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): May 13, 2025

Septerna, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-42382**	**84-3891440**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

250 East Grand Avenue **South San Francisco, California** **(Address of Principal Executive Offices)**	**94080** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 650 338-3533

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, par value $0.001 per share	SEPN	The Nasdaq Stock Market LLC

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 1.01. Entry into a Material Definitive Agreement.

On May 13, 2025, Septerna, Inc. (the "Company") and Novo Nordisk A/S ("Novo") entered into a global Collaboration and License Agreement (the "Collaboration Agreement"). Under the Collaboration Agreement, the Company and Novo will exclusively collaborate to leverage the Company's proprietary Native Complex Platform™ to discover, develop and commercialize multiple potential oral small molecule therapies for metabolic-related diseases based on certain specified molecular targets. The collaboration objective is to discover and develop several novel mono-, dual-, or triple-acting oral small molecule drug candidates directed across five GPCRs, including the GLP-1, GIP, and glucagon receptors (the "Collaboration Targets"). The collaboration includes Septerna's most advanced preclinical metabolic program focused on developing an oral small molecule agonist to the GIP receptor.

The Company and Novo will initially commence four simultaneous research and development programs (each an "R&D Program") with each pursuing one or more Collaboration Targets from discovery through development candidate selection. Beginning with investigational new drug-enabling activities, Novo will then be responsible for all further global development and commercialization for each product candidate at its sole cost and expense. Subject to certain limitations, Novo has the right to modify the research plans and explore additional combinations of the existing Collaboration Targets for one or more of such R&D Programs. Novo will reimburse the Company for 100% of the costs arising from all research and development activities undertaken by the Company under the Collaboration Agreement. Novo is also responsible for all commercialization costs subject to the Company's profit share option described below for up to one program under the collaboration.

Under the terms of the Collaboration Agreement, the Company will provide Novo with exclusive licenses to enable Novo to develop and commercialize products directed at the Collaboration Targets. The Company retains all other rights to its Native Complex Platform™ and all of the Company's other research and development programs.

The Collaboration Agreement includes potential payments to the Company exceeding $2.2 billion. Novo will pay the Company a one-time, non-refundable upfront payment of $195.0 million. For each R&D Program, the Company is also eligible to receive approximately $500.0 million in research, development, regulatory, and commercial milestone payments. In addition, the Company is entitled to escalating, tiered royalties ranging from mid-to-high single-digits based on global product sales on a country-by-country and product-by-product basis with respect to a R&D Program until the later of ten years after the date of first commercial sale of the first product in such R&D Program in such country, expiration of specified patent rights covering such product in such country or the expiration of specified regulatory exclusivity for the first product in such R&D Program in such country. The royalty payments are subject to certain step-down provisions including reductions due to valid patent claim expiration, generic product market share on a country-by-country basis, payments made under certain licenses for third party intellectual property and application of Inflation Reduction Act maximum fair price provisions (with such cumulative reductions in most cases subject to a royalty reduction floor). Subject to certain terms, conditions and limitations, the Company also has an option to elect a profit and loss sharing arrangement (in lieu of milestones and royalties) for one product candidate under the Collaboration Agreement, which must be exercised by the Company within a specified time period following completion of either IND-enabling studies or the first Phase 1 clinical trial for such product.

Novo may terminate the Collaboration Agreement in its entirety, or with respect to a R&D Program, Collaboration Target, product, or region, at any time without cause following prescribed notice periods. Either party may terminate the Collaboration Agreement in its entirety for the bankruptcy of the other party or in its entirety or with respect to a R&D Program, Collaboration Target, product, or region, in the event of an uncured material breach of the other party. Novo may terminate the Collaboration Agreement in its entirety or with respect to a R&D Program, Collaboration Target, or product for safety reasons. Septerna may terminate the Collaboration Agreement in its entirety in the event Novo brings a patent challenge suit with respect to Septerna's patents. The Collaboration Agreement is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

The Collaboration Agreement also includes customary representations and warranties, covenants and indemnification obligations.

The foregoing summary of the terms of the Collaboration Agreement is qualified in its entirety by reference to the full text of the Collaboration Agreement, a copy of which the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2025.

Item 7.01. Regulation FD Disclosure.

On May 14, 2025, the Company issued a press release entitled "Septerna and Novo Nordisk to collaborate on oral small molecule medicines for obesity and other cardiometabolic diseases." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on the Form 8-K.

In a separate business update, the Company now anticipates initiating a Phase 1 clinical trial to assess safety, tolerability, pharmacokinetics and pharmacodynamics (through an icatibant skin challenge) of SEP-631 in healthy volunteers in the third quarter of 2025. SEP-631 is a selective oral small molecule MRGPRX2 negative allosteric modulator in development for the treatment of mast cell diseases, including chronic spontaneous urticaria.

The information in this Item 7.01, including 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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding: the partnership with Novo and the intended and potential benefits thereof, including the receipt of potential milestone and royalty payments from commercial product sales, along with tiered royalties based on global net sales, if any; the continued development and advancement of Septerna's oral small molecule GPCR-targeted programs; its ability to demonstrate, and the timing of, preclinical proof-of-concept *in vivo* and *ex vivo* for multiple programs; the initiation, timing, progress, and results of conducting its research and development programs including its plans to initiate a clinical trial for SEP-631 in the third quarter of this year; the potential of its proprietary Native Complex Platform™; and its expectations regarding the implementation of its business model, strategic plans for its business, product candidates, and technology. Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include those risks and uncertainties set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, filed with the United States Securities and Exchange Commission and in its subsequent filings filed with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by Septerna, Inc. on May 14, 2025, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Septerna, Inc.

