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): September 9, 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, MA 02451
(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 2.05 Costs Associated with Exit or Disposal Activities.

On September 9, 2026, the Board of Directors (the "Board") of Sionna Therapeutics, Inc. (the "Company") approved a restructuring plan (the "Restructuring") intended to focus its resources on advancing the Company's SION-451 and SION-2222 dual combination program and extend the Company's cash runway. The Restructuring includes a reduction of the Company's workforce by approximately 46%, retaining core clinical, regulatory, technical, and corporate capabilities required to advance the dual combination program. The Company also initiated wind-down activities associated with the SION-719 add-on program, including the termination of certain clinical, manufacturing, and other vendor arrangements.

The Company currently estimates it will incur aggregate restructuring and related charges of approximately $6.4 million, consisting of approximately $5.3 million in employee severance and other post-employment benefit costs, $0.7 million of contract close-out costs associated with the SION-719 add-on program, and $0.4 million of stock-based compensation expense. The workforce reduction and wind-down of applicable vendor arrangements are expected to be substantially completed by the end of the third quarter of 2026, with related cash payments expected to continue into the fourth quarter of 2026.

The estimate of costs that the Company expects to incur and the timing thereof are subject to a number of assumptions, and actual results may differ. As the Restructuring is implemented, the Company's management will reevaluate the estimated costs and expenses set forth above and may revise the estimated restructuring charge as appropriate, consistent with generally accepted accounting principles. The Company may also incur other non-cash charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the Restructuring.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Departure of Chief Business Officer; Officer Roles

In connection with the Restructuring, the employment of Caroline Stark Beer, M.B.A., the Company's Chief Business Officer, was terminated without cause, effective as of September 15, 2026. Pursuant to the Company's Severance and Change in Control Plan (the "Severance Plan"), Ms. Stark Beer is entitled to receive certain severance benefits, subject to her execution and delivery of an irrevocable release of claims in favor of the Company and continued compliance with all applicable restrictive covenants. In addition, if Ms. Stark Beer elects to continue health and dental insurance coverage following her termination, the Compensation Committee of the Board (the "Compensation Committee") has approved the extension of her coverage period from up to nine months to up to twelve months.

Additionally, the Board approved the following changes to the roles and responsibilities of certain of the Company's executive officers, each effective as of September 16, 2026: (i) Charlotte McKee, the Company's Chief Medical Officer, assumed the additional role of Head of Research and Development; (ii) Elena Ridloff, the Company's Chief Financial Officer, assumed the additional role of Chief Business Officer; and (iii) Jennifer Fitzpatrick, the Company's Chief Legal Officer, assumed the additional role of Head of Program Management. No changes were made to the compensation arrangements of any of the foregoing officers in connection with these role expansions.

Option Repricing

On September 9, 2026, to retain and motivate employees of the Company, the Board approved a stock option repricing (the "Option Repricing"), to be effective on September 17, 2026 (the "Repricing Date"). The Option Repricing will be undertaken in accordance with, and as permitted by, the Company's 2025 Stock Option and Incentive Plan, as amended (the "2025 Plan"). Pursuant to the Option Repricing, all options granted under the 2025 Plan held by employees (including executive officers) remaining with the Company following completion of the reduction in force (each, an "Optionholder") that had a per share exercise price in excess of $18.00, together with options that had a per share exercise price of $18.00 granted under the 2025 Plan held by certain non-executive Optionholders hired shortly before the Company's initial public offering, will be repriced (each, a "Repriced Option"). The exercise price per share of each Repriced Option will be reduced to the closing price of the Company's common stock on the Nasdaq Global Market as of the Repricing Date.

Under the terms of the Option Repricing, a Repriced Option will revert to its original exercise price per share if such Repriced Option is exercised prior to the end of the "Retention Period," which shall begin on the Repricing Date and end on the earliest of the following: (i) the 18-month anniversary following the Repricing Date, (ii) the consummation of a Sale Event (as defined in the 2025 Plan), and (iii) the Optionholder's (a) termination by the Company without Cause (as defined in the 2025 Plan), (b) death or termination due to disability, or (c) if the Optionholder is an Eligible Employee and an Executive under the Severance Plan, a resignation from service for Good Reason (as such terms are defined in the Severance Plan).

The Board approved the Option Repricing after careful consideration of various alternatives, and based in part on the recommendation of the Compensation Committee. The Option Repricing is not subject to approval of the Company's stockholders.

Item 8.01 Other Events.

On September 14, 2026, the Company announced its plans to advance its SION-451 and SION-2222 dual combination program into a Phase 2a proof-of-concept trial. The Company also provided a corporate update, including with respect to the Restructuring.

