1035 Cambridge Street, Suite 18 A,
Cambridge MA 02141
617-798-6700

May 11, 2026

Dear Fellow Shareholders,

Over the past year, Ernexa Therapeutics has laid a powerful foundation for what we believe will be a transformational new chapter in our company's evolution. Today, we are moving forward with increasing confidence, strengthened by scientific validation, operational execution, and a clear vision for the future.

Most importantly, we are making meaningful progress toward fulfilling our core purpose: providing hope for patients facing some of the most difficult cancers and autoimmune diseases.

As we look ahead, we believe Ernexa is uniquely positioned to emerge as a clinical-stage biotechnology company in 2026, marking a defining inflection point in our journey and creating the potential for significant long-term value for patients and shareholders alike.

This past year has been marked by substantial progress across our platform, pipeline, and operations. We sharpened our strategic focus, streamlined operations, and significantly improved capital efficiency while continuing to advance our lead programs. In 2025, we reduced general and administrative expenses by approximately 61% year over year while successfully achieving several critical development milestones, including completion of Proof-of-Principle studies for both ERNA-101 and ERNA-201, as well as a successful pre-IND meeting with the FDA for ERNA-101.

These accomplishments have positioned Ernexa for what we believe could be a breakthrough year ahead.

Perhaps the most compelling evidence of our momentum came recently with the announcement of groundbreaking preclinical data for ERNA-101, our lead engineered iMSC therapy designed to transform immunologically “cold” tumors into immune-responsive tumors.

In preclinical ovarian cancer models, ERNA-101, in combination with PD-1 blockade, achieved complete tumor elimination and 100% long-term survival in treated mice, results that significantly exceeded those observed with either therapy alone. The therapy not only eliminated detectable tumors, but fundamentally remodeled the tumor microenvironment, activating durable immune responses and enabling powerful anti-tumor activity.

These findings represent far more than a scientific milestone. They reinforce our belief that ERNA-101 has the potential to become a foundational immunotherapy platform capable of meaningfully enhancing checkpoint inhibitor activity across ovarian cancer and potentially other highly immunosuppressive solid tumors.

Importantly, this data provides growing confidence in the underlying mechanism of our platform and further strengthens our conviction as we advance toward first-in-human clinical studies.

The year ahead is expected to be one of the most important in Ernexa’s history.

We remain on track to complete ERNA-101 clinical manufacturing process development, finalize IND-enabling studies, and submit our Investigational New Drug (IND) application in the third quarter of 2026. Pending regulatory clearance, we expect to initiate our first-in-human Phase 1 clinical trial in platinum-resistant ovarian cancer in the fourth quarter of 2026. We also anticipate important progress for ERNA-201, including a planned pre-IND meeting with the FDA later this year.

Supported by our recent financing and strengthened operational discipline, we believe we are entering this next phase from a position of growing strength and readiness.

While we are proud of the progress we have made, we recognize that our mission extends beyond milestones, data, and development timelines. At the heart of Ernexa is a deep commitment to patients and families who urgently need new treatment options.

Every advancement we make is rooted in a singular purpose: to provide hope where few options exist today.

For patients battling advanced ovarian cancer and other devastating diseases, hope matters. Innovation matters. And the possibility of changing outcomes matters profoundly.

We believe the foundation has now been firmly established. Our science is advancing. Our strategy is focused. Our team is executing. And our opportunity is expanding.

The transition from a preclinical company to a clinical-stage biotechnology company represents more than an operational milestone and reflects the emergence of Ernexa as a company positioned to potentially redefine how engineered cell therapies are used to treat cancer and autoimmune disease.

We enter this next chapter with momentum, discipline, and conviction.

On behalf of the entire Ernexa team, thank you for your continued support and belief in our mission. We are excited about the future and look forward to sharing our continued progress as we work to build a company capable of delivering meaningful innovation, transformational therapies, and long-term shareholder value.

Sincerely,

Sanjeev Luther

Sanjeev Luther
President & Chief Executive Officer
Ernexa Therapeutics Inc.
1035 Cambridge Street
Cambridge, MA 02141
Email: Sanjeev.Luther@ernexatx.com

"Laser Focus with Relentless Execution"

Forward-Looking Statements

This letter contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be covered by the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would," "contemplate," "project," "target," "objective," or the negative version of these words and similar expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Ernexa's actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this letter, including, without limitation, risks and uncertainties related to: progress and possible outcomes of the Company's lead research project, ERNA-101, and future research projects. Forward-looking statements are based upon Ernexa's current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. For a detailed description of Ernexa's risks and uncertainties, you are encouraged to review its documents filed with the SEC including its recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Ernexa does not undertake any obligation to update the forward-looking statements contained herein to reflect events that occur or circumstances that exist after the date hereof, except as required by applicable law.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 1-11460

Ernexa Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**31-1103425**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

1035 Cambridge Street, Suite 18A Cambridge, MA	**02141**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 798-6700
(Registrant's telephone number, including Area Code)

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, $0.005 par value	ERNA	The Nasdaq Stock Market LLC
Common Stock Purchase Warrants	ERNAW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2025), computed by reference to the closing sale price of the common stock on the Nasdaq Capital Market on such date, was approximately $17.5 million. For purposes of this determination shares beneficially owned by executive officers, directors and ten percent stockholders have been excluded, which does not represent an admission by the registrant as to the affiliate status of such person.

As of March 12, 2026, the registrant had 29,154,431 shares of common stock outstanding.

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "2025 Annual Report") contains "forward-looking statements" as that term is defined under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include statements related to future events, results, performance, prospects and opportunities, including statements related to our strategic plans, capital needs, and our financial position. Forward-looking statements are based on information currently available to us, on our current expectations, estimates, forecasts, and projections about the industries in which we operate and on the beliefs and assumptions of management. Forward-looking statements often contain words such as "expects," "anticipates," "could," "targets," "projects," "intends," "plans," "believes," "seeks," "estimates," "may," "will," "would," and similar expressions. In addition, any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business, and other characterizations of future events or circumstances, are forward-looking statements. Forward-looking statements by their nature address matters that are, to different degrees, subject to risks and uncertainties that could cause actual results to differ materially and adversely from those expressed in any forward-looking statements. For us, particular factors that might cause or contribute to such differences include those identified in the "Summary of Principal Risk Factors" below and the other risks and uncertainties described in Part I, Item 1A "Risk Factors" of this 2025 Annual Report and described in other documents we file from time to time with the Securities and Exchange Commission (the "SEC"), including our Quarterly Reports on Form 10-Q.

Readers are urged not to place undue reliance on the forward-looking statements in this 2025 Annual Report, which speak only as of the date of this 2025 Annual Report. We are including this cautionary note to make applicable, and take advantage of, the safe harbor provisions of the PSLRA. Except as required by law, we do not undertake, and expressly disclaim any obligation, to disseminate, after the date hereof, any updates or revisions to any such forward-looking statements to reflect any change in expectations or events, conditions or circumstances on which any such statements are based.

We believe that the expectations reflected in forward-looking statements in this 2025 Annual Report are based upon reasonable assumptions at the time made. However, given the risks and uncertainties, you should not rely on any forward-looking statements as a prediction of actual results, developments or other outcomes. You should read these forward-looking statements with the understanding that we may be unable to achieve projected results, developments or other outcomes and that actual results, developments or other outcomes may be materially different from what we expect.

Unless stated otherwise or the context otherwise requires, all references in this 2025 Annual Report to "Ernexa" refers to Ernexa Therapeutics Inc., and references to the "Company," "we," "us" or "our" refer to Ernexa and its consolidated subsidiaries, including Ernexa TX2, Inc., Novellus, Inc. and Novellus Therapeutics Limited.

SUMMARY OF PRINCIPAL RISK FACTORS

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. We urge investors to carefully review and consider the additional discussion of the risks summarized in this risk factor summary, and other risks that we face, which can be found below under the heading "Risk Factors" in Item 1A of this 2025 Annual Report, together with other information in this report, before making investment decisions regarding our securities.

Risks Related to our Business and Industry

- We will require substantial additional capital to fund our operations, and if we fail to obtain the necessary financing, we may not be able to continue as a going concern.
- We have incurred significant losses since our inception and expect to continue to incur losses for the foreseeable future, which, together with our limited financial resources and substantial capital requirements, make it difficult to assess our prospects.

- We depend substantially, and expect in the future to continue to depend, on in-licensed intellectual property. Such licenses impose obligations on our business, and if we fail to comply with those obligations, we could lose license rights, which would substantially harm our business.
- We rely heavily on in-licensed intellectual property from Factor Limited. Loss of this license or termination of the Factor L&C Agreement could significantly harm our product development and ability to enter co-development strategic partnerships, materially impacting our business.

Risks Related to New, Cutting Edge Technologies

- Our product development relies on novel, inherently risky technologies. Stem cell therapy is a relatively new field, and our efforts may not result in effective treatments for human diseases.
- We are in an industry with intense competition and rapid technological change and our competitors may develop therapies that are more advanced, safer or more effective than any therapy we may develop in the future, which may adversely affect our financial condition.
- Negative public opinion and increased regulatory scrutiny due to ethical and other concerns surrounding the use of stem cell therapy or human tissue may damage public perception of our synthetic allogeneic iMSC product candidates or adversely affect our ability to conduct our business.
- The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production.

Risks Related to Ownership of our Common Stock

- Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock.
- Anti-takeover provisions of Delaware law and provisions in our charter and bylaws could make a third-party acquisition of us difficult.

Risks Related to Regulatory Requirements and Our Intellectual Property

- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- If we are unable to obtain and maintain patent and other intellectual property protection, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our business, financial condition, results of operations, and/or prospects may be materially and adversely effected.
- If we do not obtain patent term extension for future products that our strategic partners or collaborators may successfully develop, our business may be materially harmed.
- Changes in patent law in the United States ("U.S.") and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect future products and product candidates that we or our strategic partners or collaborators may develop.
- We may not be able to protect our intellectual property rights throughout the world.
- We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

PART I

ITEM 1. Business

Overview

We are a preclinical-stage synthetic allogeneic iMSC therapy company. iMSCs are induced pluripotent stem cell ("iPSC")-derived mesenchymal stem cells. We envision a future where cell therapies powered by synthetic iMSCs can offer new options for patients with limited treatment paths and our mission is to transform the treatment of cancer and autoimmune disease by developing scalable, affordable, off-the-shelf cell therapies that restore hope.

Objectives and Business Strategy

Our lead product candidate ERNA-101 is allogenic IL-7 and IL-15-secreting iMSCs. ERNA-101 capitalizes on the intrinsic tumor-homing ability of MSCs to slip through the tumor's defenses and to deliver potent pro-inflammatory factors directly to the tumor microenvironment ("TME"), limiting systemic exposure and potential toxicity while potentially unleashing potent anti-cancer immune responses including enhancement of T-cell anti-tumor activity. Our initial focus is to develop ERNA-101 in platinum-resistant ovarian cancer. We collaborated with the University of Texas MD Anderson Cancer Center to investigate the ability of ERNA-101 to induce and modulate antitumor immunity in an ovarian cancer model. In preclinical study, ERNA-101 exhibited reduction of tumor growth and a statistically significant survival advantage in the ovarian cancer model as compared to the control group. During the fourth quarter of 2025, we had a successful pre-Investigational New Drug ("IND") meeting with the Food and Drug Administration ("FDA"), which resulted in regulatory alignment with our development approach. We expect to complete the Investigational New Drug ("IND") enabling studies and IND submission in 2026 and to subsequently enter a Phase I investigator sponsored clinical trial in the second half of 2026.

We are also investigating anti-inflammatory cytokine (e.g., IL-10)-secreting iMSCs in autoimmune disorders like rheumatoid arthritis, which we refer to as ERNA-201. MSCs have an intrinsic ability to home to inflamed tissue and have been shown to dampen inflammation and drive healing through multiple secreted mediators and cell-cell interactions. We are investigating the ability of ERNA-201 to turbocharge these anti-inflammatory and regenerative effects.

We have also been accepted as one of only ten global companies for the Japan External Trade Organization acceleration program, which will allow us to receive expert-led mentoring and market-entry guidance focused on Japan's regulatory, clinical and commercial landscape. The program also provides direct engagement opportunities with leading Japanese research and development organizations to explore potential collaborations across development, manufacturing and clinical execution.

Additionally, to expand our developmental opportunities and raise non-dilutive capital, we are actively seeking strategic partnerships to co-develop or out-license therapeutic assets and engage with potential collaborators, and we are currently applying for research grants, some of which will be used for research conducted at our Texas subsidiary, Ernexa TX2, Inc.

