



Sionna Therapeutics Reports Third Quarter 2025 Financial Results

November 5, 2025

Initiated PreciSION CF Phase 2a proof-of-concept trial evaluating NBD1 stabilizer SION-719 as an add-on to standard of care in participants with cystic fibrosis

Successfully completed drug-drug interaction study to support initiation of PreciSION CF Phase 2a

Initiated Phase 1 trial evaluating NBD1 stabilizer SION-451 in proprietary dual combinations with SION-2222 and with SION-109 in healthy volunteers

Topline data from both trials anticipated in mid-2026

Maintained strong cash position with approximately \$325.0 million in cash and cash equivalents, expected to fund operations into 2028

WALTHAM, Mass., Nov. 05, 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 September 30, 2025, and provided a business update.

“We maintain our track record of strong execution, achieving substantial progress across our pipeline in the third quarter. Following the positive data from the two Phase 1 clinical trials evaluating our first-in-class NBD1 stabilizers SION-719 and SION-451, we have initiated both the PreciSION CF 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 proprietary dual combinations. We are looking forward to sharing results from both trials in mid-2026,” said Mike Cloonan, President and Chief Executive Officer of Sionna. “Our recent engagement with the CF community at the North American Cystic Fibrosis Conference in October has reinforced the importance of our science and our mission to revolutionize the treatment paradigm for people living with CF.”

Pipeline Updates

NBD1 Stabilizers

- **Initiated PreciSION CF Phase 2a Proof-of-Concept Trial with SION-719:** In October 2025, [Sionna announced](#) initiation of the PreciSION CF Phase 2a proof-of-concept (POC) trial ([NCT07108153](#)) evaluating nucleotide binding domain 1 (NBD1) stabilizer SION-719 as an add-on to the current standard of care (SOC) in CF participants. The trial will evaluate the safety, tolerability, and pharmacokinetics (PK) of SION-719 when administered with SOC and assess change in CFTR function as measured by sweat chloride levels. Topline data from this trial are anticipated in mid-2026. Sionna also completed a successful drug-drug interaction study with midazolam, a sensitive CYP3A4 substrate, which confirmed that SION-719 can be dosed in combination with Trikafta®, the current SOC, according to its label.
- **Initiated Phase 1 Dual Combination Trial with SION-451 and Complementary Modulators:** In August 2025, [Sionna announced](#) initiation of the Phase 1 trial ([NCT07035990](#)) evaluating SION-451 in proprietary dual combinations 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 healthy volunteers. Topline data from this trial are anticipated in mid-2026.
- **Investigational New Drug (IND) Application Cleared for SION-451:** The U.S. Food and Drug Administration (FDA) has cleared an Investigational New Drug (IND) application to support the advancement of SION-451 to later-stage development.
- **Data Presented at 2025 North American Cystic Fibrosis Conference:** In October 2025, [Sionna presented data](#) at the 2025 North American Cystic Fibrosis Conference (NACFC) in Seattle, Washington. An oral presentation highlighted data from the two single agent healthy volunteer Phase 1 clinical trials of novel NBD1 stabilizers, SION-719 and SION-451. As previously disclosed, in these Phase 1 trials, both SION-719 and SION-451 were generally well tolerated and exceeded target exposure levels. Based on these data and its cystic fibrosis human bronchial epithelial (CFHBE) model, Sionna believes that its NBD1 stabilizers have the potential to deliver clinically meaningful benefit including up to wild-type levels of CFTR function with SION-719 as an add-on to SOC or with SION-451 in proprietary dual combinations. A poster with new preclinical data showed the impact of NBD1 stabilizers SION-719 and SION-451 on the half-life of F508del-CFTR protein. In preclinical studies, NBD1 stabilizers SION-719 and SION-451 increased the half-life of mature F508del-CFTR protein up to levels seen in wild-type. This effect was apparent when NBD1 stabilizers were used as single agents or when combined with complementary modulators. These data highlight the further differentiation of the NBD1 mechanism of action, which has the potential to improve both the function of CFTR and CFTR half-life up to wild-type levels.

Business Highlights

- **Strengthened Leadership:** In September 2025, Sionna appointed Caroline Stark Beer, MBA, as Chief Business Officer. Caroline brings over 20 years of experience in the life science industry to her role at Sionna, most recently as Chief Business Officer at Jnana Therapeutics until Jnana's sale to Otsuka Pharmaceutical.

Financial Results for the Quarter Ended September 30, 2025

Research and Development Expenses: Research and development expenses were \$16.0 million for the third quarter of 2025, compared to \$24.6 million for the third quarter of 2024. This decrease was mainly driven by one-time in-process research and development charges recognized in connection with a license agreement executed in the prior year, partially offset by an increase in development expenses to support the advancement of Sionna's clinical pipeline.

General and Administrative Expenses: General and administrative expenses were \$7.8 million for the third quarter of 2025, compared to \$3.4 million for the third quarter of 2024. This increase was primarily due to personnel-related costs, professional fees, and stock-based compensation expenses to support the Company's continued growth and operational activities.

Net Loss: Net loss was \$20.3 million for the third quarter of 2025, compared to a net loss of \$25.4 million for the third quarter of 2024.

Cash and Cash Equivalents: Cash, cash equivalents and marketable securities totaled \$325.0 million as of September 30, 2025. 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 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 more 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, clinical trials and studies, including the timing of topline data from Sionna's Phase 2a proof-of-concept trial and Phase 1 dual combination trial; the ability of clinical trials to demonstrate safety and efficacy of Sionna's product candidates, including the potential of an NBD1 stabilizer added to the standard of care or used in a proprietary dual combination to provide clinically meaningful benefit, including up to wild-type levels of CFTR function; the differentiation of the NBD1 mechanism of action and the potential to improve both the function of CFTR and CFTR half-life up to wild-type levels; the ability of Sionna's preclinical studies to predict later clinical trial results; 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 ongoing, 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 16,044	\$ 24,582	\$ 45,095	\$ 43,035
General and administrative	7,761	3,402	20,275	9,388
Total operating expenses	<u>23,805</u>	<u>27,984</u>	<u>65,370</u>	<u>52,423</u>
Loss from operations	(23,805)	(27,984)	(65,370)	(52,423)
Other income:				
Interest income	3,456	2,353	10,123	6,051
Other income	71	190	419	532
Total other income	<u>3,527</u>	<u>2,543</u>	<u>10,542</u>	<u>6,583</u>
Net loss	<u>\$ (20,278)</u>	<u>\$ (25,441)</u>	<u>\$ (54,828)</u>	<u>\$ (45,840)</u>
Net loss per share, basic and diluted	\$ (0.46)	\$ (5.67)	\$ (1.43)	\$ (12.81)
Weighted-average common shares outstanding, basic and diluted	44,255,053	4,485,813	38,387,388	3,579,408

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

	September 30, 2025	December 31, 2024
Cash, cash equivalents, and marketable securities	\$ 325,000	\$ 168,043
Working capital ¹	242,477	140,573
Total assets	339,270	185,752
Total stockholders' equity (deficit)	321,668	(163,713)

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