Sionna Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results

March 20, 2025

Phase 1 MAD dosing completed for SION-451 and final MAD cohort of SION-719 planned; Interim data in healthy volunteers show potential to provide clinically meaningful benefit to CF patients. Topline data anticipated in first half of 2025

On track to initiate NBD1 Phase 2a proof-of-concept trial in combination with SOC in CF patients and combination MAD trials of an NBD1 stabilizer with a complementary modulator in healthy volunteers in the second half of 2025, with topline data for both anticipated in mid-2026

Completed upsized IPO with gross proceeds of approximately $219 million, extending runway into 2028

WALTHAM, Mass., March 20, 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 fourth quarter and full year ended December 31, 2024, and provided a business update.

“2024 was an excellent year for Sionna including strong clinical execution across multiple programs. Encouraging interim Phase 1 data for SION-719 and SION-451, our highly potent nucleotide-binding domain 1 (NBD1) stabilizers, showed that both candidates were generally well tolerated and achieved target exposures—reinforcing their potential to deliver meaningful clinical benefits for people with CF,” said Mike Cloonan, President and Chief Executive Officer of Sionna. “Building on this momentum, we successfully completed an upsized IPO, a significant milestone that extends our cash runway into 2028 and provides financial and strategic flexibility. 2025 is off to a strong start with the consummation of the IPO and the progression of the Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) trials for SION-719 and SION-451. We look forward to announcing topline data in the first half of this year and initiating our Phase 2a proof-of-concept (POC) trial and the combination MAD Phase 1 program later this year.”

Pipeline Updates

NBD1 Stabilizers

- **Phase 1 MAD advancement:** Sionna has completed dosing in the MAD part of the Phase 1 healthy volunteer trial of SION-451 and the final MAD cohort of SION-719 is planned. The additional completed cohorts since Sionna reported interim Phase 1 data evaluated 225 mg and 25 mg (fed) of SION-451 and 160 mg of SION-719, dosed twice daily (BID) over 10 days. The final MAD cohort for SION-719 will evaluate 120 mg BID. All MAD data, including from the recently completed cohorts, remain blinded to individual subject treatment assignment. Both compounds were generally well tolerated in these additional completed cohorts. There were no serious adverse events (SAEs), and most treatment emergent adverse events (TEAEs) were mild to moderate. There were no TEAEs related to liver function tests and no TEAEs that led to discontinuation of trial drug. Part C of both trials, in which Sionna is evaluating the effect of food on the pharmacokinetics (PK) of each product candidate and the bioequivalence of a tablet formulation is ongoing. Topline data from both trials are expected in the first half of 2025.
- **Encouraging Phase 1 Interim Data:** Sionna previously reported encouraging Phase 1 interim data from the completed SAD part and three cohorts of the MAD part of each Phase 1 trial of SION-719 and SION-451 in healthy subjects. As of the data cutoff date of January 14, 2025, both SION-719 and SION-451 were generally well tolerated at all administered dose levels, achieving target exposures 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 plans to initiate a Phase 2a 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.
- **Combination MAD Trials:** Sionna plans to initiate combination MAD trials in the second half of 2025, evaluating dual combinations of an NBD1 stabilizer with galifactor (SION-2222), a transmembrane domain 1 (TMD1)-directed CFTR corrector and/or SION-109, an intracellular loop 4 (ICL4)-directed CFTR corrector, in healthy subjects. Topline data are expected in mid-2026.

Complementary Modulators

- **Successful Completion of Phase 1 Trial for SION-109:** In December 2024, Sionna completed a Phase 1 clinical trial of SION-109 in healthy subjects. SION-109 was generally well tolerated at all dose levels administered and its target exposure as part of a dual combination with SION-451 or SION-719 was achieved with both single and multiple doses.

Business Highlights

- **Completion of Upsized IPO:** In February 2025, Sionna completed its upsized 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.”
- **Strengthened Leadership:** Sionna enhanced its Board of Directors with the appointments of Laurie Stelzer, Marcella Kuhlman Ruddy, M.D., and Jo Viney, Ph.D., who collectively bring decades of leadership experience in the biopharmaceutical industry, further supporting Sionna’s strategic growth and innovation.

Financial Results for the Quarter and Year Ended December 31, 2024

Research and Development Expenses: Research and development expenses were $14.3 million for the fourth quarter of 2024 and $57.3 million for the year ended December 31, 2024, compared to $9.9 million and $40.6 million, respectively, for the same periods of 2023. These increases were mainly driven by direct program spend to support Sionna’s clinical pipeline. In 2024, Sionna licensed three clinical-stage assets, galicaftor (SION-2222), navocaftor (SION-3067) and SION-2851, from AbbVie Global Enterprises LTD, which resulted in the recognition of in-process research and development expenses of $13.6 million, which consisted of a $5.0 million upfront payment and $8.6 million of non-cash expense.

General and Administrative Expenses: General and administrative expenses were $3.9 million for the fourth quarter of 2024 and $13.3 million for the year ended December 31, 2024, compared to $2.7 million and $9.7 million, respectively, for the same periods of 2023. The increase was primarily due to personnel-related costs, including stock-based compensation, and professional fees.

Net Loss: Net loss was $15.8 million for the fourth quarter of 2024 and $61.7 million for the year ended December 31, 2024, compared to a net loss of $11.9 million and $47.3 million, respectively, for the same periods of 2023.

Cash and Cash Equivalents: Cash, cash equivalents and marketable securities totaled $168.0 million as of December 31, 2024. This balance excludes net proceeds from our IPO of $199.6 million after deducting underwriting discounts and commissions and other offering costs. With the net IPO proceeds, 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 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 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; 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. 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 December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 14,254	$ 9,891	$ 57,288	$ 40,626
General and administrative	3,880	2,705	13,268	9,707
Total operating expenses	18,134	12,596	70,556	50,333
Loss from operations	(18,134)	(12,596)	(70,556)	(50,333)
Other income:				
Interest income	2,119	554	8,170	2,769
Other income	167	166	698	301
Total other income	2,286	720	8,868	3,070
Net loss	$ (15,848)	$ (11,876)	$ (61,688)	$ (47,263)
Net loss per share, basic and diluted	$ (3.38)	$ (3.93)	$ (15.99)	$ (16.11)
Weighted-average common shares outstanding, basic and diluted	4,691,141	3,024,701	3,858,859	2,933,218

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

	December 31, 2024	December 31, 2023
Cash, cash equivalents, and marketable securities	$ 168,043	$ 38,521
Working capital[1]	140,573	31,170
Total assets	185,752	51,945
Total stockholders' deficit	(163,713)	(114,881)

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