License Agreement

In September 2024, we entered into the Exclusive License and Collaboration Agreement ("the Factor L&C Agreement") with Factor Bioscience Limited ("Factor Limited"). Under the Factor L&C Agreement, we have obtained an exclusive license in the fields of cancer, autoimmune disorders, and rare diseases with respect to certain licensed technology and we have the right to develop the licensed technology directly or enter into co-development agreements with partners who can help bring such technology to market. The Factor L&C Agreement also provides for certain services and materials to be provided by Factor to facilitate our development of the licensed technology and to enable us to scale up production at third party facilities.

The initial term of the Factor L&C Agreement was one year after the effective date, and it automatically renews yearly thereafter. We may terminate the Factor L&C Agreement for any reason upon 90 days' written notice to Factor, and the parties otherwise have customary termination rights, including in connection with certain uncured material breaches and specified bankruptcy events.

Pursuant to the Factor L&C Agreement, we paid Factor $0.2 million per month for the first twelve months and $0.1 million per month for the first nine months toward patent costs. We will also pay certain milestone payments, royalty payments on net sales of commercialized products and sublicensing fee payments.

Nasdaq Compliance

Our common stock is listed on The Nasdaq Capital Market ("Nasdaq"). Nasdaq requires that listed companies satisfy certain continued listing requirements. Listing Rule 5550(a)(2) requires that listed companies maintain a minimum bid price of their common stock of at least $1.00 per share (the "Bid Price Rule"). Listing Rule 5550(b) requires that listed companies have: (1) stockholders' equity of at least $2.5 million (the "Stockholders' Equity Rule"; (2) a market value of listed securities (the "MVLS Rule") of at least $35 million; or (3) net income from continuing operations of $500,000 in the company's most recently completed fiscal year or in two of the three most recently completed fiscal years (the "Net Income Rule").

Our stockholders' equity at December 31, 2025 was approximately $2.4 million and we do not currently meet the MVLS Rule or the Net Income Rule. However, on February 10, 2026, we completed a public offering for the sale of our common stock and accompanying warrants for net proceeds of approximately $9.5 million. As a result, as of the date of this 2025 Annual Report, our stockholders' equity exceeds $2.5 million, as required under the Stockholders' Equity Rule.

Since February 3, 2026, the closing bid price of our common stock has been trading below $1.00. Upon the 30th consecutive business day of trading below $1.00, we expect to receive a notice from Nasdaq informing us that we do not meet the Bid Price Rule. To regain compliance, we must maintain a closing bid price of at least $1.00 for a minimum of 10 consecutive business days.

Because we effected a reverse stock split within the last 12 months to regain compliance with the Bid Price Rule, Nasdaq rules provide that if our common stock fails to meet the minimum bid price requirement within one year following that reverse stock split, we would not be eligible for any compliance period under Nasdaq Listing Rule 5810(c)(3)(A). In such event, Nasdaq would issue a Staff Delisting Determination with respect to our common stock, which we could appeal to a Nasdaq hearings panel in accordance with applicable Nasdaq rules.

Patent Portfolio

Our strategy is to develop and advance a pipeline of therapeutic products both internally and through strategic partnerships, leveraging our in-licensed synthetic allogeneic iMSC therapy, with the near-term focus on deploying our synthetic allogeneic iMSC therapy through strategic partnerships.

Patents

As of March 12, 2026, we had in-licensed 13 patent families filed in the U.S. and other major markets worldwide, including 33 granted patents, 31 pending non-provisional patent applications or provisional patent applications, and 4 pre-nationalization PCT application. Patent protection for the iMSC technology platform includes:

Family Number and Title	United States or Foreign Jurisdiction	Earliest Effective Date of Patent Application
FAB-001: "Methods and Products for Transfecting Cells"	**Granted:** US (Nos. 10829738, 10982229, 11692203, 10472611, 11466293, 10662410, 12227757; 12391961); EP (No. 2788033 (CH; DE; FR; GB; IE)); EP (No. 3260140 (BE; CH; DE; DK; FR; GB; IE; NL); CA (No. 2,858,148); JP (Nos. 6073916, 6294944);	12/05/2011

Family Number and Title	United States or Foreign Jurisdiction	Earliest Effective Date of Patent Application
	KR (No. 10-2196339) **Pending**: US, EP, CA	
FAB-003: "Methods and Products for Transfection"	**Granted**: US (Nos. 8497124, 9127248, 11492600, 9399761, 9562218, 9695401, 9879228, 9969983, 10131882, 10301599, 10443045, 12227768) **Pending**: US	5/07/2012
FAB-005: "Methods and Products for Expressing Proteins in Cells"	**Granted**: JP (Nos. 6510416, 6890565, 6793146, 7436406); KR (No. 10-2121086); CA (No. 2890110) **Pending**: JP, US	11/01/2012
FAB-009: "Nucleic Acid Products and Methods of Administration Thereof"	**Granted**: JP (Nos. 7199809, 7638844) **Pending**: CA, JP	02/16/2016
FAB-010: "Nucleic Acid Products and Methods of Administration Thereof"	**Pending**: US, CA, EP	08/17/2017
FAB-011: "Nucleic Acid-Based Therapeutics"	**Pending:** US, EP	03/27/2019
FAB-013: "Engineered Gene-Editing Proteins"	**Pending**: US, EP	05/12/2021
FAB-016: "Mesenchymal Stem Cell Therapies"	**Pending**: US, EP, JP	04/28/2021
FAB-017: "Engineered Immune Cell Therapies"	**Pending:** US, CA, EP and JP	03/04/2022
FAB-018: "Circular RNA"	**Pending:** US, CA, EP and JP	04/27/2022
FAB-019: "Methods for reprogramming and gene editing cells"	**Pre-nationalization PCT**	01/05/2022
FAB-021: "Methods for reprogramming and gene editing cells"	**Pre-nationalization PCT**	05/01/2024
FAB-023: "Methods for reprogramming and gene editing cells"	**Pre-nationalization PCT** **Pending**: US	09/20/2024 04/19/2024

Patent Families

Descriptions of our patent families are as follows:

- FAB-001: "Methods and Products for Transfecting Cells" - The present invention relates in part to nucleic acids encoding proteins, nucleic acids containing non-canonical nucleotides, therapeutics comprising nucleic acids, methods, kits, and devices for inducing cells to express proteins, methods, kits, and devices for transfecting, gene editing, and reprogramming cells, and cells, organisms, and therapeutics produced using these methods, kits, and devices. Methods for inducing cells to express proteins and for reprogramming and gene-editing cells using RNA are disclosed. Methods for producing cells from patient samples, cells produced using these methods, and therapeutics comprising cells produced using these methods are also disclosed.
- FAB-003: "Methods and Products for Transfection" - The present invention relates in part to methods for producing tissue-specific cells from patient samples, and to tissue-specific cells produced using these

methods. Methods for reprogramming cells using RNA are disclosed. Therapeutics comprising cells produced using these methods are also disclosed.

- FAB-005: “Methods and Products for Expressing Proteins in Cells” - The present invention relates in part to nucleic acids encoding proteins, therapeutics comprising nucleic acids encoding proteins, methods for inducing cells to express proteins using nucleic acids, methods, kits and devices for transfecting, gene editing, and reprogramming cells, and cells, organisms, and therapeutics produced using these methods, kits, and devices. Methods and products for altering the DNA sequence of a cell are described, as are methods and products for inducing cells to express proteins using synthetic RNA molecules. Therapeutics comprising nucleic acids encoding gene-editing proteins are also described.
- FAB-009: “Nucleic Acid Products and Methods of Administration Thereof” - The present invention relates in part to nucleic acids, including nucleic acids encoding proteins, therapeutics and cosmetics comprising nucleic acids, methods for delivering nucleic acids to cells, tissues, organs, and patients, methods for inducing cells to express proteins using nucleic acids, methods, kits and devices for transfecting, gene editing, and reprogramming cells, and cells, organisms, therapeutics, and cosmetics produced using these methods, kits, and devices.
- FAB-010: “Nucleic Acid Products and Methods of Administration Thereof” - The present invention relates in part to nucleic acids, including nucleic acids encoding proteins, therapeutics and cosmetics comprising nucleic acids, methods for delivering nucleic acids to cells, tissues, organs, and patients, methods for inducing cells to express proteins using nucleic acids, methods, kits and devices for transfecting, gene editing, and reprogramming cells, and cells, organisms, therapeutics, and cosmetics produced using these methods, kits, and devices.
- FAB-011: “Nucleic Acid-Based Therapeutics” - The present invention relates in part to nucleic acids, including nucleic acids encoding proteins, therapeutics and cosmetics comprising nucleic acids, methods for delivering nucleic acids to cells, tissues, organs, and patients, methods for inducing cells to express proteins using nucleic acids, methods, kits and devices for transfecting, gene editing, and reprogramming cells, and cells, organisms, therapeutics, and cosmetics produced using these methods, kits, and devices.
- FAB-013: “Engineered Gene-Editing Proteins” - The present invention relates in part to nucleic acids encoding gene editing proteins, including novel engineered variants.
- FAB-016: “Mesenchymal Stem Cell Therapies” - Cell-based therapies based on MSCs are described.
- FAB-017: “Engineered Immune Cell Therapies” - The present disclosure relates in part to engineered immune cells that are, inter alia, silenced from a host immune response.
- FAB-018: “Circular RNA” - Nucleic acid structures that promote formation of circular RNAs (circRNAs), which may comprise hybridization of substantially complementary regions within the nucleic acid and contact with an RNA ligase. The nucleic acid structures may be used in gene editing and/or therapeutic applications. In some embodiments, the nucleic acid comprises the structure: 5'-X-Y-A-IRES-B-CDS-C-Y'-Z-3', wherein X, Y, Y' and Z each independently comprise one or more nucleotides; Y and Y' are substantially complementary; X and Z are not substantially complementary; IRES comprises an internal ribosome entry site; CDS comprises a coding sequence; and A, B, and C are each independently a spacer comprising one or more nucleotides or null.
- FAB-019: “Methods for reprogramming and gene editing cells” The present disclosure provides improved methods for reprogramming and gene editing cells, including manufacturing a population of cells comprising cells of the lymphoid lineage and/or cells of the myeloid lineage.
- FAB-021: “Methods for reprogramming and gene editing cells” The present disclosure provides improved methods for reprogramming and gene editing cells. The present disclosure provides a method of inserting a sequence in a DNA site by introducing a single-strand break followed by insertion of the sequence using a single-stranded repair template. In another aspect, the present disclosure provides a method of activating gene expression in a cell during its differentiation. In another aspect, the present disclosure methods and compositions related to iPSC-derived mesenchymal stroma/stem cells that overexpressed IDO1. In another aspect, the present disclosure provides a solid support comprising iPSC-derived mesenchymal stem cells that can be used to treat organ damage.

- FAB-023: “Methods for reprogramming and gene editing cells” The present disclosure provides improved methods for reprogramming and gene editing cells. The present disclosure provides a method for gene editing a cell using an engineered chromatin opening sequence at the DNA target site. The cells can be induced pluripotent stem cells. The disclosure is also directed to the targeting the inhibition of tumor promoting genes.

Patent Term and Term Extensions

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the U.S. and the European Union are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the U.S. Food and Drug Administration (“FDA”) regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the restoration period cannot extend the patent term beyond 14 years from FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically are also 20 years from the earliest effective filing date. All taxes or annuities for a patent, as required by the USPTO and various foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product-by-product basis, from country to country, and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see “Risk Factors-Risks Related to Our Intellectual Property” contained in this prospectus.

Supply and Manufacturing

We expect to rely on contract manufacturing relationships for any products that we may develop or acquire in the future. In October 2025, for example, we entered into a master services agreement with Cellipont Bioservices (“Cellipont”) for certain cell and gene therapy development and manufacturing services, along with a statement of work focused on engineering, differentiation and production (“EDP”) activities to advance ERNA-101 toward clinical trials in ovarian cancer. The statement of work provides for a $0.1 million nonrefundable project initiation fee as well as monthly progress payments and milestone payments.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration (“DEA”) and corresponding state agencies to ensure strict compliance with current good manufacturing practices (“cGMPs”) and other state and federal regulations. Our contractors, if any, in Europe face similar challenges from the numerous European Union and member state regulatory agencies and authorized bodies. We do not have control over third-party manufacturers’ compliance with these regulations and standards, other than through contractual obligations. If our contractors are deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped, and supplies could be delayed or otherwise disrupted, which could have a materially adverse effect on our business.

