February 20, 2026

Via EDGAR

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, D.C. 20549

Attn: Jessica Dickerson
Joe McCann

Re: LeonaBio, Inc.
Registration Statements on Form S-3
Filed January 20, 2026
File Nos. 333-292826 and 292829

Ladies and Gentlemen:

LeonaBio, Inc. ("***we***", "***our***" or the "***Company***") submits this letter in response to comments from the staff (the "***Staff***") of the Securities and Exchange Commission (the "***Commission***") received by letters dated February 11, 2026, relating to the Company's Registration Statements on Form S-3 (File Nos. 333-292826 and 292829) each originally filed with the Commission on January 20, 2026 (the "***Forms S-3***").

In this letter, we have recited the comment from the Staff in italicized, bold type and have followed the comment with the Company's response.

Unless otherwise indicated, defined terms used herein have the meanings set forth in the Forms S-3.

Registration Statement on Form S-3

General

1. ***We note from your Current Report on Form 8-K filed December 18, 2025, as amended, that, in December 2025, you entered into an in-licensing agreement with Sermonix Pharmaceuticals, Inc. and that, pursuant to that agreement, you assumed the obligation for the ongoing phase 3 trial for lasofoxifene in the licensed territories; you assumed Sermonix's agreements with third parties, including contract manufacturers that have been supplying drug substances and drug***

products; and you are required to make payments to Sermonix's third party service providers. Please tell us whether you will be providing the Sermonix financial statements. If you will not be providing them, please tell us why.

The Company respectfully advises the Staff that the grant of exclusive licenses and rights to the Company to develop, manufacture and commercialize oral forms of the selective estrogen-receptor modulator known as lasofoxifene from Sermonix Pharmaceuticals, Inc. ("***Sermonix***") pursuant to the Sermonix License (described below) did not constitute the acquisition of a business for purposes of Rule 8-04 of Regulation S-X ("***Rule 8-04***") and Item 11(b) of Form S-3. Accordingly, Sermonix financial statements are not required to be filed.

Background

Reference is made to the Company's Current Report on Form 8-K, as amended, dated December 18, 2025, and the description therein of the Company's license agreement with Sermonix, dated December 18, 2025 (the "***Effective Date***" and such agreement the "***Sermonix License***"), pursuant to which the Company received from Sermonix an exclusive, sublicensable license, under relevant patents and know-how owned or in-licensed by Sermonix, to develop, manufacture, commercialize and otherwise exploit oral forms of the estrogen-receptor modulator known as lasofoxifene (referred to generally herein as "***lasofoxifene***," and the rights licensed by the Sermonix License, the "***Licensed Rights***") in all countries outside of Asia and certain countries in the Middle East (the "***Licensed Territory***").

Applicable Rules

Rule 8-04 of Regulation S-X and Item 11(b) of Form S-3 require audited financial statements to be filed if, during the most recent fiscal year or subsequent interim period for which a balance sheet is required, a business acquisition has occurred. In deciding whether the provisions of Rule 8-04 apply, an issuer must first determine, in accordance with guidance set forth in Article 11 of Regulation S-X, whether the acquired component constitutes the acquisition of a business rather than an acquisition of assets or other rights.

Under Rule 11-01(d), a business is identified by evaluating the facts and circumstances involved and whether there is sufficient continuity of the acquired entity's operations prior to and after the transaction so that disclosure of prior financial information is material to an understanding of future operations. There is a presumption under Rule 11-01(d) that a separate entity, subsidiary, or division is a business; however, a lesser component of an entity, such as a product line or an operating real estate property, may also be considered a business. In evaluating whether a lesser component is a business, Rule 11-01(d) requires registrants to consider (1) whether the nature of the revenue-producing activity of the component will remain generally the same as before the transaction; and (2) whether the physical facilities, employee base, market distribution system, sales force, customer base, operating rights, production techniques, or trade names remain with the component after the transaction.

Analysis

The Company has considered the definition of a business as contemplated by Article 11 of Regulation S-X. In particular, Rule 11-01(d) states that a business should be evaluated in light of the facts and circumstances involved and whether there is sufficient continuity of the acquired entity's operations prior to and after the transactions so that disclosure of prior financial information is material to an understanding of future operations.

