
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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 26, 2026

LeonaBio, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39503
(Commission
File Number)

45-3368487
(IRS Employer
Identification No.)

18706 North Creek Parkway, Suite 104
Bothell, WA 98011
(Address of principal executive offices, including zip code)

(425) 620-8501
(Registrant's telephone number, including area code)
(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 (see General Instruction A.2. below):

- ☐ 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
Common Stock, \$0.0001 par value per share

Trading Symbol(s)
LONA

Name of each exchange on which registered
The Nasdaq Stock Market LLC
(The Nasdaq Capital 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 26, 2026, LeonaBio, Inc. (the “Company”) announced that it had enrolled the 500th subject in its ongoing Phase 3 ELAINE-3 clinical trial (NCT05696626) for lasofoxifene in combination with abemaciclib, a CDK4/6 inhibitor, as a targeted therapy for estrogen receptor-positive (ER+), HER2-negative, ESR1-mutated metastatic breast cancer, following progression on aromatase inhibitors and CDK4/6 inhibitors (the “ELAINE-3 Trial”).

In connection with the private placement financing that the Company completed in December 2025 (the “December 2025 Private Placement”), the Company issued warrants to purchase shares of the Company’s common stock, including 23,031,494 Series A Common Warrants (the “Series A Common Warrants”). The Series A Common Warrants have an exercise price of \$6.35 per share, to be paid in cash, unless a resale registration statement registering the resale of the shares of common stock issuable upon exercise of the Series A Common Warrants is unavailable at the time of exercise, in which case the Series A Common Warrants will be exercisable on a cashless net exercise basis.

The Series A Common Warrants are exercisable, at each holder’s option, after the earlier of (1) the latest of (a) June 30, 2026, (b) the date on which the Company publicly announces, by means of a widely disseminated press release or a Current Report on Form 8-K, the enrollment of the 500th subject or the last subject, whichever is earlier, in the ELAINE-3 Trial (the “ELAINE-3 Enrollment Date”), and (c) the date on which the U.S. Food and Drug Administration approves, or issues a complete response letter with respect to, the marketing application, including any supplement to a new drug application, for imlunestrant in combination with abemaciclib in breast cancer submitted by Eli Lilly & Co., and (2) October 31, 2026 (such earlier date, the “Series A Common Warrant Initial Exercise Date”). The Series A Common Warrants will remain exercisable, at each holder’s option, until the 30th day following the Series A Common Warrant Initial Exercise Date (the “Series A Common Warrant Termination Date”), which Series A Common Warrant Termination Date will be no later than November 30, 2026.

This Current Report on Form 8-K constitutes the Company’s public announcement, for purposes of clause (1)(b) above, of the enrollment of the 500th subject in the ELAINE-3 Trial and, accordingly, establishes the ELAINE-3 Enrollment Date as of the date hereof.

If exercised in full, the Series A Common Warrants would provide the Company with approximately \$146.2 million of additional capital.

Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, including statements regarding: the amount of proceeds, if any, the Company may receive upon exercise of the Series A Common Warrants. These forward-looking statements are based on the Company’s current expectations and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely, including that: enrollment, data, or regulatory outcomes relating to the ELAINE-3 Trial or to third-party products such as imlunestrant may differ from current expectations; some or all of the Series A Common Warrants may expire unexercised, or may be exercised on a cashless net exercise basis providing less or no cash proceeds to the Company; and the other risks described under the heading “Risk Factors” in the Company’s Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q and other filings with the SEC. These forward-looking statements speak only as of the date hereof, and the Company undertakes no obligation to update any forward-looking statements, except as required by law.

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.

LeonaBio, Inc.

Date: August 26, 2026

By: /s/ Mark Litton
Mark Litton
President and Chief Executive Officer