If we need to change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections and associated regulatory submissions to ensure compliance with FDA regulations and standards, which collectively may result in significant lead times, delay and cost. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

Regulatory Matters

Government regulation and product approval

Drugs and biologics must be approved by the FDA through the New Drug Application ("NDA") process or the Biologic License Application ("BLA") process before they may be legally marketed in the U.S. We use the terms "marketing application" or "MA" to apply to both.

There are two centers within the FDA that are responsible for the review and approval of drug and biologic marketing applications and general regulatory oversight: the Center for Drug Evaluation and Research ("CDER") and the Center for Biologics Evaluation and Research ("CBER"). While all conventional drug products are regulated by CDER, biologic products can be regulated by either CDER or CBER, depending on the product's classification.

The majority of BLA submissions are assigned to CBER; however, BLAs for certain biologic product categories are reviewed by CDER. These product categories include monoclonal antibodies for in vivo use, most proteins for therapeutic use, and categories such as cytokines, enzymes, and other novel proteins. Regardless of the category, NDAs for all drug products fall under the jurisdiction of CDER.

In the U.S., drugs are subject to rigorous regulation by the FDA under the federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations, and biologics under the FDCA, the Public Health Services Act ("PHSA"), and their implementing regulations. Additionally, drugs and biologics are subject to other federal and state statutes. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to the FDA's good laboratory practice, or GLP, regulations;
- submission of an investigational new drug application ("IND"), which must become effective before human clinical trials may begin and which must include approval by an institutional review board ("IRB") at each clinical site before the trials are initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use conducted in compliance with federal regulations and good clinical practice ("GCP"), an international standard meant to protect the rights and health of human clinical trial subjects and to define the roles of clinical trial sponsors, administrators, and monitors;
- submission to, and acceptance by, the FDA of a MA;
- satisfactory completion of an FDA inspection of our manufacturing facility or other facilities at which the drug or biologic is produced to assess compliance with current good manufacturing practice ("cGMP"), regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the non-clinical and clinical trial sites that generated the data in support of the MA: and
- FDA review and approval of the MA.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain.

United States drug development process

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. Prior to beginning human clinical trials, a sponsor must submit an IND to the FDA, which includes the results of the preclinical tests, together with manufacturing information and analytical data. Some preclinical or non-clinical testing may continue even after the IND is submitted. In addition to including the results of the preclinical studies, the IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated, if the trial lends itself to an efficacy evaluation. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trial. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under the terms authorized by the FDA.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of one or more qualified investigators in accordance with federal regulations and GCP.

Clinical trials must be conducted under protocols detailing the objectives of the trial and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, an IRB affiliated with each institution participating in the clinical trial must review and approve each protocol before any clinical trial commences at that institution. All research subjects must provide informed consent, and informed consent information must be submitted to the IRB for approval prior to initiation of the trial and prior to providing it to potential subjects. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events or other certain types of other changes occur.

Human clinical trials are typically conducted in three phases. A fourth, or post-approval, phase may include additional clinical studies. These phases generally include the following, and may be sequential, or may overlap or be combined:

- Phase 1 clinical trials involve the initial introduction of the drug or biologic into human subjects. These studies are designed to determine the safety of usually single doses of the compound and determine any dose limiting intolerance, as well as evidence of the metabolism and pharmacokinetics of the drug in humans. For some products for severe or life-threatening diseases, especially if the product may be too toxic to administer to healthy humans, the initial clinical trials may be conducted in individuals having a specific disease for which the tested product is indicated.

- Phase 2 clinical trials usually involve studies in a limited patient population to evaluate the safety and efficacy of the drug or biologic for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks.

- In Phase 3, if a compound is found to be potentially effective and to have an acceptable safety profile in Phase 2 (or occasionally Phase 1) studies, the Phase 3 studies will be conducted to further confirm clinical efficacy, optimal dosage and safety within an expanded population which may involve geographically diverse clinical trial sites. Generally, but not always, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a marketing application.

- Phase 4 clinical trials are studies required of or agreed to by a sponsor that are conducted after the FDA has approved a product for marketing. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement. Failure to promptly conduct Phase 4 clinical trials where necessary could result in withdrawal of approval for products approved under accelerated approval regulations.

While Phase 1, Phase 2, and Phase 3 studies are generally required for approval of a marketing application, certain drugs and biologics may not require one or more steps in the process depending on other testing and the

situation involved. Additionally, the FDA, an IRB, or the sponsor may stop testing at any time if results show patients being exposed to unnecessary health risks or overly dangerous side effects. Prior to the initiation of a clinical trial or at any time during the conduct of studies with human subjects, the FDA may place a study on clinical hold, during which patients may not be enrolled and ongoing trial activities are suspended until questions around potential safety issues with investigational products are addressed.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the mechanism of action and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other requirements, the manufacturer must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and validated, and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life.

Additional Regulation for Cell Therapy Clinical Trials

In addition to the regulations discussed elsewhere in this section, there are a number of additional standards that apply to clinical trials involving the use of cell therapy. The FDA has issued various guidance documents regarding cell therapies, which outline additional factors the FDA will consider at each of the above stages of development and relate to, among other things: the proper preclinical assessment of cell therapies; the CMC information that should be included in an IND application; the proper design of tests to measure product potency in support of an IND or BLA application; and measures to observe delayed adverse effects in subjects who have been exposed to investigational cell therapies when the risk of such effects is high. Further, the clinical study requirements set by the FDA vary significantly based on a product's type, complexity, novelty, intended use, and target market. Obtaining regulatory approval for innovative therapies like ours can be more costly and time-consuming compared to more familiar or well-studied treatments. Additionally, negative outcomes in other cell therapy trials could prompt regulators to revise approval requirements for our product candidates.

United States drug review and approval process

Following completion of clinical studies, the results are evaluated and, depending on the outcome, submitted to the FDA in the form of an NDA or BLA in order to obtain FDA approval of the product and authorization to commence commercial marketing. In responding to an NDA or BLA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose a post-approval study and other commitments or reporting requirements or other restrictions on product distribution, or may deny the application. The timing of final FDA review and action varies greatly but can take years in some cases and may involve the input of an FDA advisory committee of outside experts. Product sales in the U.S. may commence only upon FDA approval of an NDA or BLA.

FDA approval of a marketing application is required before marketing of the product may begin in the U.S. The MA must include the results of product development, preclinical studies and clinical studies, together with other detailed information, including information on the chemistry, manufacture and controls utilized in manufacture of the product. In addition, an MA must also demonstrate purity, specifically in terms of showing that the final product does not contain extraneous material. The FDA has 60 days from its receipt of the MA to review the application to ensure that it is sufficiently complete for substantive review before accepting it for filing. The FDA may request additional information rather than accept an MA for filing. In this event, the MA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The submission of an MA is also subject to the payment of a substantial application fee (although a waiver of such fee may be obtained under certain limited circumstances, including when the drug that is subject of the application has received Orphan Drug Designation for the indication sought). Further, the sponsor of an approved MA is subject to an annual program fee. User fees typically increase annually. The approval process is lengthy and complex, and the FDA may refuse to approve an MA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data

and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA reviews an application to determine, among other things, whether a product is safe and effective for its intended use. Before approving an MA, the FDA will inspect the facility or facilities where the product is manufactured to determine whether its manufacturing is cGMP–compliant to assure and preserve the product's identity, potency, quality, purity and stability.

If the FDA's evaluation of the marketing submission or manufacturing facilities is not favorable, the FDA will issue a complete response letter. The complete response letter outlines the deficiencies in the submission and often requires additional testing or information in order for the FDA to reconsider the application. Even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of an MA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

Once an MA is approved, changes to the conditions of approval, including additional indications, are made by the submission of a supplement to the MA The supplemental NDA ("sNDA") or the supplemental BLA ("sBLA") must contain all of the information necessary to support the change. In the case of a new indication, that information usually consists of at least one clinical trial, and often more. Like an MA, FDA determines whether the supplemental application is sufficiently complete to permit review before it is filed. FDA then reviews the supplemental application. The FDA can either approve or issue a complete response letter outlining the deficiencies.

Manufacturing readiness

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP. Manufacturers must expend significant time, money and effort to ensure continued compliance, and the FDA conducts periodic inspections to verify compliance. If a manufacturer fails to comply or cannot remedy regulator identified deficiencies, then the FDA may prohibit the product from being marketed.

If the FDA grants approval, the approval will be limited to those conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the MA. Certain changes to an approved MA, including, with certain exceptions, any significant changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products manufactured or distributed pursuant to FDA approvals are subject to continuing monitoring and regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA permits in the labeling and advertising of products will generally be limited to those specified in FDA approved labeling, and the advertising of products will be subject to comprehensive monitoring and regulation by the FDA. Products whose review was accelerated may carry additional restrictions on marketing activities, including the requirement that all promotional materials are pre-submitted to the FDA. Claims exceeding those contained in approved labeling will constitute a violation of the FDCA. Violations of the FDCA or regulatory requirements at any time during the product development process, approval process, or marketing and sale following approval may result in agency enforcement actions, including corrective advertising, cessation of violative promotion, withdrawal of approval, recall, seizure of products, warning letters, injunctions, fines and/or civil or criminal penalties.

In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes.

Post-approval requirements and consideration

Once an MA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA and Federal Trade Commission closely regulate the post-approval marketing and promotion of drugs and biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. As a condition of MA

approval, the FDA may also require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the drug or biologic outweigh the potential risks. REMS can include medication guides, communication plans for the healthcare professionals, and other Elements to Assure Safe Use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug or biologic.

Drugs and biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new MA supplement before the change can be implemented. An MA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing MA supplements as it does in reviewing MAs.

Adverse event reporting and submission of periodic reports are required following FDA approval of an MA. The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug and biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Foreign regulatory requirements

In addition to regulation by the FDA and certain state regulatory agencies, there are a variety of foreign regulations governing clinical trials and the marketing of products. Outside of the U.S., the ability of a company to market a product depends upon receiving a marketing authorization from the appropriate regulatory agencies. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, a company will only be permitted to commercialize its products if the appropriate regulatory agency is satisfied that the company presented adequate evidence of safety, quality and efficacy. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The regulatory approval and oversight process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above.

Under the European Union regulatory system, applications for drug approval may be submitted either in a centralized or decentralized manner. Under the centralized procedure, a single application to the European Medicines Agency ("EMA") may lead to an approval granted by the European Commission which permits marketing of the product throughout the European Union. The decentralized procedure provides for mutual recognition of nationally approved decisions and is used for products that do not comply with requirements for the centralized procedure. Under the decentralized procedure, the holders of national marketing authorization in one of the countries within the European Union may submit further applications to other countries within the European Union, who will be requested to recognize the original authorization based on an assessment report provided by the country in which marketing authorization is held.

Pharmaceutical pricing and reimbursement

In both U.S. and foreign markets, the ability of a company to commercialize its products successfully, and to attract commercialization partners for its products, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the U.S., governmental payors such as Medicare and Medicaid, managed care organizations, private commercial health insurers and pharmacy benefit managers ("PBMs"). Third party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. Companies may need to conduct expensive pharmacoeconomic

or other studies to further demonstrate the value of its products. Even with the availability of such studies, products may be considered less safe, less effective or less cost-effective than alternative products, and third-party payors may not provide coverage and reimbursement for any product, in whole or in part.

Political, economic and regulatory influences are subjecting the health care industry in the U.S. to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect the development and commercialization of products, including the Patient Protection and Affordable Care Act of 2010 (the "ACA").

In the U.S., Congress, state legislatures, and private sector entities are expected to continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures could include:

- controls on government-funded reimbursement for drugs;
- mandatory rebates or additional charges to manufacturers for their products to be covered on Medicare Part D formularies;
- controls on healthcare providers;
- controls on pricing of pharmaceutical products, including the possible reference of the pricing of U.S. drugs to non-U.S. drug pricing for the same product;
- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;
- reform of drug importation laws;
- entering into contractual agreements with payors; and
- expansion of use of managed-care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person

The Inflation Reduction Act of 2022 (the "IRA") contained several provisions designed to curb the prices of drugs and biologics to Medicare beneficiaries. For instance, the IRA will require the federal government to directly negotiate the prices of certain drugs and biologics beginning in 2026. Additionally, beginning in 2023, the IRA requires manufacturers of drugs and biologics to offer rebates if the price of the drug or biologic raises faster than inflation.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business.