Rule 11-01(d)(1)

Rule 11-01(d)(1) includes as a relevant factor or circumstance "whether the nature of the revenue producing activity of the component will remain generally the same as before the transaction." Lasofoxifene is a clinical stage drug candidate and is not approved for commercial sale anywhere in the world. Even if the Company is ultimately successful in completing clinical trials and obtaining regulatory approval for the commercial sale of lasofoxifene, any revenue from sales of the approved product is years away. The absence of any revenue generated by Sermonix before the Company obtained the Licensed Rights and the substantial uncertainty of generating any potential revenue in the future supports the Company's determination that there was no acquisition of a business within the meaning of Article 11 of Regulation S-X.

Rule 11-01(d)(2)

In accordance with Rule 11-01(d)(2), the Company has considered whether physical facilities, employee base, market distribution system, sales force, customer base, operating rights, production techniques, or trade names were acquired in connection with the Sermonix License.

Physical Facilities

The Company did not acquire any physical facilities of Sermonix in connection with the Sermonix License, supporting the Company's determination that there was no acquisition of a business within the meaning of Article 11 of Regulation S-X.

Employee Base

The Sermonix License does not now, and did not at the Effective Date, require the Company to offer continuing employment to any Sermonix employees. Subsequent to entry into the Sermonix License, the Company elected to enter into separate arrangements with six employees of Sermonix to provide services to the Company relating to the development of lasofoxifene. Of these six, four were engaged as consultants to provide certain limited services and two were hired by the Company as employees. The Company's decision to engage the six Sermonix employees as either consultants or new Company employees was made solely at the Company's discretion to obtain limited clinical or advisory support for the global phase 3 clinical trial of oral lasofoxifene (the "***ELAINE-3 Study***"). These arrangements were not a condition to closing, nor were they negotiated, arranged, or otherwise facilitated by Sermonix. Rather, these agreements were

executed after the Effective Date for convenience and to support the clinical development of lasofoxifene, and these individuals are not expected to significantly contribute to future research and development activities. The Company also notes that the engagement of the six Sermonix employees was neither necessary nor sufficient for the continued development of lasofoxifene. As of the date of this letter, there are 32 people supporting the clinical development of lasofoxifene and the general operations of the Company. Of these 32 people, 20 are Company employees (excluding the two former Sermonix employees hired by the Company after the Effective Date) and six are consultants engaged by the Company (excluding the four Sermonix employees engaged as consultants by the Company after the Effective Date). Because their employment or engagement was not required by the Sermonix License, and because the Sermonix employees engaged by the Company are neither necessary nor sufficient for the continued clinical development of lasofoxifene, the Company submits to the Staff that this factor supports the Company's determination that there was no acquisition of a business within the meaning of Article 11 of Regulation S-X.

Market Distribution System

Sermonix did not have a market distribution system in place for lasofoxifene as of the Effective Date. Lasofoxifene is a clinical stage drug candidate and is not approved for commercial sale anywhere in the world. Even if lasofoxifene ultimately obtains regulatory approval for commercial sale, any such approval is years away, and whether the Company will ultimately invest in building out a market distribution system is not yet known. The lack of a transfer of a market distribution system by Sermonix to the Company supports the Company's determination that there was no acquisition of a business within the meaning of Article 11 of Regulation S-X.

Sales Force

Sermonix did not have a sales force in place for lasofoxifene as of the Effective Date because lasofoxifene is a clinical stage drug candidate and is not approved for commercial sale anywhere in the world. Even if lasofoxifene receives regulatory approval for commercial sale, whether the Company will ultimately invest in hiring and deploying a sales force is not yet known. The lack of a transfer of a sales force by Sermonix to the Company supports the Company's determination that there was no acquisition of a business within the meaning of Article 11 of Regulation S-X.

Customer Base

Because lasofoxifene is a clinical stage drug candidate and is not approved for commercial sale anywhere in the world, there were no customers of lasofoxifene before the Effective Date and there are none as of the date hereof. The lack of a transfer of customers by Sermonix to the Company supports the Company's determination that there was no acquisition of a business within the meaning of Article 11 of Regulation S-X.