The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Forward-Looking Statements

This Current Report on Form 8-K 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 the Company's beliefs and expectations regarding: its ability to preserve cash and continue the clinical development of the Company's product candidates; the expected timing, scope, costs and benefits of its workforce reduction and other cost-saving measures; its planned option repricing; its interpretation of the results of the PreciSION CF trial and the impact of confounding factors on the interpretation of those results; the potential for NBD1 stabilization to improve CFTR function and produce clinical benefit, including beliefs about biological activity of SION-719 in PreciSION CF and the translatability of preclinical and in vitro assay data to clinical outcomes; the objectives, design, timing, initiation and conduct of a planned Phase 2 proof-of-concept trial of SION-451 and SION-2222; the therapeutic potential, clinical benefits and safety of SION-451 and SION-2222; the Company's ability to retain the capabilities and personnel needed to advance SION-451 and SION-2222 and operate as a public company; the Company's expected cash runway; and other statements that are not historical facts. In some cases, 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 Current Report on Form 8-K 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 Current Report on Form 8-K. Factors that could cause actual results to differ include, but are not limited to, the risk that the restructuring costs and charges may be greater than anticipated or incurred in different periods than anticipated; the risk that the Company's restructuring efforts may not generate their intended benefits, including runway extension, to the extent or as quickly as anticipated, may negatively impact the Company's business operations and reputation and may adversely affect the Company's internal programs and the Company's ability to retain key personnel; uncertainties inherent in developing product candidates; 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; risks associated with the Company's ability to continue the clinical development of its SION-451 and SION-2222 dual combination program, including designing and conducting the planned Phase 2a trial; the Company's ability to demonstrate that its candidates are safe and effective and obtain regulatory feedback or approvals; and general economic, industry and market conditions. These risks and uncertainties are described in the section entitled "*Risk Factors*" in the Company'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 the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release of Sionna Therapeutics, Inc. dated September 14, 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: September 14, 2026

By: /s/ Michael Cloonan
Name: Michael Cloonan
Title: President and Chief Executive Officer

Sionna Therapeutics Announces Plans to Advance SION-451 + SION-2222 Dual Combination into Phase 2a Proof-of-Concept Trial

Post hoc analyses of SION-719 PreciSION CF subset showed a mean placebo-adjusted sweat chloride reduction of up to -8.6 mmol/L consistent with NBD1 biological activity

Dual combination Phase 2a trial expected to initiate in first quarter of 2027

46% workforce reduction and other cost-saving measures prioritize advancing the dual combination program and extend cash runway into the second half of 2029

Sionna to host conference call today at 4:30 p.m. ET

WALTHAM, Mass., Sept. 14, 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 announced plans to advance SION-451 + SION-2222, its preferred proprietary dual combination, into the AscenSION CF Phase 2a proof-of-concept (POC) trial, and results from the company's post hoc analysis of the PreciSION CF Phase 2a trial. The decision to advance SION-451 + SION-2222 follows an extensive review of clinical, pharmacokinetic (PK) and nonclinical data from PreciSION CF. Learnings from that trial and the previous Phase 1 dual combination trial will inform the development strategy for the dual combination.

"It was important for us to take the time to complete a comprehensive post hoc data analysis to better understand the SION-719 PreciSION CF trial results and their potential implications before determining the right path forward for our dual combination," said Mike Cloonan, President and Chief Executive Officer of Sionna. "The analysis identified important factors that we believe complicated interpretation of the trial and may have blunted the impact of NBD1 stabilization. The post hoc findings, together with the favorable Phase 1 results for SION-451 + SION-2222, support advancing the dual combination into Phase 2a. We have been inspired by the CF community, whose voices continue to reinforce the need for new treatment options."

"Despite the substantial progress made, there remains a significant need for new options for people with CF," said Gregory S. Sawicki, M.D., M.P.H., Director of the Cystic Fibrosis Center at Boston Children's Hospital and Associate Professor of Pediatrics at Harvard Medical School. "Directly stabilizing NBD1 continues to represent a differentiated approach to addressing the underlying biology of CF. I'm excited to see Sionna proceed with a Phase 2a trial of SION-451 + SION-2222, which will be an important next step in further exploring whether the NBD1 biology can translate into meaningful benefit for people with CF."

Post Hoc Analysis of SION-719 PreciSION CF Phase 2a Clinical Trial

PreciSION CF Phase 2a (NCT07108153) was a randomized, double-blind, placebo-controlled, crossover trial that evaluated the safety and tolerability of SION-719 when added to Trikafta® in 15 adult participants with CF homozygous for F508del. Change in sweat chloride, an important measure of CFTR function, was the key activity endpoint. As previously announced, the trial did not achieve its key activity endpoint, and Sionna is not advancing SION-719 as an add-on to SOC.

Following the announcement of topline results, Sionna conducted a comprehensive analysis of the clinical, PK, and nonclinical data to better understand the PreciSION CF outcome, including implications for the NBD1 mechanism and the SION-451 + SION-2222 dual combination.