Competition

Biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our novel iMSC technology, expertise, technological capabilities, and scientific resources give us a strong competitive edge, we face competition from many multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research organizations that are developing various approaches to the treatment of solid tumors and other autoimmune diseases.

Our synthetic iMSC technology competes with both existing MSC-based therapies and emerging technologies. Mesoblast an Australia-based regenerative medicine company was the first to launch an MSC-based therapy RYONCIL® in the U.S. for the treatment of steroid-refractory acute graft-versus-host disease (GVHD). Additionally, other U.S.-based companies like BrainStorm Cell Therapeutics, RESTEM, Celltex, Baylx, Calidi Bio, Akan Biosciences, ImStem, among others, are developing MSC therapies in solid tumor and inflammatory diseases, which we believe could be considered our primary competitors.

In addition to competition from MSC-based and related cell therapy approaches, we face competition in our lead indication, platinum-resistant ovarian cancer. Currently marketed therapies include Avastin® (bevacizumab), a vascular endothelial growth factor ("VEGF") inhibitor marketed by Genentech, a member of the Roche Group, and

ELAHERE® (mirvetuximab soravtansine), an antibody-drug conjugate marketed by ImmunoGen. Also, multiple pharmaceutical and biotechnology companies, including Corcept Therapeutics, Daiichi Sankyo, Genmab, Merck & Co., and Genelux Corporation, among others, are advancing late-stage or clinical-stage product candidates targeting platinum-resistant ovarian cancer through a variety of therapeutic modalities. These therapies may achieve regulatory approval or commercial adoption before our product candidates and may limit market acceptance, pricing, or commercial opportunities for our programs.

Many of our competitors have significantly greater financial, marketing, technical, research and human resources than we do, and may also have strategic partnerships and collaborative arrangements with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate the discovery and development of technology that could make our technology obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or discovering, developing and commercializing technology that is competitive with or superior to our technology.

Human Capital Resources

Employees

We operate in a highly competitive industry and recognize that our success relies upon our ability to attract, develop and retain a diverse team of talented individuals. We place high value on the satisfaction and well-being of our employees and operate with fair labor standards and industry-competitive compensation and benefits. As of March 12, 2026, we had five full-time employees, which includes three research and development positions and two administrative positions. We also have two part-time employees in administrative positions. None of our employees are covered by collective bargaining agreements.

Compensation, Benefits and Development

Our approach to employee compensation and benefits is designed to deliver cash, equity and benefit programs that are competitive with those offered by leading companies in the biotechnology and pharmaceutical industries to attract, motivate and retain talent with a focus on encouraging performance, promoting accountability and adherence to our values and alignment with the interests of our stockholders.

Our base pay program aims to compensate our employees relative to the value of the contributions of their role, which takes into account the skills, knowledge and abilities required to perform each position, as well as the experience brought to the job. We may also provide our employees with opportunities to earn performance-based cash and equity compensation to reward the achievement of company-wide goals established annually and designed to drive aspects of our strategic priorities that support and advance our strategy across our company. Our employees are also eligible to receive equity awards under our long-term incentive program that are designed to align their interests with the interests of our stockholders. All employees also participate in a regular performance measurement process through which staff receive performance and development feedback, which is taken into account in determining annual compensation.

Our benefit programs are generally broad-based, promote health and overall well-being and emphasize saving for retirement. All employees are eligible to participate in the same health and retirement savings plans.

Code of Business Conduct and Ethics

We are committed to conducting business in accordance with the highest ethical standards. Our Code of Conduct and Ethics, which applies to all our employees, emphasizes the importance of integrity, honesty, forthrightness, respect and fairness.

Health, Safety and Well-Being

We actively promote the safety, health and well-being of our employees. For example, we focused on employee safety throughout the COVID-19 pandemic by implementing extensive safety measures, which included on-site COVID-19 testing protocols and flexible remote working options for most of our employees.

Corporate Information

Our principal executive offices are located at 1035 Cambridge Street, Suite 18A, Cambridge, Massachusetts 02141, and our phone number is (617) 798-6700. We maintain a website at www.ernexatx.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website as soon as reasonably practicable after such reports are available on the Securities and Exchange Commission (SEC) website at www.sec.gov. Additionally, copies of our Annual Report will be made available, free of charge, upon written request. Information contained on, or accessible through, our website is not a part of and is not incorporated by reference into this 2025 Annual Report.

ITEM 1A. Risk Factors

Our business, financial condition and operating results can be affected by many factors, whether currently known or unknown, many of which are not exclusively within our control, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our financial condition and operating results to differ materially from historical or anticipated future financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and stock price. We urge investors to carefully consider the risk factors described below in evaluating our stock and the information in this 2025 Annual Report, including the consolidated financial statements and the notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Risks Related to our Business and Industry

We will require substantial additional capital to fund our operations and execute our business strategy, and we may not be able to raise adequate capital on a timely basis, on favorable terms, or at all.

Based on our current financial condition and forecasts of available cash, we will not have sufficient capital to fund our operations for the 12 months following the issuance date of the accompanying consolidated financial statements. We can provide no assurance that we will be able to obtain additional capital when needed, on favorable terms, or at all. If we cannot raise capital when needed, on favorable terms or at all, we will need to reevaluate our planned operations and may need to reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock.

Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the timing, progress, costs and results of ERNA-101 and ERNA-201;
- the costs of any other product development programs we may initiate, including the costs to conduct the studies;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the pace and success of our potential strategic partners in co-developing our product candidates and the proceeds to us, if any, as a result;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our potential co-development strategic partners or collaborators; and
- the effect of competing market developments.

We may seek to raise additional capital through a variety of means, including through equity, equity-linked or debt securities offerings, collaborations, strategic alliances or marketing, distribution or licensing arrangements

with third parties. Our past success in raising capital through equity and convertible note offerings should not be viewed as an indication we will be successful in raising capital through those or any other means in the future.

To the extent that we raise additional capital by issuing equity or equity-linked securities, existing stockholder ownership may experience substantial dilution, and the securities may include preferred shares with liquidation or other preferences that could harm the rights of a common stockholder. Servicing the interest and principal repayment obligations under any debt we incur will divert funds that might otherwise be available to support our operations. In addition, debt financing may involve covenants that restrict our ability to operate our business. To the extent we raise additional capital through arrangements with third parties, such arrangements would likely require us to relinquish valuable rights to our technologies or grant licenses on terms that may not be favorable to us.

Unstable and unfavorable market and economic conditions may harm our ability to raise additional capital.

An economic downturn, recession or recessionary concerns, increased inflation, rising interest rates, adverse developments affecting financial institutions or the financial services industry, or the occurrence or continued occurrence of events similar to those in recent years, such as the COVID-19 pandemic or other public health emergencies, geopolitical conflict, natural/environmental disasters, terrorist attacks, strained relations between the U.S. and a number of other countries, social and political discord and unrest in the U.S. and other countries, and government shutdowns, among others, increase market volatility and have long-term adverse effects on the U.S. and global economies and financial markets. Volatility and deterioration in the financial markets and liquidity constraints or other adverse developments affecting financial institutions may make equity or debt financings more difficult, more costly or more dilutive and may increase competition for, or limit the availability of, funding from other third-party sources, such as from strategic collaborations.

We cannot be certain that additional capital will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our business activities, or potentially discontinue operations altogether. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm its ability to execute on our business strategy.

We have incurred significant losses since our inception and expect to continue to incur losses for the foreseeable future, which, together with our limited financial resources and substantial capital requirements, make it difficult to assess our prospects.

We have incurred significant net losses since inception. As of December 31, 2025, we had an accumulated deficit of approximately $245.6 million. Since inception, we have primarily financed our operations by raising capital through the sale of shares of our common stock, warrants to purchase shares of our common stock and convertible notes.

We have not been profitable since we commenced operations and may never achieve profitability. If we do successfully obtain regulatory approval to market any of our product candidates, our revenue will be dependent upon, in part and among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for any such product candidate. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of any of our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability. Failure to become and remain profitable may adversely impact the market price of the common stock and our ability to raise capital and continue operations.

We depend substantially, and expect in the future to continue to depend, on in-licensed intellectual property. Such licenses impose obligations on our business, and if we fail to comply with those obligations, we could lose license rights, which would substantially harm our business.

We rely on patents, know-how and proprietary technology licensed from Factor Limited under the Factor L&C Agreement. We may in the future become party to additional license agreements pursuant to which we in-license key intellectual property. The Factor L&C Agreement imposes various sublicense fees and other obligations on us. For example, we paid Factor Limited $0.2 million per month for the first twelve months and $0.1 million per month

for the first nine months toward patent costs. We are also obligated to pay certain milestone payments, royalty payments on net sales of commercialized products and sublicensing fee payments. The parties have customary termination rights under the Factor L&C Agreement, including in connection with certain uncured material breaches of the Factor L&C Agreement and specified bankruptcy events. Any termination of our existing or future licenses could result in the loss of significant rights and would harm our business significantly.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other intellectual property to third parties under the license agreement;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the priority of invention of patented technology; and
- the ownership of inventions and know-how resulting from any joint creation or use of intellectual property by our licensors and us or our partners.

If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully enter into co-development strategic partnerships. In addition, the resolution of any such disputes could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, we may have limited control over the maintenance, prosecution or enforcement of rights we in-license, and we may also have limited control over activities previously or separately conducted by our licensors. For example, we cannot be certain that activities conducted by Factor Limited or any other present or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may also have limited control over other intellectual property that is not licensed to us but that may be related to our in-licensed intellectual property. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer or the intellectual property or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate and our business, financial condition, results of operations and prospects could suffer.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we own, as we are for intellectual property that we license. If we or our licensors fail to adequately protect the intellectual property underlying our synthetic iMSC technology platform and any other in-licensed intellectual property, our ability to enter into co-development strategic partnerships could materially suffer.

Our intellectual property rights may not adequately protect our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. For example:

- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating any of our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business;
- we may choose not to file a patent in order to maintain certain trade secrets or proprietary know- how, and a third party may subsequently file a patent covering such intellectual property; and
- our trade secrets or proprietary know-how may be unlawfully disclosed, thereby losing their trade secret or proprietary status.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

We rely heavily on in-licensed intellectual property from Factor Limited. Loss of this license or termination of the Factor L&C Agreement could significantly harm our product development and ability to enter co-development strategic partnerships, materially impacting our business.

Our business is substantially dependent upon the synthetic iMSC technology licensed from Factor Limited. Pursuant to the Factor L&C Agreement, Factor Limited has customary termination rights, including in connection with certain uncured material breaches of the Factor L&C Agreement, failure to make payments and specified bankruptcy events. Our ability to develop therapeutics products or enter into co-development partnerships using the Factor Patents depends entirely on the effectiveness and continuation of the Factor L&C Agreement. If the Factor L&C Agreement is terminated, there is no guarantee that we will be able to enter into a new license agreement that aligns with our business strategy on the same or similar terms, if at all, and our competitors could in-license the technology, which would result in a significant market disadvantage to us.

We or our licensors may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that we own or license now or in the future.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we in-license or that we may own or in-license in the future. While it is our policy to require our employees or contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own or such assignment may not be self-executing, for example, as part of employment or consulting agreements, or may be breached. Our licensors may face similar obstacles. Litigation may be necessary to defend against any claims challenging inventorship or ownership, including in derivation proceedings in the USPTO. If we or our licensors fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition.

Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cyber-security.

Our computer systems, as well as those of various third parties on which we rely, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including

hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development and other programs. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and it could have a material adverse effect on our business, results of operations and financial condition. See Part I, Item 1C. Cybersecurity for more information on information regarding our cybersecurity risk management, strategy, and governance.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive life science industry depends in large part upon the ability to attract highly qualified personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock options and/or restricted stock units that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in the price of the common stock, which we cannot control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Competition for skilled personnel in our industry is intense, and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, our employees may terminate their employment with us on short notice.

Other companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do, and such companies also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, our business, results of operations and financial condition may be materially adversely affected.

Risks Related to New, Cutting-Edge Technologies

Our product development relies on novel, inherently risky technologies. Synthetic mesenchymal stem cell therapy is a relatively new field, and our efforts may not result in effective treatments for human diseases.