Operating Rights

Separate from the license of lasofoxifene, under the Sermonix License, the Company also licensed certain know-how, obtained the rights to manufacturing technology and inventory, assumed certain service provide agreements and discharged amounts owing to certain of Sermonix's third-party service providers. As part of the consideration to be paid by the Company for the Licensed Rights, the Company agreed to discharge approximately $16.8 million owed to certain of Sermonix's third-party service providers. The Company's decision to discharge these payables directly was made solely for administrative convenience and does not reflect the Company's substantive involvement in, or benefit derived from, the underlying agreements. In addition, the Company assumed various service provider agreements, including contract research organization ("***CRO***") contracts, contract manufacturing organization ("***CMO***") contracts, and agreements with certain other service providers that will directly conduct or support the ELAINE-3 Study. While there are numerous qualified service providers available to provide services similar to those provided by the CROs, CMOs and other service providers whose agreements were assumed by the Company, the Company notes for the Staff that switching key service providers like a CRO or CMO during the conduct of a clinical trial can introduce significant risk of delays and additional interactions with regulatory agencies. It is customary in licensing transactions in the life sciences industry for the licensee to continue working with service providers that were selected by the licensor prior to any license agreement. The Company notes to the Staff that it has full discretion to terminate any of the service provider agreements in accordance with their terms, and to seek out alternate service providers at any time and is not obligated to Sermonix to retain any particular service provider.

As examples of this flexibility, the Company notes that it has entered into agreements with five service providers to provide clinical research services, assay testing services, drug substance manufacturing, drug product/packaging services, and regulatory operation services with respect to the ELAINE-3 Study following the Effective Date. Of particular note is the Company's direct agreement with the primary CRO for the ELAINE-3 Study, which was entered into by the Company and the CRO after the Effective Date and was not an agreement to which Sermonix was previously a party. The budgeted expenses under this agreement are expected to represent the substantial majority of anticipated research and development spend for the ELAINE-3 Study. In addition, the Company expects to use certain of its existing service providers as well as new service providers to advance the ELAINE-3 Study. The Company submits to the Staff that the facts that the Company assumed certain service provider arrangements from Sermonix solely for convenience and to maintain the continuity of the ELAINE-3 Study, and that the Company is augmenting the clinical development of lasofoxifene with additional service providers, supports the Company's determination that there was no acquisition of a business within the meaning of Article 11 of Regulation S-X.

Production Techniques

Under the Sermonix License, while the Company licensed certain know-how, and obtained rights to manufacturing technology and inventory from Sermonix relating to lasofoxifene, neither Sermonix nor the Company themselves have any manufacturing or production capabilities. The Company intends to utilize CMOs and other service providers to manufacture lasofoxifene in quantities sufficient to advance the ELAINE-3 Study. The Company does not expect to engage CMOs to manufacture lasofoxifene for commercial sale until the Company is successful in completing clinical trials and obtaining regulatory approval. For these reasons, the Company submits to the Staff that this aspect of the Sermonix License supports the Company's determination that there was no acquisition of a business within the meaning of Article 11 of Regulation S-X.

Trade Names

The Sermonix License grants the Company the right to brand lasofoxifene in the Licensed Territory using trademarks, logos and trade names that the Company determines appropriate. Given the pre-commercial nature of lasofoxifene and the significant amount of time required to advance lasofoxifene to potential regulatory approval, Sermonix and the Company have agreed to cooperate with respect to developing and implementing a global branding strategy for lasofoxifene in the future. Although Sermonix assigned to the Company certain trademarks that Sermonix had previously obtained in anticipation of commercialization of lasofoxifene in the future, these trademarks have no brand value given the pre-commercial status of lasofoxifene. In addition, the Company is not required to use such trade names and, even if the Company were to elect to use such trade names, such trade names would not be used for years, assuming the Company is able to meet or exceed its anticipated clinical development timelines and obtain regulatory approval permitting commercial sales. For the foregoing reasons, the Company submits to the Staff that this aspect of the Sermonix License supports the Company's determination that there was no acquisition of a business for purposes Article 11 of Regulation S-X.

Other Considerations

Rule 11-01(d) states that the factors set forth in Rule 11-01(d)(1) and (2) are among the facts and circumstances to be analyzed. The Company therefore notes other elements that support the conclusion that there was no acquisition of a business within the meaning of Article 11 of Regulation S-X.