Date: May 14, 2025

By: /s/ Jeffrey Finer, M.D., Ph.D.
Jeffrey Finer, M.D., Ph.D.
President and Chief Executive Officer

press release

Septerna and Novo Nordisk to collaborate on oral small molecule medicines for obesity and other cardiometabolic diseases

Collaboration combines Novo Nordisk's scientific leadership in obesity and cardiometabolic diseases with Septerna's expertise in G protein-coupled receptor (GPCR) drug discovery

Goal is to develop multiple oral small molecule therapies for key GPCR targets, including GLP-1, GIP and glucagon receptors

Septerna is eligible to receive approximately 2.2 billion US dollars, including more than 200 million dollars in upfront and near-term payments

South San Francisco, California, US and Bagsværd, Denmark, 14 May 2025 – Septerna, Inc. (Nasdaq: SEPN) and Novo Nordisk today announced an exclusive global collaboration and license agreement to discover, develop and commercialise oral small molecule medicines for obesity, type 2 diabetes and other cardiometabolic diseases.

The companies will initially commence four development programmes for potential small molecule therapies directed to one or more select G protein-coupled receptor (GPCR) targets, including the GLP-1, GIP and glucagon receptors.

"Novo Nordisk has a rich history of innovation in obesity and diabetes. We are building on our scientific leadership in this space and developing a broad pipeline across various targets and modalities, including peptides and small molecules. Leveraging different modalities creates important optionality in our pipeline in terms of potential targets, dosing regimens and scalability," said Marcus Schindler, executive vice president and chief scientific officer of Novo Nordisk. "Septerna has demonstrated strong capabilities in GPCR drug discovery, and we are excited about the opportunity to develop oral small molecule medicines directed at multiple targets."

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GPCRs represent the largest and most diverse family of cell membrane receptors, with hundreds of different GPCRs regulating physiological processes in nearly every organ system of the human body. Using its proprietary Native Complex Platform™, Septerna aims to unlock the full potential of GPCR therapies. The company is focused on the discovery and development of a pipeline of oral small molecules for multiple therapeutic areas, initially focused on endocrinology, immunology and inflammation, and metabolic diseases.

“Novo Nordisk has a long-standing track record of bringing transformative therapies to market, particularly in the field of metabolic disease, which makes them the ideal partner to advance a suite of programmes targeting critical GPCRs for treating obesity, type 2 diabetes and other related conditions,” said Jeffrey Finer, M.D., Ph.D., chief executive officer and co-founder of Septerna. “This collaboration provides a significant opportunity to create multiple potentially groundbreaking oral medicines, while also providing Septerna with the operational flexibility and resources to advance our diverse portfolio of other GPCR-targeted programmes.”

Under the terms of the agreement, Septerna is eligible to receive approximately 2.2 billion US dollars from Novo Nordisk across an upfront payment and research, development and commercial milestone payments. This includes more than 200 million dollars in upfront and near-term milestone payments. Septerna is also eligible to receive tiered royalties on global net sales of marketed products. Novo Nordisk will cover all research and development expenses for partnered programs under the collaboration.

The companies will jointly conduct research activities from discovery through development candidate selection. Starting at IND-enabling activities, Novo Nordisk will have sole responsibility for all global development and commercialisation activities. In addition, Septerna has the right to opt in to a worldwide profit share for one program in the collaboration in lieu of future milestones and royalties for that product candidate.

The agreement is subject to customary closing conditions, including the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Closing is expected to occur in the second quarter of 2025.

About GPCRs and Septerna’s Native Complex Platform

G protein-coupled receptors (GPCRs) represent the largest and most diverse family of cell membrane receptors, with hundreds of different GPCRs regulating physiological processes in nearly every organ system of the human body. They have been the most productive target class in drug discovery history, accounting for approximately one-third of all FDA-approved drugs.

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However, around 75% of potential GPCR therapeutic targets remain undrugged, representing a substantial untapped opportunity for future drug discovery.

Septerna has developed proprietary technologies to isolate, purify, and reconstitute GPCRs outside of cells into complexes with ligands, transducer proteins, and lipid bilayers which mimic cell membranes. These reconstituted assemblies are called Native Complexes because they replicate the natural structure, function, and dynamics of GPCRs in purified biochemical formats.

The Native Complex Platform™ is powered by a suite of tools and technologies that allow screening of billions of candidate molecules. It is designed to target specific GPCRs, uncover novel binding pockets for validated receptors, and pursue a wide spectrum of pharmacologies, including agonists (which activate GPCR signalling), antagonists (which inhibit GPCR signalling), and allosteric modulators (which either increase or decrease the degree of GPCR activation by endogenous ligands), to affect GPCR signalling in different ways to achieve desired therapeutic effects.

About Septerna

Septerna, Inc. is a biotechnology company pioneering a new era of GPCR drug discovery powered by its proprietary Native Complex Platform™. Its industrial-scale platform aims to unlock the full potential of GPCR therapies and has led to the discovery and development of its deep pipeline of oral small molecule product candidates focused initially on treating patients in three therapeutic areas: endocrinology, immunology and inflammation, and metabolic diseases. Septerna was launched by preeminent drug discovery company builders and scientific leaders in the biochemistry, structural biology, and pharmacology of GPCRs. For more information, please visit www.septerna.com.

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases, built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 77,400 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, X, LinkedIn and YouTube.

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