Cellular immunotherapies, synthetic mesenchymal stem cell therapies, and iPSC-derived product candidates represent relatively new therapeutic areas, and the FDA has cautioned consumers about potential safety risks associated with them. To date, there are relatively few approved cell therapies. As a result, the regulatory approval process for cellular therapy product candidates is uncertain and may be more expensive and take longer than the approval process for product candidates based on other, better known or more extensively studied technologies and therapeutic approaches.

Cell reprogramming technology and related cell therapy products using iPSC lines represent novel therapeutic approaches, and to our knowledge, no iPSC-derived cell products are currently approved for commercial sale anywhere in the world. As such, it is difficult to accurately predict the type and scope of challenges that we may confront in developing and advancing a pipeline of iPSC-derived therapeutic products. We thus face uncertainties associated with the preclinical and clinical development, manufacture, and regulatory compliance for the initiation and conduct of clinical trials, regulatory approval, and reimbursement required for successfully commercializing future product candidates. Further, the processes and requirements imposed by the FDA or other applicable regulatory authorities may cause delays and additional costs in obtaining approvals for marketing authorization for any future product candidates. Because our platform is novel, and cell- based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates using our synthetic iMSC technology platform. This novelty may lengthen the regulatory review process, including the time it takes for the FDA to review IND applications if and when such applications are submitted, increase development costs, and delay or prevent commercialization of future products, if such products are approved for marketing.

Due to the rapid advancements in cellular technologies, regulatory processes and requirements in the U.S. and in other jurisdictions governing cellular therapy products are evolving and the FDA or other regulatory bodies may change the requirements, or identify different regulatory pathways, for the clinical testing and approval of these product candidates. For example, in recent years the FDA has issued several new guidance documents related to developing and manufacturing cellular therapy products. In addition, adverse developments in clinical trials of cellular therapy products conducted by others, or in treated patients after such products are commercialized, may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. For example, in November 2023, the FDA announced that it was investigating reports of T-cell malignancy in patients following their treatment with B cell maturation antigen-directed or CD19-directed autologous chimeric antigen receptor (CAR) T-cell immunotherapies, although more recent public statements by agency leadership indicate that the benefits of such treatments are expected to still outweigh those risks. Future adverse events or safety issues could lead to more significant regulatory action applicable to either a specific product or a broader product class, based on case-by-case science-based benefit-risk assessments. Similarly, the EMA oversees the development of cellular therapies in the EU and may issue new guidelines concerning the development and marketing authorization for cellular therapy products and require that we comply with these new guidelines. These regulatory agencies and committees and any new regulations, requirements or guidelines they promulgate may lengthen the regulatory review process, which may reduce the anticipated benefits of our co-development strategic partnerships or adversely affect the commercialization of any future therapeutic products we may develop.

Accordingly, we may be required to change regulatory strategies or to modify applications for clinical investigations or regulatory approval, which could delay and impair our ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, our product candidates. Changes in regulatory authorities and advisory groups, or any new regulations, requirements or guidelines we promulgate, may lengthen the regulatory review process, require additional studies, increase development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of product candidates we develop or lead to significant post-approval limitations or restrictions that may reduce the our anticipated benefits.

The clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. Due to the novelty and complexity of cellular products, the regulatory approval process for such product candidates is uncertain and may be more expensive and take longer than the approval process for product candidates based on other, better known or more extensively studied technologies. It is difficult to determine the time or cost required to obtain regulatory approvals for product candidates using this technology in either the U.S. or the E.U., or how long it will take to commercialize any product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

We are in an industry with intense competition and rapid technological change, and our competitors may develop therapies that are more advanced, safer, or more effective than any therapy we develop in the future, which may adversely affect our financial condition.

We have competitors both in the U.S. and internationally, including major multinational pharmaceutical companies, biotechnology companies, universities, and other research institutions. Many of our competitors have substantially greater financial, technical, research and human resources than we do, and may also have strategic partnerships and collaborative arrangements with leading companies and research institutions. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective, safer, or less costly than any products that we may develop in the future, or achieve patent protection, marketing approval, product commercialization, and market penetration earlier than us. Additionally, technologies developed by our competitors may render any product candidates we are seeking to develop uneconomical or obsolete. For additional information regarding our competition, see “Part I, Item 1. Business—Competition”.

Negative public opinion and increased regulatory scrutiny due to ethical and other concerns surrounding the use of stem cell therapy or human tissue may damage public perception of our synthetic allogeneic iMSC product candidates or adversely affect our ability to conduct our business.

Concerns about the safety or ethics of cell therapy, even if unrelated to our product candidates, could lead to stricter regulations, public resistance, patient recruitment challenges, regulatory delays, labeling restrictions, and reduced demand for our therapies. Such developments could significantly affect our business, financial condition, and the commercialization of future cell therapy products.

The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production.

The manufacture of biotechnology products, including cellular and gene therapy products, is complex and requires significant expertise and capital investment. Manufacturers for any product candidates developed using our synthetic iMSC technology platform will be required to comply with cGMP regulations and guidelines for clinical trial product manufacture and subsequently for commercial product manufacture. Manufacturers of biotechnology products often encounter difficulties in production, particularly in scaling up, addressing product quality, product comparability, validating production processes and mitigating potential sources of contamination. These problems include difficulties with raw material procurement, production costs and yields, quality control, product quality, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Any delay or interruption in the supply of preclinical study supplies (or clinical trial supplies in the future) could delay the completion of such studies, increase the costs associated with the affected development programs and depending upon the period of delay, require new studies to be commenced at additional expense or terminated completely.

Risks Related to Ownership of our Common Stock

There may be future sales or other dilution of our equity, which may adversely affect the market price of our common stock.

We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. To raise additional capital, we may in the future sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that are lower than the prices paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, which could result in substantial dilution to the interests of existing stockholders. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or the perception that such sales could occur.

In addition, under the terms of an asset purchase agreement pursuant to which we acquired assets from a company (the "Seller") in April 2023, we agreed to issue to the Seller shares of our common stock as contingent consideration. If our market capitalization equals or exceeds $100 million during the three-year period commencing on April 26, 2023 and ending on the three-year anniversary thereof, the number of shares of common stock we would issue is determined by a formula specified in the asset purchase agreement. In addition, if our market capitalization equals or exceeds $200 million during the same three-year period, we agreed to issue to the Seller additional shares of our common stock determined by a formula specified in the asset purchase agreement. The contingent consideration period expires on April 26, 2026.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock.

Our common stock is listed on The Nasdaq Capital Market. Nasdaq requires that listed companies satisfy certain continued listing requirements. Listing Rule 5550(a)(2) requires that listed companies maintain a minimum compliance with the Bid Price Rule. Listing Rule 5550(b) requires that listed companies maintain compliance with : (1) the Stockholders' Equity Rule; (2) the MVLS Rule; or (3) the Net Income Rule.

Our stockholders' equity at December 31, 2025 was approximately $2.4 million and we do not currently meet the MVLS or Net Income Rule However, on February 10, 2026, we completed a public offering for the sale of our common stock and accompanying warrants for net proceeds of approximately $9.5 million. As a result, as of the date

of this 2025 Annual Report, our stockholders' equity exceeds $2.5 million, as required under the Stockholders' Equity Rule.

Since February 3, 2026, the closing bid price of our common stock has been trading below $1.00. Upon the 30th consecutive business day of trading below $1.00, we expect to receive a notice from Nasdaq informing us that we do not meet the Bid Price Rule. To regain compliance, we must maintain a closing bid price of at least $1.00 for a minimum of 10 consecutive business days.

Because we effected a reverse stock split within the last 12 months to regain compliance with the Bid Price Rule, Nasdaq rules provide that if our common stock fails to meet the minimum bid price requirement within one year following that reverse stock split, we would not be eligible for any compliance period under Nasdaq Listing Rule 5810(c)(3)(A). In such event, Nasdaq would issue a Staff Delisting Determination with respect to our common stock, which we could appeal to a Nasdaq hearings panel in accordance with applicable Nasdaq rules.

If we fail to satisfy any of the Nasdaq continued listing requirements, Nasdaq may take steps to delist our common stock. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with Nasdaq continued listing requirements would be successful.

If our common stock is ultimately delisted by Nasdaq, and we are not able to list our securities on another national securities exchange, we expect our securities could be quoted on an over-the-counter market. If this were to occur, then we could face significant material adverse consequences, including: a material reduction in the liquidity of our common stock and a corresponding material reduction in the trading price of our common stock; a more limited market quotations for our securities; a determination that our common stock is a "penny stock" that requires brokers to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; more limited research coverage by stock analysts; loss of reputation; more difficult and more expensive equity financings in the future; the potential loss of confidence by investors; and fewer business development opportunities.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." If our common stock remains listed on Nasdaq, our common stock will be covered securities. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. If our securities were no longer listed on Nasdaq and therefore not "covered securities," we would be subject to regulation in each state in which we offer our securities.

Anti-takeover provisions of Delaware law and provisions in our charter and bylaws could make a third-party acquisition of us difficult.

Because we are a Delaware corporation, the anti-takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. We are subject to the provisions of Section 203 of the General Corporation Law of Delaware, which prohibits us from engaging in certain business combinations, unless the business combination is approved in a prescribed manner. In addition, our restated certificate of incorporation and restated bylaws also contain certain provisions that may make a third-party acquisition of us difficult, including the ability of our board of directors to issue preferred stock and the inability of our stockholders to call a special meeting or act by written consent.

Risks Related to our Financial Position and Capital Requirements

We may acquire businesses, assets or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses, assets or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising intellectual property, markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new acquisition. Difficulties may prevent us from realizing its expected benefits or enhancing our business. We cannot assure you that, following any

such acquisition, we will achieve the expected synergies to justify the transaction.

Our ability to utilize our net operating loss carryforwards and tax credit carryforwards may be subject to limitations.

Our ability to use our federal and state net operating losses ("NOLs") to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

Under Section 382 and Section 383 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 "ownership change" is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. Even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Risks Related to Regulatory Requirements

We are subject to extensive and costly government regulation.

Product candidates employing medical technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective foreign equivalents. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for one or more uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling medical products. Even if we or our strategic partners are able to obtain regulatory approval for a particular product candidate, the approval may limit the indicated medical uses for the product, may otherwise limit the ability to promote, sell, and distribute the product, may require costly post-marketing surveillance, and/or may require ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of a product candidate. For example, regulatory agencies may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. Regulators may approve a product candidate for a smaller patient population, a different drug formulation or a different manufacturing process, than we or our strategic partners are seeking.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we may be unable to produce revenue and our business will be substantially harmed.

A product cannot be commercialized until the appropriate regulatory authorities have reviewed and approved the product candidate. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors, including the type, complexity, and novelty of the product candidates involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept an application for review, or may decide that our data are insufficient for approval and require additional non-clinical, clinical or other studies.

We may never be able to obtain regulatory approval for any product candidates that we develop in the future. If our future product candidates are ultimately not approved for any reason, our business, prospects, results of operations and financial condition would be adversely affected.

In addition, even once clinical development of a future product candidate is initiated, such clinical studies may not start or be completed on schedule, if at all. The completion or commencement of clinical studies can be delayed or prevented for a number of reasons, including, among others:

- the FDA or comparable foreign regulatory authorities may not authorize us or our future clinical investigators to commence planned clinical studies, or require that we suspend ongoing clinical studies through imposition of clinical holds;
- negative results from our ongoing studies or other industry studies involving engineered or gene-edited cell therapy product candidates;
- delays in reaching or failing to reach agreement on acceptable terms with prospective clinical research organizations ("CROs") and clinical study sites, the terms of which can be subject to considerable negotiation and may vary significantly among different CROs and study sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical studies, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining ethics committee or IRB, approval to conduct a clinical study at a prospective site or sites;
- challenges in recruiting and enrolling subjects to participate in clinical studies, the proximity of subjects to study sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical study programs for similar indications;
- severe or unexpected drug-related side effects experienced by subjects in a clinical study, such as severe neurotoxicity and cytokine release syndrome;
- the FDA or comparable foreign regulatory authorities may disagree with a proposed clinical study design, implementation of clinical trials or our interpretation of data from clinical studies, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical studies;
- reports from non-clinical or clinical testing of other competing candidates that raise safety or efficacy concerns; and
- difficulties retaining subjects who have enrolled in a clinical study but may be prone to withdraw due to rigors of the clinical studies, lack of efficacy, side effects, personal issues, or loss of interest.

Changes in regulatory requirements, agency guidance or unanticipated events during our non-clinical studies and future clinical studies of our future product candidates may occur, which may result in changes to non-clinical or clinical study protocols or additional non-clinical or clinical study requirements, which could result in increased costs to us and could delay our projected development timeline.