No Entity or Division Acquisitions

The Sermonix License did not include the acquisition of any separate entity, subsidiary, or division of Sermonix, supporting the conclusion that the transaction did not involve a business within the meaning of Article 11 of Regulation S-X.

Sermonix Financial Statements are not Material to Investors' Understanding of Future Operations

Prior to the entry into the Sermonix License with the Company, Sermonix acquired rights to develop lasofoxifene and subsequently conducted various pre-clinical and clinical activities. However, the expenses incurred by Sermonix prior to the Effective Date in the performance of such activities are different in type and amount from those undertaken and to be undertaken by the Company in conducting and completing the ELAINE-3 Study (as well as other potential clinical studies required by regulatory authorities), seeking regulatory approval and commercializing lasofoxifene if approval is obtained. As a result, the financial statements of Sermonix would provide little value to investors in evaluating the Company's future results of operations.

The Company's future operations will involve significant effort and expense to develop, obtain regulatory approval for and commercialize lasofoxifene, including (1) advancing the ELAINE-3 Study to completion (and potentially other studies as well); (2) submitting a new drug application to U.S. and foreign regulatory authorities; (3) complying with any additional requirements for marketing approval; (4) negotiating and executing manufacturing agreements with service providers to be able to manufacture a sufficient amount of lasofoxifene to support commercial sales; (5) undertaking significant marketing and promotional activities; and (6) continued safety and associated regulatory activities following marketing approval. The financial statements of Sermonix would provide little value to investors in evaluating these future operations.

The Company believes that investors are instead focused on the Company's anticipated cash runway, the timing of clinical development milestones for lasofoxifene and the Company's other product candidates, the likelihood of success of the ELAINE-3 Study and the potential addressable market of lasofoxifene if commercial approval is obtained. The Company's public statements since the entry into the Sermonix License have addressed each of the foregoing areas of investor focus and the Company submits that Sermonix's historical financial statements would not meaningfully inform such considerations.

A central concept to the term business under Rule 11-01(d) is whether "there is sufficient continuity of the acquired entity's operations prior to and after the transactions so that disclosure of prior financial information is material to an understanding of future operations." For the reasons discussed above, the Company submits to the Staff that there is no significant continuity of operations and financial statements would not be material to an understanding of future operations and therefore there was no business acquisition within the meaning of Rule 11-01(d).

Reversion of Licensed Rights Upon Termination

The Sermonix License may terminate in accordance with its terms, and all rights and licenses granted under the agreement revert to Sermonix upon termination.[1] The Sermonix License will remain in effect until the Company, its affiliates or sublicensees are no longer developing or commercializing lasofoxifene in the Licensed Territory, unless earlier terminated by either party in accordance with the terms of the agreement. The Sermonix License may be terminated by each party for an uncured material breach by or insolvency of the other party. The Company also has the right to terminate the Sermonix License for safety reasons or for convenience at any time after the topline data readout of the ELAINE-3 Study. Upon termination, all rights and licenses granted to the Company will revert to Sermonix. Upon reversion of any such rights, Sermonix would hold all rights that the Company licensed pursuant to the Sermonix License. Unlike the acquisition of a business with continuity of operations before and after the transaction, the Sermonix License imposes ongoing obligations on the Company and provides mechanisms for each of the Company and Sermonix to terminate the agreement under specified circumstances. This ability to terminate and have the Licensed Rights revert back to Sermonix highlights that the Sermonix License is not the acquisition of a business.

Necessity of Ligand License

In order to secure rights to develop lasofoxifene, the Company was required to secure rights not only from Sermonix (under the Sermonix License) but also from Ligand Pharmaceuticals Incorporated ("***Ligand***"), through a separate license agreement (the "***Ligand License***"). This separate agreement granted the Company an exclusive, sublicensable license, under relevant know-how and certain patents owned or in-licensed by Ligand, to develop, manufacture and sell lasofoxifene in the Licensed Territory.

