a proof-of-concept trial of SION-719 as an add-on to standard of care in cystic fibrosis patients is on track for the second half of 2025 with topline data expected in mid-2026

Advancement of Phase 1 healthy volunteer trial of SION-451 in two proprietary dual combinations is on track for the second half of 2025 with topline data expected in mid-2026

Maintained strong cash position with approximately $337.3 million in cash and cash equivalents, expected to fund operations into 2028

WALTHAM, Mass., Aug. 11, 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 June 30, 2025, and provided a business update.

"We are pleased with the progress we've made this past quarter, underscored by the encouraging tolerability and PK data from the Phase 1 trials of our first-in-class NBD1 stabilizers, SION-719 and SION-451," said Mike Cloonan, President and Chief Executive Officer of Sionna. "These data reinforce our confidence in advancing both NBD1 stabilizers into the next stages of development. We are preparing to initiate the Phase 2a proof-of-concept trial of SION-719 as an add-on to standard of care and the Phase 1 trial of SION-451 in dual combinations this year and look forward to sharing topline results from both studies in mid-2026. Supported by a clear development plan and a strong financial position, we are excited to be advancing CF therapies that have the potential to make a meaningful difference for people affected by the disease."

Pipeline Updates

NBD1 Stabilizers

- **Positive Phase 1 Results for SION-719 and SION-451:** In June 2025, Sionna announced positive Phase 1 data for its first-in-class nucleotide binding domain 1 (NBD1) stabilizers, SION-719 and SION-451. The randomized, double-blind, placebo-controlled trials enrolled over 200 healthy volunteers and evaluated each compound's safety, tolerability, and pharmacokinetics (PK) across single and multiple ascending dose cohorts. Both NBD1 stabilizers were generally well tolerated and exceeded target exposure levels that Sionna believes, based on its cystic fibrosis human bronchial epithelial (CFHBE) model, have the potential to deliver clinically meaningful benefit as add-on therapies to standard of care (SOC) or in proprietary dual combinations with complementary modulators. These data reinforce Sionna's decision to progress SION-719 and SION-451 to the next phases of development.
- **Phase 2a Proof-of-Concept Trial with SION-719:** Sionna is on track to progress SION-719 into a proof-of-concept (POC) trial in the second half of 2025 evaluating the compound as an add-on to SOC in CF patients, with topline data anticipated in mid-2026. The trial is designed to demonstrate the unique mechanism of NBD1 stabilization and the potential opportunity to drive improved CFTR function beyond the current SOC, as defined by sweat chloride. The midazolam drug-drug interaction study to confirm SION-719 can be dosed in combination with the SOC according to its label has initiated and is on track to be completed prior to initiation of the Phase 2a trial.
- **Phase 1 Dual Combination Trial with SION-451 and Complementary Modulators:** Sionna is on track to advance a Phase 1 healthy volunteer trial evaluating SION-451 in combination with SION-2222 (galicaftor), a transmembrane domain 1 (TMD1)-directed CFTR corrector, and with SION-109, an intracellular loop 4 (ICL4)-directed CFTR corrector, in the second half of 2025. Topline data are anticipated in mid-2026.
- **Preclinical Data Presented at 48th European Cystic Fibrosis Conference:** In June 2025, Sionna presented preclinical data at the European Cystic Fibrosis Society's (ECFS) 48 th Annual Conference demonstrating that Sionna's NBD1 stabilizers, in dual combinations with proprietary complementary modulators, enable full correction of F508del-CFTR in CF models. Sionna believes that these findings highlight the strong mechanistic rationale and the synergy of its dual combination approach to restoring CFTR function, suggesting the potential for these dual combinations to produce meaningful clinical outcomes and improved quality of life for people with CF.

Financial Results for the Quarter Ended June 30, 2025

Research and Development Expenses: Research and development expenses were $15.4 million for the second quarter of 2025, compared to $8.2 million for the second 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 $6.5 million for the second quarter of 2025, compared to $3.1 million for the second quarter of 2024. This increase was primarily due to personnel-related costs, including stock-based compensation, and professional fees.

Net Loss: Net loss was $18.1 million for the second quarter of 2025, compared to a net loss of $8.6 million for the second quarter of 2024.

Cash and Cash Equivalents: Cash, cash equivalents and marketable securities totaled $337.3 million as of June 30, 2025. Sionna continues to expect 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 cystic fibrosis (CF) by developing novel medicines that normalize the function of the cystic fibrosis transmembrane conductance regulator (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 Sionna's Investor Relations website, in addition to following Sionna'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: its goal of transforming the treatment paradigm for CF and providing clinically meaningful benefit to CF patients; the initiation, timing, progress and results of Sionna's research and development programs, preclinical studies and clinical trials and studies, including the timing of the planned initiation of a Phase 2a proof-of-concept trial and Phase 1 healthy volunteer dual combination 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 and support Sionna's dual combination approach to restoring CFTR function; and 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. 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 Sionna's planned and future clinical trials and studies; the company's ability to replicate positive results from earlier preclinical studies or clinical trials in current or future clinical trials; Sionna's ability to demonstrate that its 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 Quarterly Report on Form 10-Q as well as any subsequent filings with the Securities and Exchange Commission. 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 June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 15,383	$ 8,233	$ 29,051	$ 18,453
General and administrative	6,523	3,059	12,514	5,986
Total operating expenses	21,906	11,292	41,565	24,439
Loss from operations	(21,906)	(11,292)	(41,565)	(24,439)
Other income:				
Interest income	3,667	2,566	6,667	3,698
Other income	171	174	348	342
Total other income	3,838	2,740	7,015	4,040
Net loss	$ (18,068)	$ (8,552)	$ (34,550)	$ (20,399)
Net loss per share, basic and diluted	$ (0.41)	$ (2.71)	$ (0.98)	$ (6.54)
Weighted-average common shares outstanding, basic and diluted	44,116,997	3,159,815	35,404,928	3,121,225

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

	June 30, 2025	**December 31, 2024**
Cash, cash equivalents, and marketable securities	$ 337,270	$ 168,043
Working capital[1]	259,196	140,573
Total assets	352,048	185,752
Total stockholders' equity (deficit)	336,429	(163,713)

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