Changes in regulatory requirements or FDA or EMA guidance, or unanticipated events during our non-clinical studies and future clinical studies, may force us to amend non-clinical studies and future clinical study protocols. The FDA, EMA or comparable foreign regulatory authorities may also impose additional non-clinical studies and clinical study requirements. Amendments to protocols for or other aspects of our non-clinical studies may increase the cost or delay the timing or successful completion of those studies. If we experience delays completing, or if we terminate, any of our non-clinical or future clinical studies, or if we are required to conduct additional non-clinical or clinical studies, the commercial prospects for our future product candidates may be harmed and our ability to recognize product revenue will be delayed.

Disruptions at the FDA and other government agencies caused by funding shortages or other events or conditions outside of their control could negatively impact our business.

The ability of the FDA to review and approve INDs, proposed clinical trial protocols, or new product candidates can be affected by a variety of factors, including, but not limited to, government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other

government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other regulatory agencies may also slow the time necessary for new product candidates to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. In addition, during the COVID-19 pandemic, the FDA's inspectional activities were interrupted and restarted on a risk-based basis, which had the effect of delaying review and potential approval of product candidate marketing applications.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our future regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

We maintain quantities of various flammable and toxic chemicals in our facilities in Massachusetts that are used for our research and development activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We believe our procedures for storing, handling and disposing these hazardous materials in our laboratory facilities comply with the relevant guidelines of the relevant local, state, and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Any insurance coverage we have may not be sufficient to cover these liabilities. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations which would adversely affect our business.

Healthcare legislative reform measures may have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the U.S. and certain foreign jurisdictions, there have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our therapeutic candidates, if we obtain marketing approval;
- our ability to receive or set a price that we believe is fair for our future products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

The ACA includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers in the U.S. It also included the provisions that created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The ACA continues to significantly impact the U.S.'s pharmaceutical industry.

Moreover, there has been heightened governmental scrutiny over the manner in which prescription drug and biological product manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 ("IRA"), which includes (among other things) multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the U.S.. A manufacturer of drug products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. The IRA is in the process of being implemented by CMS and its impact on the pharmaceutical industry in the U.S. remains uncertain at this time, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing a separate price negotiation program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in recent years, several states have formed prescription drug affordability boards ("PDABs"). These PDABs have attempted to implement upper payment limits on drugs sold in their respective states in both public and commercial health plans. For example, in August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts similarly remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits.

We expect that the ACA, the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any future approved therapeutic product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability, or commercialize our future therapeutic candidates, if approved.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, an adequate level of reimbursement might not be available for such products and third-party payors' reimbursement policies might adversely affect our ability to sell any future products profitably.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for biologic therapeutics, and FDA's statutory authorities are periodically amended by Congress. For example, as part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional authorities related to the accelerated approval pathway for human drugs and biologics. Under these recent amendments to the FDCA, the agency may require a sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The amendments also give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our therapeutic candidates, if any, may be. Increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-approval testing and other requirements.

In addition, in April 2023 the European Commission issued a proposal that will revise and replace the existing general pharmaceutical legislation governing drug and biological products intended for the EU market. If adopted and

implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the EU.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our therapeutic candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Risks Relating to Our Intellectual Property

If the licensors of our in-licensed technology are unable to obtain and maintain patent and other intellectual property protection, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to those derived from such intellectual property, and our ability to achieve profitability may be adversely affected.

Our ability to compete effectively will depend, in part, on maintaining the proprietary nature of our in-licensed technology and manufacturing processes. We rely on research, manufacturing and other know-how, patents, trade secrets, license agreements and contractual provisions to establish our intellectual property rights. These legal means, however, afford only limited protection and may not adequately protect our rights.

We cannot predict whether the patent applications related to our in-licensed technology will issue as patents, or whether the claims of any resulting patents will provide us with a competitive advantage or whether the licensor will be able to successfully pursue patent applications in the future relating to such products and product candidates. Moreover, the patent application and approval processes are expensive and time-consuming. The licensor may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities for the licensor to seek additional patent protection. Defects of form in the preparation or filing of patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If the licensor fails to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents.

Even if they are unchallenged, our in-licensed patents and patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of the future products and product candidates that we or our strategic partners or collaborators may develop but that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications is not sufficiently broad to impede such competition, the successful commercialization of such product candidates could be negatively affected.

Other parties, many of whom have substantially greater resources and have made significant investments in competing technologies, have developed or may develop technologies that may be related or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent applications, either by claiming the same compositions, formulations or methods or by claiming subject matter that could dominate our patent position. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. As a result, any patents we may in-license in the future may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to future products and product candidates that we or our strategic partners or collaborators may develop.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the U.S. or in many foreign jurisdictions. The standards applied by the USPTO and foreign patent offices in

granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs or aBLAs to the FDA in which they claim that the patents related to our in-licensed technology are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert these patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find the in-licensed patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, we cannot offer any assurances regarding which, if any, patents will issue, the scope of any such issued patents, whether any such patents will be found invalid and unenforceable, whether they may be challenged by third parties or whether they will effectively prevent others from commercializing competing technologies and drug candidates.

In addition to patent protection, we expect to rely heavily on trade secrets, know-how and other unpatented technology, which are difficult to protect. Although we seek such protection in part by entering into confidentiality agreements with our vendors, employees, consultants and others who may have access to proprietary information, we cannot be certain that these agreements will not be breached, adequate remedies for any breach would be available, or our trade secrets, know-how and other unpatented proprietary technology will not otherwise become known to or be independently developed by our competitors. If we are unsuccessful in protecting our intellectual property rights, sales of our products may suffer, and our ability to generate revenue could be severely impacted.

If the licensor of our in-licensed technology does not obtain patent term extension for future products that we, our strategic partners or collaborators may successfully develop, our business may be materially harmed.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering future products and product candidates that we or our strategic partners or collaborators may develop are obtained, once the patent life has expired for a particular product, we or our strategic partners or collaborators may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are approved and commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In the future, if we obtain an issued patent covering one of the product candidates that we or our strategic partners or collaborators may develop, depending upon the timing, duration and specifics of any FDA marketing approval of such product candidates, such patent may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process for drugs and biologics. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. A patent may only be extended once and only based on a single approved product. However, the patent owner may not be granted an extension because of, for example, failure to obtain a granted patent before approval of a product candidate, failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents or otherwise our failure to satisfy applicable requirements. A patent licensed to us by a third party may not be available for patent term extension. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Changes in patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect future products and product candidates that we or our strategic partners or collaborators may develop.

Changes in either the patent laws or the interpretation of the patent laws in the U.S. or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. When implemented, the Leahy-Smith Act included several significant changes to U.S. patent law that impacted how patent rights could be prosecuted, enforced and defended. In particular, the Leahy-Smith Act also included provisions that switched the U.S. from a "first-to-invent" system to a "first-to-file" system, allowed third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures governing the administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first to file provisions, only became effective on March 16, 2013. Some of the Company's patents and patent applications have effective dates later than March 16, 2013 and thus will be subject to the provisions of the Leahy-Smith Act.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent rulings from the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining, defending and enforcing patents on products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. could be less extensive than those in the U.S.. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products. There can be no assurance that we will obtain or maintain patent rights in or outside the U.S. under any future license agreements. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from utilizing our inventions in all countries outside the U.S., even in jurisdictions where we pursue patent protection, or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with future products and product candidates that we or our strategic partners or collaborators may develop and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the U.S. and Europe do not afford intellectual property protection to the same extent as the laws of the U.S. and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries including India and China, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our in-licensed patents or marketing of competing products in violation of our proprietary rights generally. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the U.S. and Europe. In addition, many countries limit the enforceability of patents against

government authorities or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Proceedings to enforce our patent rights, even if obtained, in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. They could also put our patents at risk of being invalidated or interpreted narrowly, put our patent applications at risk of not issuing and provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. While we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the U.S. and abroad that is relevant to or necessary for the commercialization of our drug candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Some of these employees may be subject to proprietary rights, non-disclosure and non competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co- inventor. For example, we or our collaborators may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. In addition, our patents may become, involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time-consuming, and our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both.

In an infringement proceeding, a court may decide that a patent is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing drug candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. Furthermore, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities.

We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, with the USPTO and with comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any proprietary name we have proposed to use with our drug candidates in the U.S. must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed proprietary product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

ITEM 1B. Unresolved Staff Comments

We do not have any unresolved comments issued by the SEC Staff.

ITEM 1C. Cybersecurity

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We monitor cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that we use through third party providers that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We engage consultants in connection with our risk assessment processes. These service providers assist us in designing and implementing our cybersecurity policies and procedures, as well as monitoring and testing our safeguards. We require each third-party service provider to certify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company.

As of December 31, 2025, and through the date of the filing of this report, we are not aware of any cybersecurity incidents that have materially affected or are reasonably likely to materially affect us, including our

business strategy, results of operations or financial condition. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "Risk Factors," in this 2025 Annual Report.

Governance

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its cybersecurity risk oversight function through its audit committee, which provides oversight of our cybersecurity program as part of its periodic review of enterprise risk management.

Our President and Chief Executive Officer and Senior Vice President of Finance are primarily responsible for assessing and managing our material risks from cybersecurity threats. In this regard, our President and Chief Executive Officer and Senior Vice President of Finance have assistance from consultants.

Our President and Chief Executive Officer and Senior Vice President of Finance oversee our cybersecurity policies and processes, including those described in "Risk Management and Strategy" above. Under such policies and processes, our President and Chief Executive Officer and Senior Vice President are responsible for reporting to our audit committee regarding any cybersecurity incidents.

The audit committee, in turn, provides periodic reports to our board of directors regarding our cybersecurity processes, including the results of cybersecurity risk assessments.

ITEM 2. Properties

We currently lease approximately 4,000 square feet of office and laboratory space in New York and Massachusetts. The term of our Manhattan lease was to expire in January 2027, but we entered into a lease termination agreement with the landlord, effective March 13, 2026. See Note 18 to the consolidated financial statement for more information regarding the lease termination agreement. The term of our Massachusetts lease expires in June 2028. We believe that our leased property is generally well maintained, in good operating condition and meets our current business needs.

ITEM 3. Legal Proceedings

For a description of our legal proceedings, refer to Note 13 to the consolidated financial statements, which is incorporated herein by reference.

ITEM 4. Mine Safety Disclosures

Not Applicable.

PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock and warrants are listed on The Nasdaq Capital Market under the symbol "ERNA" and "ERNAW," respectively.

Holders of Common Stock

As of March 12, 2026, there were approximately 121 stockholders of record of our common stock. The number of stockholders of record is based upon the actual number of holders registered on our books at such date. A substantially greater number of holders of our common stock are "street name" or beneficial holders, whose shares are held by banks, brokers and other financial institutions.

Preferred Stock

We have 156,112 shares of Series A Preferred Stock issued and outstanding. The Series A Preferred Stock provides for a cumulative annual dividend of 10 cents per share, payable in semi-annual installments in June and December. Dividends may be paid in cash or in shares of our common stock. In 2025, we issued approximately 7,000 shares of common stock as payment of the dividends to the holders of our Series A Preferred Stock. We expect to pay the dividends on our Series A Preferred Stock in accordance with its terms.

Dividend Policy

We have not declared or paid any cash dividends on our common stock. We currently do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws and contractual limitations, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this report.

Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the period covered by this report that were not previously reported in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Issuer Purchases of Equity Securities

None.

ITEM 6. [Reserved]

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our consolidated financial statements and the notes thereto included in Part II, Item 8 of this report. The following discussion contains forward-looking statements. See "CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS" in Part I of this report. Forward-looking statements are not guarantees of future activities or results. Many factors could cause our actual activities or results to differ materially from those anticipated in forward-looking statements, including those discussed in "Item 1A. Risk Factors" of Part I of this report.

Overview

We are a preclinical-stage synthetic allogeneic iMSC therapy company. iMSCs are induced pluripotent stem cell-derived mesenchymal stem cells. We envision a future where cell therapies powered by synthetic iMSCs can offer new options for patients with limited treatment paths, and our mission is to transform the treatment of cancer and autoimmune disease by developing scalable, affordable, off-the-shelf cell therapies that restore hope.

