UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): November 10, 2026

SIONNA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-42504	84-2801521
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

SIONNA THERAPEUTICS, INC.
21 Hickory Drive, Suite 500
Waltham, MA02451
(Address of principal executive offices, including zip code)

617-819-2020
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	SION	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 10, 2026, Sionna Therapeutics, Inc. issued a press release announcing its financial results and business highlights for the quarter ended September 30, 2026. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth under this Item 2.02 and in Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release of Sionna Therapeutics, Inc. dated November 10, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Sionna Therapeutics, Inc.

Date: November 10, 2026

By: /s/ Jennifer Fitzpatrick

Name: Jennifer Fitzpatrick

Title: Chief Legal Officer and Head of Program Management

Sionna Therapeutics Reports Third Quarter 2026 Financial Results

Advancing SION-451 + SION-2222 dual combination to AscenSION CF Phase 2 proof-of-concept trial, expected to initiate in the first quarter of 2027

Clinical and nonclinical data presented at 2026 NACFC support advancement of SION-451 + SION-2222 and the potential of NBD1 stabilizer combinations to benefit a broad population of people with CF

Strong cash position of $249.8 million as of September 30, 2026, expected to fund operations into the second half of 2029

WALTHAM, Mass., Nov 10, 2026 (GLOBE NEWSWIRE) – Sionna Therapeutics, Inc. (Nasdaq: SION), a clinical-stage biopharmaceutical company on a mission to develop novel medicines for cystic fibrosis (CF), today reported financial results for the third quarter ended September 30, 2026, and provided a business update.

“During the third quarter, we established a focused path forward for Sionna centered on SION-451 + SION-2222, our proprietary, NBD1-anchored dual combination,” said Mike Cloonan, President and Chief Executive Officer of Sionna. “We believe the findings from the PreciSION CF post hoc analyses, together with the dual combination’s favorable Phase 1 results, support advancing the dual combination into the next phase of development. With our resources focused on developing this program and cash runway expected into the second half of 2029, we are well-positioned to execute our strategy to deliver new treatment options for people with CF.”

Pipeline Updates

- **SION-451 + SION-2222 Dual Combination Advancing into AscenSION CF Phase 2 proof-of-concept:** Sionna plans to initiate the AscenSION CF Phase 2 proof-of-concept (POC) trial in the first quarter of 2027. SION-451 is an NBD1 stabilizer and SION-2222 (galicaftor) is a transmembrane domain 1 (TMD1)-directed CFTR corrector. The open-label trial will evaluate participants with CF homozygous for F508del treated with SION-451 + SION-2222 for 28 days after switching from Trikafta®. The trial will assess sweat chloride, safety, and pharmacokinetics (PK), and its design will incorporate key learnings from PreciSION CF related to dosing adherence and sweat chloride variability. SION-451 + SION-2222 was selected as the dual combination based on the totality of the clinical, PK, and nonclinical data, including achievement of the safety, tolerability, and PK objectives in the Phase 1 healthy volunteer trial.
- **Completed Comprehensive Analysis of SION-719 PreciSION CF:** As previously announced, the PreciSION CF Phase 2a trial of SION-719 added to Trikafta did not achieve its key activity endpoint, and Sionna is not advancing SION-719 as an add-on to standard of care. Post hoc analyses excluding three participants with drug exposures consistent with dosing non-adherence showed a mean placebo-adjusted sweat chloride reduction of up to -8.6 mmol/L when SION-719 was added to Trikafta, which Sionna believes is indicative of NBD1 biological activity. The analyses also identified other potential confounding factors related to the complex interaction of SION-719 combined with Trikafta that may have blunted the additional benefit of NBD1 stabilization. These findings, together with results from the Phase 1 dual combination trial,

informed the decision to advance SION-451 + SION-2222 and the design of the AscenSION CF trial.

- **Presented Clinical and Nonclinical Data at 2026 North American Cystic Fibrosis Conference:** In October 2026, Sionna presented clinical and nonclinical data in an oral presentation and poster at the North American Cystic Fibrosis Conference (NACFC) in Atlanta, Georgia. The oral presentation summarized the previously disclosed post hoc analyses of PreciSION CF and the rationale for advancing SION-451 + SION-2222 into AscenSION CF. The poster evaluated the effects of Sionna's NBD1 stabilizers, SION-451 and SION-719, in combination with complementary CFTR modulators, including SION-2222 and SION-109, in primary CF human bronchial epithelial cells from donors with either two copies of F508del or one copy of F508del and a null CFTR mutation. Across both donor groups, the NBD1 stabilizer-based combinations demonstrated improved CFTR trafficking and function up to wild-type levels, supporting their potential to benefit a broad population of people with CF.

