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): **January 27, 2026**

Serina Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**1-38519**	**82-1436829**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

601 Genome Way, Suite 2001
Huntsville, Alabama 35806
(Address of principal executive offices)

(256) 327-9630
(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	Name of exchange on which registered
Common Stock, par value $0.0001 per share	SER	NYSE American

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 Items

On January 28, 2026, the Company issued a press release announcing that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for SER-252, an investigational therapy for advanced Parkinson's disease. The IND clearance allows Serina to proceed with regulatory and site-level activities to support initiation of a planned Phase 1b registrational clinical study evaluating SER-252 in patients with advanced Parkinson's disease. A copy of the press release is filed as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated January 28, 2026, announcing FDA Clearance of IND Application for SER-252 for the Treatment of Advanced Parkinson's disease
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.

SERINA THERAPEUTICS, INC.

Date: January 28, 2026

By: */s/ Steve Ledger*

Chief Executive Officer

Serina Therapeutics Announces FDA Clearance of IND Application for SER-252 for the Treatment of Advanced Parkinson's disease

- *Phase 1b clinical site start-up and regulatory activities in Australia underway to support the global registrational program -*

HUNTSVILLE, AL, January 28, 2026 (GLOBE NEWSWIRE) -- **Serina Therapeutics, Inc.** ("Serina" or the "Company") (NYSE American: SER), a clinical-stage biotechnology company advancing drug candidates enabled by its proprietary POZ Platform™ drug optimization technology, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for SER-252, an investigational therapy for advanced Parkinson's disease.

The IND clearance allows Serina to proceed with regulatory and site-level activities to support initiation of a planned Phase 1b registrational clinical study evaluating SER-252 in patients with advanced Parkinson's disease.

"FDA clearance of the IND is a major milestone for Serina and underscores the promise of the SER-252 program," said Steve Ledger, Chief Executive Officer of Serina Therapeutics. "As we initiate our registrational study, we will begin generating meaningful clinical data for SER-252 in patients with advanced Parkinson's disease. With FDA alignment on a registrational development strategy under a 505(b)(2) NDA pathway, we believe SER-252 has a clear and efficient path forward toward addressing a significant unmet medical need."

As previously disclosed, Serina has engaged in multiple regulatory interactions with the FDA regarding the SER-252 program, including receipt of written FDA feedback supporting the proposed registrational clinical trial design under a 505(b)(2) NDA pathway.

About Serina Therapeutics
Serina is a clinical-stage biotechnology company developing a pipeline of wholly owned drug product candidates to treat neurological diseases and other indications. Serina's POZ Platform™ provides the potential to improve the integrated efficacy and safety profile of multiple modalities including small molecules, RNA-based therapeutics and antibody-based drug conjugates (ADCs). Serina is headquartered in Huntsville, Alabama on the campus of the HudsonAlpha Institute of Biotechnology.

About the POZ Platform™
Serina's proprietary POZ technology is based on a synthetic, water soluble, low viscosity polymer called poly(2-oxazoline). Serina's POZ technology is engineered to provide greater control in drug loading and more precision in the rate of release of attached drugs delivered via subcutaneous injection. The therapeutic agents in Serina's product candidates are typically well-understood and marketed drugs that are effective but are limited by pharmacokinetic profiles that can include toxicity, side effects and short half-life. Serina believes that by using POZ technology, drugs with narrow therapeutic windows can be designed to maintain more desirable and stable levels in the blood.

Serina's POZ platform delivery technology has potential for use across a broad range of payloads and indications. Serina intends to advance additional applications of the POZ platform via out-licensing, co-development, or other partnership arrangements, including the non-exclusive license agreement with Pfizer, Inc. to use Serina's POZ polymer technology for use in lipid nanoparticle drug (LNP) delivery formulations.

About SER-252 (POZ-apomorphine)
SER 252 is an investigational apomorphine therapy developed with Serina's POZ platform and designed to provide continuous dopaminergic stimulation (CDS). CDS has been shown to reduce the severity of levodopa-related motor complications (dyskinesia) in Parkinson's disease. Preclinical studies support the potential of SER 252 to provide CDS without skin reactions.

Cautionary Statement Regarding Forward-Looking Statement

References in this Report to “Serina,” “the Company,” “we” or “us” refer to Serina Therapeutics, Inc. This release contains forward-looking statements within the meaning of federal securities laws. All statements that are not historical fact, including statements about Serina’s planned clinical programs, including timing for first-patient-in and resolution of the clinical hold and customary regulatory and ethics approvals, the potential of Serina’s POZ polymer technology, are forward-looking statements that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These statements are based on management’s current expectations, plans, beliefs or forecasts for the future, and are subject to uncertainty and changes in circumstances. Undue reliance should not be placed on these forward-looking statements which speak only as of the date they are made, and the facts and assumptions underlying these statements may change.

Actual results may differ materially from those projected in such statements due to a variety of important factors including, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; Serina’s ability to continue as a going concern; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any applications may be filed for any drug or vaccine candidates in any jurisdictions; whether and when regulatory authorities may approve any potential applications that may be filed for any drug or vaccine candidates in any jurisdictions, which will depend on a myriad of factors, including making a determination as to whether the product’s benefits outweigh its known risks and determination of the product’s efficacy and, if approved, whether any such drug or vaccine candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any drug or vaccine candidates; and competitive developments. These risks as well as other risks are more fully discussed in the company’s Annual Report on Form 10-K for the year ended December 31, 2024, and the company’s other periodic reports and documents filed from time to time with the SEC. The information contained in this release is as of the date hereof, and Serina assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

For inquiries, please contact:
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