2026 Public Offering

On February 6, 2026, we entered into a placement agency agreement (the "Placement Agency Agreement") with Brookline Capital Markets, a division of Arcadia Securities, LLC (the "Placement Agent"), pursuant to which we engaged the Placement Agent for the public offering of (i) 19.0 million shares (the "Shares") of our common stock and accompanying warrants to purchase 19.0 million shares of common stock (the "Milestone Warrants"), at a combined offering price of $0.50 per share of common stock and accompanying Milestone Warrant and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase 2.0 million shares of common stock and accompanying Milestone Warrants to purchase 2.0 million shares of common stock, at a combined offering price of $0.49 per Pre-Funded Warrant and accompanying Milestone Warrant (the "2026 Offering"). In connection with the 2026 Offering, we also entered into a securities purchase agreement (each, a "Purchase Agreement") with certain investors who purchased Shares, Pre-Funded Warrants and Milestone Warrants in the 2026 Offering.

The Pre-Funded Warrants are immediately exercisable subject to certain ownership limitations, have an exercise price of $0.01 per share, and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. On February 11, 2026 and February 18, 2026, the holder of the Pre-Funded Warrants exercised 1.3 million and 0.7 million Pre-Funded Warrants, respectively, for an aggregate exercise price of approximately $20,000. There are no remaining Pre-Funded Warrants related to the 2026 Offering outstanding.

On February 6, 2026, the Milestone Warrants commenced trading on The Nasdaq Capital Market under the symbol "ERNAW." The Milestone Warrants are immediately exercisable subject to certain ownership limitations, have an exercise price of $0.68 per share, and expire on the earlier of (i) the five (5)-year anniversary of the original issuance date or (ii) the 180th calendar day following the public release by us of clinical trial data from the first cohort of the Phase 1 study of ERNA-101.

Pursuant to the Placement Agency Agreement, we paid the Placement Agent an aggregate cash fee of approximately $0.5 million, which was equal to 6.5% of the aggregate purchase price paid by investors in the Offering (or 1.5% with respect to certain existing investors). We will also pay the Placement Agent a cash fee as compensation for gross proceeds we receive from any exercise of any Milestone Warrants sold in connection with the 2026 Offering, payable quarterly on each January 1, April 1, July 1 and October 1 following the closing of the 2026 Offering (or the following business day if such day is not a business day), at the same percentage and as calculated in the manner as set forth above. We also issued approximately 0.2 million shares of common stock to the Placement Agent, which was equal to 1.5% of the aggregate number of Shares and Pre-Funded Warrants sold in the Offering (or 0.5% with respect to sales to certain existing investors). In addition, we reimbursed the Placement Agent for its accountable offering-related legal expenses in an amount of $125,000.

The 2026 Offering closed on February 10, 2026, for aggregate gross proceeds of approximately $10.5 million before deducting Placement Agent fees and other offering expenses payable by us. We intend to use the net proceeds from the 2026 Offering to support the advancement of our development programs, working capital and general corporate purposes.

The Placement Agency Agreement and the Purchase Agreements contain customary representations, warranties and agreements by us, customary conditions to closing, indemnification obligations of us, the Placement Agent, or the investors, as the case may be, and other obligations of the parties.

Pursuant to the terms of the Purchase Agreements and the Placement Agency Agreement, we have agreed that for a period of ninety (90) days from the closing of the 2026 Offering, that neither we nor any subsidiary may (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or common stock equivalents or (ii) file any registration statement or prospectus, or any amendment or supplement thereto, in each case, subject to certain exceptions. We have also agreed not to effect or enter into an agreement to

effect any issuance of common stock or common stock equivalents involving a Variable Rate Transaction, as defined in the Purchase Agreements, for a period of ninety (90) days following the closing of the 2026 Offering, subject to certain exceptions, unless waived by the Placement Agent. In addition, as part of the Purchase Agreement, subject to certain exceptions, our officers and directors entered into lock-up agreements, pursuant to which they agreed not to sell or otherwise dispose of any of the common stock for a period of ninety (90) days following the date of closing of the 2026 Offering.

On February 10, 2026, we also entered into a Warrant Agent Agreement with the transfer agent pursuant to which the transfer agent agreed to act as warrant agent with respect to the Milestone Warrants.

Amendments to Restated Articles of Incorporation, as Amended

Effective June 2, 2025, we filed a certificate of amendment to our Restated Certificate of Incorporation, as amended (the "Amended COI"), with the Secretary of State of Delaware to increase the authorized shares of our common stock from 100 million to 150 million (the "Authorized Shares Amendment").

Also effective June 2, 2025, we filed a certificate of amendment to our Amended COI with the Secretary of State of Delaware to allow for action required or permitted to be taken by our stockholders to be effected by written consent of such stockholders in addition to duly called annual or special meetings of such stockholders ("the Written Consent Amendment")

On June 10, 2025, we filed a certificate of amendment to our Amended COI with the Secretary of State of Delaware to effect a reverse stock split of our common stock at a ratio of 1-for-15 effective at 12:01 a.m. (the "Reverse Stock Split"). Upon the effectiveness of the Reverse Stock Split, every fifteen shares of the issued and outstanding common stock were automatically combined and reclassified into one issued and outstanding share of common stock. The Reverse Stock Split did not alter the par value of the common stock, and the number of authorized shares of common stock remains unchanged at 150 million. No fractional shares were issued in connection with the Reverse Stock Split, and no cash or other consideration was paid in connection with any fractional shares. Stockholders who otherwise would have held a fractional share after giving effect to the Reverse Stock Split instead owned one whole share of the post-reverse stock split common stock. We issued an aggregate of 153 shares for rounding up fractional shares to whole shares.

All share and per share data in this Annual Report have been adjusted for all periods presented to reflect the Reverse Stock Split.

The Authorized Shares Amendment, Written Consent Amendment, and Reverse Stock Split Amendment were approved by our stockholders at our 2025 Annual Meeting of Stockholders on June 2, 2025 (the "Annual Meeting").

2025 Private Placement of Equity

On March 31, 2025, we entered into a securities purchase agreement (the "SPA") with certain accredited investors and a related registration rights agreement. Pursuant to the SPA, we agreed to issue and sell to the investors, and the investors agreed to purchase, in a private placement, an aggregate of approximately 4,621,000 shares of common stock at a purchase price of $1.569 per share (or pre-funded warrants in lieu of common stock at a purchase price of $1.494 per pre-funded warrant). The pre-funded warrants will be exercisable until exercised in full at a nominal exercise of $0.075 per share and may not be exercised to the extent such exercise would cause the holder to beneficially own more than 4.99% or 9.99%, as applicable, of our outstanding common stock.

Upon the initial closing of the SPA on April 2, 2025 (the "First Closing"), we sold to the investors an aggregate of approximately 662,000 shares of common stock and 34,000 pre-funded warrants (such shares, including the shares underlying the pre-funded warrants, equal to 19.99% of our outstanding shares as of March 31, 2025). Following shareholder approval at the Annual Meeting, on June 9, 2025, we sold to the investors an aggregate of approximately 3,182,000 shares of common stock and 622,000 pre-funded warrants, and on June 27, 2025, we sold the remaining approximately 121,000 shares of common stock (the June 9, 2025 and June 27, 2025 issuances collectively referred to as the "Second Closing"). The Company raised approximately $7.2 million in gross proceeds under the SPA.

Basis of Presentation

Revenue

Revenue is related to an exclusive option and license agreement we had with a customer, under which we granted the customer an option to obtain an exclusive sublicense to certain of our technology for preclinical, clinical and commercial purposes in exchange for a non-refundable up-front payment to us of $0.3 million. We also began developing certain induced pluripotent stem cell lines in exchange for a cell line customization fee. The customer paid us $0.4 million towards the customization fee, which we were recognizing ratably over the customization period for the year ended December 31, 2024. The Company did not recognize any revenue during the year ended December 31, 2025.

In September 2024, we entered into an agreement with Factor Limited (and together with Factor Bioscience Inc. and its other affiliates, "Factor Bioscience") whereby we assigned the customer contract to Factor Bioscience (the "Assignment Agreement"). The Assignment Agreement with Factor Bioscience assigned all our rights and obligations under the customer contract to Factor Bioscience. Payments to us related to the customer contract will now be subject to the Assignment Agreement, which provides for Factor Bioscience paying us thirty percent (30%) of all amounts it receives from the customer in the event that the customer obtains a sublicense from Factor Bioscience. Upon receipt of future payments for the customization activities set forth in the customer contract, Factor Bioscience will pay us twenty percent (20%) of all amounts Factor Bioscience receives from the customer. For the year ended December 31, 2025, we received approximately $0.5 million from Factor Bioscience under the Assignment Agreement, which is recognized as other income in the consolidated statements of operations, as this income did not qualify as revenue.

Because we have no further obligations under the agreement with the customer, there is no revenue recognized for the year ended December 31, 2025. For additional information, see Note 4 to the accompanying consolidated financial statements. We have no other revenue generating contracts at this time.

Cost of Revenues

We recognize direct labor and supplies associated with generating our revenue as cost of revenues. We were also obligated to pay Factor Bioscience 20% of any amounts we received from the customer contract discussed above under a previous license agreement we had with Factor Bioscience, which has since been terminated, and such costs were also recognized as cost of revenues.

Research and Development Expenses

We expense our research and development costs as incurred. Research and development expenses consist of costs incurred for company-sponsored research and development activities. Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred if the technology is not expected to have any alternative future uses other than the specific research and development project for which it was intended.

The major components of research and development costs include salaries and employee benefits, stock-based compensation expense, supplies and materials, preclinical study costs, expensed licensed technology, consulting, scientific advisors and other third-party costs, as well as allocations of various overhead costs related to our product development efforts.

We have contracted with third parties to perform various services. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. We accrue for third party expenses based on estimates of the services received and efforts expended during the reporting period. If the actual timing of the performance of the services or the level of effort varies from the estimate, the accrual is adjusted accordingly. The expenses for some third-party services may be recognized on a straight-line basis if the expected costs are expected to be incurred ratably during the period. Payments under the contracts depend on factors such as the achievement of certain events or milestones, the allocation of responsibilities among the parties to the agreement, and the completion of portions of the preclinical study or similar conditions.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries, benefits and other costs, including equity-based compensation, for our executive and administrative personnel, legal and other professional fees, travel, insurance, and other corporate costs.

Comparison of the Years Ended December 31, 2025 and 2024

	Year ended December 31,		
(In thousands)	**2025**	**2024**	**Change**
Revenue	$ -	$ 582	$ (582)
Cost of revenues	-	96	(96)
Gross profit	-	486	(486)
Operating expenses:			
Research and development	4,156	4,604	(448)
General and administrative	5,163	13,132	(7,969)
Gain on lease termination	-	(1,576)	1,576
Total operating expenses	9,319	16,160	(6,841)
Loss from operations	(9,319)	(15,674)	6,355
Other expense, net:			
Forward sales contract expense	(5,847)	-	(5,847)
Gain (loss) on extinguishment of debt	765	(22,440)	23,205
Change in fair value of convertible notes	-	1,017	(1,017)
Change in fair value to bridge notes derivative liability	-	(1,459)	1,459
Change in fair value of warrant liabilities	1	414	(413)
Change in fair value of contingent consideration	-	66	(66)
Interest income	83	249	(166)
Interest expense	(27)	(6,752)	6,725
Other income, net	215	70	145
Total other expense, net	(4,810)	(28,835)	24,025
Loss before income taxes	(14,129)	(44,509)	30,380
Benefit (provision) for income taxes	45	(30)	75
Net loss	$ (14,084)	$ (44,539)	$ 30,455

Revenue

During the year ended December 31, 2024, we recognized revenue related to the cell line customization activities we performed for a customer, including the acceleration of recognizing approximately $0.5 million of deferred revenue related to nonrefundable payments we received from the customer due to the Assignment Agreement we entered into on September 24, 2024 with Factor Limited discussed earlier. We did not have any revenue recognizing contracts during the year ended December 31, 2025.

Cost of Revenue

During the year ended December 31, 2024, our cost of revenues included direct labor and materials to perform customization cell line activities for a customer. We did not have any cost of revenues during the year ended December 31, 2025.

Research and Development Expenses

	Years ended December 31,		
	2025	2024	Change
(in thousands)			
MSA/license fees	$ 1,847	$ 3,017	$ (1,170)
Payroll-related	502	591	(89)
Professional fees	812	291	521
Study fees	667	468	199
Other expenses, net	328	237	91
Total research and development expenses	$ 4,156	$ 4,604	$ (448)

Total research and development expenses decreased by approximately $0.5 million for the year ended December 31, 2025 compared to the year ended December 31, 2024, primarily due to decreased MSA/license fees as a result of the new Factor L&C Agreement and payroll-related expenses, offset by increased professional fees due to an increase in consulting services, third party study fees related to our development programs, and other expenses incurred for the year ended December 31, 2025 compared to the year ended December 31, 2024.