Corporate Update

- **Implemented Workforce Reduction and Cost-Saving Measures:** In September 2026, following a comprehensive review of its operations, Sionna implemented a workforce reduction of approximately 46% and other cost-saving measures to focus resources on advancing SION-451 + SION-2222 and extend its operating runway.

Financial Results for the Quarter Ended September 30, 2026

Research and Development Expenses: Research and development expenses were $22.0 million for the third quarter of 2026, compared to $16.0 million for the third quarter of 2025. This increase was primarily driven by development expenses incurred during the period, personnel-related costs, including stock-based compensation expenses, and restructuring related costs associated with the workforce reduction.

General and Administrative Expenses: General and administrative expenses were $12.8 million for the third quarter of 2026, compared to $7.8 million for the third quarter of 2025. This increase was primarily due to personnel-related costs, including stock-based compensation expenses, and restructuring related costs associated with the workforce reduction.

Net Loss: Net loss was $32.4 million for the third quarter of 2026, compared to a net loss of $20.3 million for the third quarter of 2025.

Cash and Cash Equivalents: Cash, cash equivalents and marketable securities totaled $249.8 million as of September 30, 2026. Sionna expects its current cash position to fund operations into the second half of 2029.

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 improve 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 meaningful improvements in clinical outcomes and quality of life for people with CF. 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 for people with CF; the potential of Sionna's product candidates, including the SION-451 + SION-2222 dual combination, to expand therapeutic options for people with CF, including the potential of NBD1 stabilizer combinations to benefit a broad population of people with CF; Sionna's interpretation of the results of the PreciSION CF trial and the impact of potential confounding factors on the interpretation of those results; the potential for NBD1 stabilization to improve CFTR function and produce clinical benefit, including beliefs about NBD1 biological activity in PreciSION CF and the translatability of preclinical and in vitro assay data to clinical outcomes; the objectives, design, timing, initiation and conduct of the AscenSION CF Phase 2 proof-of-concept trial of SION-451 + SION-2222; the therapeutic potential, clinical benefits and safety of SION-451 + SION-2222; the ability of clinical trials to demonstrate safety and efficacy of Sionna's product candidates; the ability of Sionna's nonclinical studies or earlier clinical trials, including post hoc analyses of the PreciSION CF trial, to predict later clinical trial results; the expected benefits of Sionna's workforce reduction and other cost-saving measures, including the ability to focus resources on advancing SION-451 + SION-2222 and to extend its operating runway; 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; uncertainties in interpreting the PreciSION CF results and potential confounding factors; the inherent limitations of post hoc analyses, which are exploratory and may not reliably predict future outcomes; the risk that in vitro and preclinical data may not translate to clinical benefit; the risk that results observed with one compound may not be predictive of results with a different compound or combination; uncertainties in designing and conducting the AscenSION CF Phase 2 trial; Sionna's ability to replicate positive results from earlier nonclinical studies or clinical trials, or results of post hoc analyses thereof, 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; the ability to obtain regulatory feedback or approvals; the ability to achieve anticipated restructuring savings and runway extension; the ability to retain key personnel and capabilities following the workforce reduction; the ability to secure sufficient funding; regulatory developments in the United States and foreign countries; the competitive landscape for CF treatments, including existing therapies; 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 September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 22,025	$ 16,044	$ 62,852	$ 45,095
General and administrative	12,794	7,761	34,036	20,275
Total operating expenses	34,819	23,805	96,888	65,370
Loss from operations	(34,819)	(23,805)	(96,888)	(65,370)
Other income:				
Interest income	2,407	3,456	7,814	10,123
Other income (expense), net	(6)	71	(9)	419
Total other income	2,401	3,527	7,805	10,542
Net loss	$ (32,418)	$ (20,278)	$ (89,083)	$ (54,828)
Net loss per share, basic and diluted	$ (0.72)	$ (0.46)	$ (1.98)	$ (1.43)
Weighted-average common shares outstanding, basic and diluted	45,208,940	44,255,053	45,094,349	38,387,388

Sionna Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(In thousands)

(Unaudited)

	September 30, 2026	December 31, 2025
Cash, cash equivalents, and marketable securities	$ 249,797	$ 310,302
Working capital[1]	212,108	229,707
Total assets	263,261	325,953
Total stockholders' equity	240,524	306,833

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