The Ligand License will continue in effect until the Company, its affiliates or sublicensees are no longer developing, manufacturing, using or commercializing lasofoxifene in the Licensed Territory, unless earlier terminated by either party in accordance with the terms of the Ligand License. Each party may terminate the Ligand License in its entirety for uncured material breach by or insolvency of the other party. The Company may also terminate the Ligand License in its entirety for safety reasons or for failure to achieve the primary efficacy endpoint in any clinical trial of lasofoxifene. Ligand may also terminate the Ligand License if the Company takes certain actions to challenge Ligand's patent rights with respect to lasofoxifene. Upon termination, all rights and licenses granted to Company will revert to Ligand.

The Company submits to the Staff that the insufficiency of the Sermonix License to grant full rights to develop lasofoxifene further illustrates that there was no acquisition of a business from Sermonix.

ASC 805

[1] The Company also notes to the Staff that Sermonix has retained rights with respects to lasofoxifene outside the Licensed Territory and has separately sublicensed them to a third party.

Lastly, although the analytical framework under Accounting Standards Codification ("***ASC***") 805 differs from the requirements of Rule 8-04 and Rule 11-01(d), the Company notes to the Staff that, in connection with the preparation of the Company's 2025 financial statements, the Company utilized the guidance in ASC 805 and concluded that the Sermonix License did not constitute the acquisition of a business.

ASC 805 provides a two-step framework for entities to use in evaluating whether an integrated set of assets and activities (collectively a "set") should be accounted for as an acquisition of a business or a group of assets. Under the first step, if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the set is not considered a business. If this is not the case, the second step is to consider the inputs, processes, and outputs associated with the acquisition. A business consists of inputs and processes applied to those inputs that have the ability to contribute to the creation of outputs. Although businesses usually have outputs, outputs are not required for an integrated set to qualify as a business.

In applying the first step of the two-step framework, the Company determined that the acquired set includes in-process research and development ("***IPR&D***") as well as the assignment of certain service provider arrangements. The acquired IPR&D includes the Licensed Rights within the Licensed Territory, together with all related patents, proprietary know-how, investigational new drug applications and other regulatory documentation, manufacturing process data, and existing inventories of drug substance and drug product. These assets are considered a group of complementary assets as no component is capable of being sold, transferred, licensed, rented or exchanged separately without the underlying rights to the Licensed Rights. As a result, these assets would be recognized and measured as a single asset in a business combination.

Furthermore, the IPR&D assets relate to a single IPR&D project focused on advancing lasofoxifene as a potential therapy for metastatic breast cancer. The Company considered the service provider arrangements described above as well and determined that such arrangements do not give rise to separate assets that would be recognized in a business combination. Further, the Company determined that the service agreements with the six Sermonix employees were separate from the Sermonix License and not considered a part of the acquired asset. Accordingly, the Company concluded that substantially all of the fair value for the acquired set was concentrated in the IPR&D asset, indicating the set is not a business

As a result, based on the Company's qualitative assessment, no further evaluation under Step 2 of the ASC 805 framework is required. Because the acquired set does not meet the definition of a business under ASC 805, the Company determined that the Licensed Rights should be accounted for as the acquisition of an asset rather than a business combination. While the Company acknowledges that the analytical framework under ASC 805 differs from the requirements of Rule 8-04 and Rule 11-01(d), the Company finds the conclusion of its ASC 805 analysis reinforcing of its conclusion discussed in this response that the Sermonix License did not constitute the acquisition of a business for purposes of Rule 8-04 and Item 11(b) of Form S-3.

Conclusion

Based on the foregoing facts and circumstances, the Company determined that there was insufficient continuity of operations prior to and following the Sermonix License such that disclosure of Sermonix financial information would not be material to an understanding of future operations of the Company and there was no acquisition of a business within the meaning of Article 11 of Regulation S-X under Rule 11-01(d) of Regulation S-X. For this reason, no financial statements relating to the Sermonix License were required to be filed pursuant to Rule 8-04 of Regulation S-X and Item 11(b) of Form S-3.

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If you have any questions or comments, please contact me.

Sincerely,

/s/ Mark Litton

Mark Litton
President and Chief Executive Officer

cc: Mark Worthington, LeonaBio, Inc.
Robert Renninger, LeonaBio, Inc.

Michael Nordtvedt, Wilson Sonsini Goodrich & Rosati, P.C.
Bryan D. King, Wilson Sonsini Goodrich & Rosati, P.C.
Laura Duncan, Wilson Sonsini Goodrich & Rosati, P.C.