The primary analysis in the trial assessed placebo-adjusted sweat chloride change using Day 1 as baseline. A prespecified secondary analysis assessed placebo-adjusted sweat chloride change using the baseline measured at the start of each treatment period. Across the 14 evaluable participants, results were similar under both methodologies, with placebo-adjusted sweat chloride changes of -1.0 mmol/L in the primary analysis and -1.1 mmol/L in the secondary analysis.

The post hoc analysis identified three factors that may have confounded the observed treatment effect:

- **PK outliers:** Three participants had drug exposures (one with SION-719 and two with the components of Trikafta (elexacaftor/tezacaftor/ivacaftor; ETI) at key timepoints consistent with non-adherence. Excluding these confounded participants resulted in mean placebo-adjusted sweat chloride change of -8.6 mmol/L using the secondary analysis of baseline measured at the start of each treatment period. The Company believes the secondary analysis to assess sweat chloride best accounts for variability observed between treatment periods.
- **Trikafta Exposure Levels:** ETI exposures were lower during SION-719 treatment periods, with mean exposures of all three components declining by approximately 25-30% on average while remaining relatively stable during placebo periods.
- **CFTR Channel Biology:** Post hoc analysis of preclinical CFHBE assay data suggests that the interaction between an NBD1 stabilizer, like SION-719, and a potentiator, like ivacaftor, may have blunted the additional benefit of NBD1 stabilization. This interaction is not observed when an NBD1 stabilizer is combined with complementary correctors targeting TMD1 or ICL4.

Sionna believes these analyses suggest that SION-719 was biologically active in the trial, but that PK outliers and complex interactions between SION-719 and Trikafta may have affected the observed outcome and blunted a potential treatment signal.

SION-451 + SION-2222 Dual Combination Phase 2 Development Plan

Sionna plans to advance SION-451 + SION-2222 into the AscenSION CF Phase 2a POC trial. The Company continues to believe that directly stabilizing NBD1 in combination with a complementary CFTR modulator has the potential to meaningfully improve CFTR function.

The AscenSION CF POC will be an open-label trial evaluating adults with CF homozygous for F508del treated with SION-451 + SION-2222 for 28 days. Participants will switch from Trikafta to SION-451 + SION-2222, and the trial will assess sweat chloride, safety, and PK. The design will incorporate key learnings from PreciSION CF with respect to dosing adherence and sweat chloride variability, and the trial is expected to initiate in the first quarter of 2027.

The decision to advance SION-451 + SION-2222 is supported by results from the Phase 1 healthy volunteer trial of SION-451-based dual combinations, for which the Company announced topline results on August 10, 2026. The trial achieved its safety, tolerability, and PK objectives. SION-451 + SION-2222 was identified as the preferred dual combination based on target exposure coverage, and the go-forward SION-451 twice daily (BID) + SION-2222 once daily (QD) regimen demonstrated a favorable tolerability profile. Phase 1 exposures of the planned doses were within the range associated with meaningful improvement in CFTR function in Sionna's CFHBE assay.

Corporate Update

Following the completion of a comprehensive review of its operations, Sionna's Board of Directors has approved a workforce reduction of approximately 46% and the Company has implemented other cost-saving measures to focus its resources on advancing SION-451 + SION-2222 and extend its operating runway. Sionna expects to retain the core clinical, scientific, regulatory, technical, and corporate capabilities required to advance the dual combination program. The Company currently estimates it will incur aggregate restructuring and related charges of approximately $6.4 million.

Sionna ended Q2 2026 with approximately $268.3 million in cash, cash equivalents, and marketable securities. The Company estimates that the workforce reduction, discontinuation of investment in SION-719 as an add-on to standard of care, and other cost-saving measures will extend its cash runway into the second half of 2029.

Webcast Details

Sionna Therapeutics' live webcast will begin at 4:30 p.m. ET today, September 14th, 2026, and can be accessed via this link. Participants who prefer to listen via telephone, or ask a question, may register on Sionna's Investor Relations website or by clicking here. A replay will be available on the "Events" page in the "Investors" section of Sionna's website at https://investors.sionnatx.com/news-events/events.

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 meaningful improvements in clinical outcomes and quality of life for people with CF. For more information about Sionna, visit www.sionnatx.com.

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; its 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 biological activity of SION-719 in PreciSION CF and the translatability of preclinical and in vitro assay data to clinical outcomes; the objectives, design, timing, initiation and conduct of a planned Phase 2a proof-of-concept trial of SION-451 + SION-2222; the therapeutic potential, clinical benefits and safety of SION-451 + SION-2222; the expected timing, scope, costs and benefits of the workforce reduction and other cost-saving measures; the Company's ability to retain the capabilities and personnel needed to advance SION-451 + SION-2222 and operate as a public company; the Company's expected cash runway; and other statements that are not historical facts.

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