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): August 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, 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 8.01 Other Events.

On August 10, 2026, Sionna Therapeutics, Inc., or the Company, announced topline data from both its PreciSION CF Phase 2a proof-of-concept trial of SION-719 when added to current standard of care and its Phase 1 trial of SION-451-based proprietary dual combinations in healthy subjects. The Company also provided a corporate update, including that it is not advancing SION-719 as an add-on to standard of care and plans to preserve capital while evaluating next steps for its SION-451 dual combination program.

A copy of the press release announcing these matters is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release of Sionna Therapeutics, Inc. dated August 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: August 10, 2026

By: /s/ Jennifer Fitzpatrick
Name: Jennifer Fitzpatrick
Title: Chief Legal Officer

Sionna Therapeutics Reports Topline Data from Two Development Programs in Cystic Fibrosis and Provides Corporate Update

SION-719 Phase 2a proof-of-concept trial did not achieve key activity endpoint of sweat chloride reduction when added to standard of care; Company is not advancing SION-719 as an add-on to standard of care

Potential confounders in SION-719 Phase 2a trial are being evaluated to inform next steps for the SION-451 dual combination clinical program

Ended Q2 with approximately $268.3 million in cash and plans to take actions to preserve capital while evaluating next steps

Sionna to host conference call today at 8:00 a.m. ET

WALTHAM, Mass., August 10th, 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 topline data from two nucleotide binding domain 1 (NBD1) stabilizer programs, the PreciSION CF Phase 2a proof-of-concept (POC) trial of SION-719 when added to Trikafta® (elexacaftor/tezacaftor/ivacaftor) in CF participants, and the Phase 1 trial of SION-451-based proprietary dual combinations in healthy subjects.

Phase 2a PreciSION CF Trial

- The PreciSION CF trial did not meet its key activity endpoint, with a -1.0 mmol/L mean placebo-adjusted sweat chloride change (p=0.7).
- Potential confounders were observed in the trial, including, for example, higher than anticipated levels of variability in individual sweat chloride levels and differences in Trikafta exposure levels between the SION-719 and placebo periods. The Company is evaluating the impact of these on the interpretation of the trial data.
- SION-719 was generally well tolerated when added to Trikafta for 14 days with most treatment emergent adverse events mild to moderate, no serious adverse events, and no meaningful trends in adverse events related to liver function tests. Based on these results, Sionna does not plan to advance SION-719 as an add-on to standard of care. The Company received the topline data on Friday, August 7, 2026, and is continuing to analyze the results of the PreciSION CF study.

Phase 1 Healthy Volunteer Dual Combination Trial

- The Phase 1 trial of SION-451 in dual combinations with either SION-2222 or SION-109 in healthy subjects, achieved the safety, tolerability, and pharmacokinetic (PK) objectives, including target exposures defined prior to the Phase 2a PreciSION CF results.
- Based on the totality of the data and target coverage observed, SION-451 + SION-2222 was identified as the preferred dual combination.
- All SION-451 twice-daily + SION-2222 once-daily doses were generally well tolerated. One participant discontinued due to rash.
- In the SION-451 twice-daily + SION-2222 twice-daily cohorts, most treatment emergent adverse events were mild to moderate, and no serious adverse events were reported. Two participants discontinued due to elevated liver function tests and flu-like symptoms. The SION-451 + SION-109 regimens were all generally well tolerated.
- Sionna is evaluating next steps for the SION-451 program.

“We are disappointed in the unexpected results from the Phase 2a trial. We are further evaluating the data to decide on next steps for the SION-451 dual combination,” said Mike Cloonan, President and Chief Executive Officer of Sionna. “We would like to thank the CF study participants, investigators, and sites for their support in the PreciSION CF study and also thank the broader CF community, our employees, and our shareholders for their support throughout the process.”

Sionna ended Q2 with approximately $268.3 million in cash, cash equivalents, and marketable securities. The Company intends to take actions to preserve capital while evaluating next steps.

Webcast Details

Sionna Therapeutics’ live webcast will begin at 8:00 a.m. ET today, Monday, August 10th, 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 the PreciSION CF Phase 2a Proof-of-Concept Trial

The PreciSION CF Phase 2a trial (NCT07108153) was a randomized, double-blind, placebo-controlled, crossover trial that enrolled 15 adult participants with CF homozygous for F508del on a stable dose of physician-prescribed Trikafta. The primary objective was to evaluate the safety and tolerability of SION-719 when added to SOC. Secondary objectives were to assess the PK of SION-719 and the change in sweat chloride levels, an important measure of CFTR function, when SION-719 was added to SOC.

About the Phase 1 Healthy Volunteer Dual Combination Trial

The Phase 1 healthy volunteer trial (NCT07035990) evaluated the safety, tolerability, and PK of varying doses of SION-451 in 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. A total of 120 participants were dosed across both dual combinations.

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. 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; the objectives and results of the development of its clinical and preclinical pipeline; the therapeutic potential, clinical benefits and safety of Sionna’s product

candidates, particularly in light of the PreciSION CF trial 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, including, without limitation, risks associated with: uncertainties inherent in the development of product candidates, including the results of the PreciSION CF trial, potential confounders, and once studied further, what the data may mean for next steps for the SION-451 dual combination program, the CFHBE translational framework, future development of the Company’s pipeline, and operations; uncertainties about the impact of steps to preserve capital on the Company’s ability to engage in development; the Company’s ability to replicate positive results from earlier preclinical studies or clinical trials in current or future clinical trials; the Company’s ability to demonstrate that its product candidates are safe and effective for their proposed indications; the timing and outcome of interactions with regulatory authorities, and any regulatory developments in the United States and foreign countries; the availability of funding sufficient for the Company’s operating expenses and capital expenditure requirements; 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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