General and Administrative Expenses

	Years ended December 31,		
	2025	2024	Change
(in thousands)			
Occupancy expense	$ 29	$ 5,074	$ (5,045)
Professional fees	1,668	4,168	(2,500)
Insurance	269	497	(228)
Payroll-related	1,431	1,607	(176)
Stock-based compensation	1,433	1,431	2
Other expenses, net	333	355	(22)
Total general and administrative expenses	$ 5,163	$ 13,132	$ (7,969)

Our general and administrative expenses decreased by approximately $8.0 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily due to decreases in occupancy expense as a result of terminating our Somerville sublease effective August 31, 2024, professional fees related to a reduction in legal services for litigation matters and consultants, insurance expense due to lower premiums and payroll-related expenses during the year ended December 31, 2025 compared to the year ended December 31, 2024.

Gain on Lease Termination

In August 2024, we and the sublessor of our Somerville sublease entered into a sublease termination agreement effective August 31, 2024. Pursuant to this sublease termination agreement, we agreed to surrender and vacate the premises, all of our right, title and interest in all furniture, fixtures and laboratory equipment at the premises will become the property of the sublessor, and both parties will be released of their obligations under the sublease. As a result of the sublease termination, we recognized a gain on lease termination of approximately $1.6 million for the year ended December 31, 2024. There was no similar transaction during the year ended December 31, 2025.

Forward sales contract expense

For the year ended December 31, 2025, we recognized $5.8 million in expense related to a forward sales contract for the sale of shares of the Company's common stock and prefunded warrants (the "2025 Private Placement"), $5.3 million of which was initially recognized at the contract inception date because the fair value of the shares that were expected to be issued under a securities purchase agreement (the "2025 SPA") exceeded the proceeds, and the remaining $0.5 million loss was related to the change in fair value that was remeasured immediately prior to the respective settlement of the shares issued under the 2025 SPA. See Note 15 to the accompanying consolidated financial statements for more information on the 2025 Private Placement. There was no similar transaction for the year ended December 31, 2024.

Gain (Loss) on Extinguishment of Debt

During the year ended December 31, 2025, we recognized a gain on extinguishment of debt of approximately $0.8 million related to liabilities that have been deemed to be time-barred from collection under the respective state laws. See Note 10 to the accompanying consolidated financial statements for more information.

During the year ended December 31, 2024, we recognized a $22.4 million loss on extinguishment of debt related to (i) agreements to exchange certain convertible notes and warrants into shares of our common stock (the "Exchange Agreements") and (ii) a securities purchase agreement for the sale of common stock (the "2024 Private Placement"), both of which were entered into on September 24, 2024. See Note 15 to the accompanying consolidated financial statements for more information on these transactions.

Change in Fair Value of Convertible Notes

Because the modification of our convertible notes was accounted for as an extinguishment of debt and marked to fair value upon entering into the Exchange Agreements, we recognized income of approximately $1.0 million during the year ended December 31, 2024 related to the change in fair value of the convertible notes. This was due to such convertible notes being marked to fair value as of October 29, 2024 when such convertible notes were converted to shares of common stock. There was no similar transaction during the year ended December 31, 2025.

Change in Fair Value of Bridge Notes Derivative Liability

We recognized expense of $1.6 million during the year ended December 31, 2024 related to the initial measurement of the incremental fair value of a derivative liability for convertible bridge notes we entered into (the "Bridge Notes") over the carrying value of the Bridge Notes due to bifurcation of an embedded conversion feature. This expense was offset by a $0.2 million credit for the change in fair value of the Bridge Notes derivative liability due to remeasuring the liability at each reporting period or immediately prior to converting the Bridge Notes into shares of our common stock. There was no similar transaction during the year ended December 31, 2025. See Note 11 to the accompanying consolidated financial statements for more information on the Bridge Notes.

Change in Fair Value of Warrant Liabilities

The change in the fair value of the warrant liabilities for the year ended December 31, 2025 was *de minimis.* We recognized income of $0.4 million for the year ended December 31, 2024 for the change in the fair value of our warrant liabilities, which includes certain warrants under the Exchange Agreements that were reclassified to a liability in September 2024 and then exchanged for shares of common stock in October 2024. See Note 15 to the accompanying consolidated financial statements for more information on the exchanged warrants.

Change in Fair Value of Contingent Consideration

As of December 31, 2024, we remeasured a contingent liability and recognized a credit of less than $0.1 million for the year ended December 31, 2024 due to a decrease in the fair value of the liability. There were no amounts recognized for the year ended December 31, 2025. The contingent consideration liability will expire in April 2026.

Interest Income

We recognized a decrease in interest income of approximately $0.2 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 due to lower cash balances in interest-bearing accounts.

Interest Expense

We recognized a decrease in interest expense for the year ended December 31, 2025 of approximately $6.7 million compared to the year ended December 31, 2024 primarily due to no longer having convertible notes outstanding during the year ended December 31, 2025 as a result of the Exchange Agreements entered into during the year ended December 31, 2024.

Other Income, Net

During the year ended December 31, 2025, we recognized approximately $0.5 million of income from Factor Limited as a result of the Assignment Agreement, offset by approximately $0.2 million of financing fees that we expensed for the 2025 Private Placement, as the related securities purchase agreement was accounted for as a liability until its settlement. See Note 15 to the accompanying consolidated statement of operations for more information on the 2025 Private Placement.

For the year ended December 31, 2024, we recognized other income related to amounts earned from Factor Limited under the Assignment Agreement of approximately $0.1 million.

Benefit (Provision) for Income Taxes

For the year ended December 31, 2025, we incurred state minimum income tax liabilities related to our operations. However, we recognized an overall income tax benefit due to a reduction of a deferred tax liability, which was recorded through the accompanying consolidated statement of operations. We continue to maintain a full valuation allowance for all deferred tax assets, including our net operating loss carryforwards, since we could not conclude that we were more likely than not able to generate future taxable income to realize these assets. The effective tax rate differs from the statutory tax rate due primarily to our full valuation allowance.

Liquidity and Capital Resources

As of December 31, 2025, we had cash of approximately $1.9 million, and we had an accumulated deficit of approximately $245.6 million. We have to date incurred operating losses, and we expect these losses to continue in the future. For the year ended December 31, 2025, we incurred a net loss of $14.1 million, and we used $7.0 million of cash in operating activities.

On March 11, 2025 and March 20, 2025, we received $1.5 million and $0.8 million, respectively, for the issuance of two promissory notes with an aggregate principal amount of $2.3 million to an investor. The promissory notes had a maturity date of the earlier of (i) June 15, 2025 or (ii) upon us receiving greater than $5 million in aggregate proceeds from a subsequent capital raise. Interest accrued at a rate of 5.0% per annum, payable at maturity. During the year ended December 31, 2025, the Company repaid the notes in full for $2.3 million, including accrued interest.

During the year ended December 31, 2025, we raised $7.2 million in gross proceeds from the 2025 Private Placement. We used a portion of the proceeds from this financing to repay the notes, as discussed above.

On May 1, 2025, our $10.0 million standby equity purchase agreement ("SEPA") with Lincoln Park Capital Fund, LLC ("Lincoln Park") expired. The Company did not sell any shares of common stock under the SEPA during either of the years ended December 31, 2025 or 2024. We do not currently have a new SEPA in place.

On February 10, 2026, we received approximately $9.6 million in net proceeds from the 2026 Offering of (i) 21.0 million shares of the Company's common stock or pre-funded warrants and (ii) accompanying warrants to purchase 21.0 million shares of the Company's common stock (the "Milestone Warrants").

Based on our current financial condition and forecasts of available cash, we will not have sufficient capital to fund our operations for the 12 months following the issuance date of the accompanying consolidated financial statements. We can provide no assurance that we will be able to obtain additional capital when needed, on favorable terms, or at all. If we cannot raise capital when needed, on favorable terms or at all, we will need to reevaluate our planned operations and may need to reduce expenses, file for bankruptcy, reorganize, merge with another entity, or cease operations. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock. See the risk factor in Item 1A of Part II of this report titled, "We will require substantial additional capital to fund our operations, and if we fail to obtain the necessary financing, we may not be able to pursue our business strategy."

Historically, the cash used to fund our operations has come from a variety of sources and predominantly from sales of shares of our common stock and convertible notes. We will continue to evaluate and plan to raise additional funds to support our working capital needs through public or private equity offerings, debt financings, strategic

partnerships, out-licensing our intellectual property, grants or other means. There can be no assurance that capital will be available when needed or that, if available, it will be obtained on terms favorable to us and our stockholders. Our ability to raise capital through sales of our common stock will depend on a variety of factors including, among others, market conditions, the trading price and volume of our common stock, and investor sentiment. In addition, macroeconomic factors and volatility in the financial market, which may be exacerbated in the short term by concerns over inflation, interest rates, impacts of the wars in Ukraine and the Middle East, strained relations between the U.S. and several other countries, and social and political discord and unrest in the U.S., among other things, may make equity or debt financings more difficult, more costly or more dilutive to our stockholders.

In addition, equity or debt financings may have a dilutive effect on the holdings of our existing stockholders, and debt financings may subject us to restrictive covenants, operational restrictions and security interests in our assets. If we raise capital through collaborative arrangements, we may be required to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us.

We prepared the accompanying consolidated financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. As discussed above, there is substantial doubt about our ability to continue as a going concern because we do not have sufficient cash to satisfy our working capital needs and other liquidity requirements over at least the next 12 months from the date of issuance of the accompanying consolidated financial statements. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and reclassification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty of our ability to remain a going concern.

Cash Flows

Cash flows from operating, investing and financing activities, as reflected in the accompanying consolidated statements of cash flows, are summarized as follows:

(in thousands)	**2025**	**2024**	**Change**
Cash (used in) provided by:			
Operating activities	$ (7,017)	$ (15,836)	$ 8,819
Investing activities	(37)	(365)	328
Financing activities	7,209	6,260	949
Net increase (decrease) in cash and cash equivalents	$ 155	$ (9,941)	$ 10,096

Net Cash Used in Operating Activities

There was a decrease of approximately $8.8 million in cash used in operating activities for the year ended December 31, 2025 compared to the year ended December 31, 2024. This change was due a $6.8 million decrease in net loss, after giving effect to adjustments made for non-cash transactions, primarily due to a decrease in occupancy expense and professional fees, and by a decrease of $2.0 million in cash used in operating assets and liabilities for the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily related to terminating our facility sublease and reduced payments to Factor limited.

Net Cash Used in Investing Activities

We used approximately $0.4 million to pay for the purchases of property and equipment during the year ended December 31, 2024. There was an immaterial amount of investing activities during the year ended December 31, 2025.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 includes $2.3 million of gross proceeds received from the issuance of two promissory notes and $4.9 million of proceeds received from the 2025 Private Placement, net of offsetting $2.3 million of a receivable related to 2025 Private Placement due from a related party with the outstanding notes payable, including accrued interest, due to the same related party.

Net cash provided by financing activities for the year ended December 31, 2024 includes $6.3 million of gross proceeds received from (i) the issuance of convertible notes in January 2024 and the fees related to such issuance and (ii) proceeds received from the Bridge Notes and 2024 Private Placement.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses during the reporting periods. We continually evaluate our judgments, estimates and assumptions. We base our estimates on the terms of underlying agreements, our expected course of development, historical experience and other factors we believe are reasonable based on the circumstances, the results of which form our management's basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. We believe the following critical accounting estimates affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Goodwill Impairment Evaluation

Goodwill represents the excess of the purchase price over the fair value of identifiable assets acquired and the liabilities assumed. Goodwill is not amortized but is tested for impairment annually or more frequently if events occur or circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that would indicate impairment and trigger an interim impairment assessment include, but are not limited to, macroeconomic conditions, industry and market considerations, cost factors, overall financial performance and other relevant events. Management evaluates our company as a single reporting unit, therefore, our goodwill is tested for impairment at the entity level. Goodwill is tested for impairment as of December 31st of each year, or more frequently as warranted by events or changes in circumstances mentioned above. Accounting guidance also permits an optional qualitative assessment for goodwill to determine whether it is more likely than not that the carrying value of a reporting unit exceeds its fair value. If, after this qualitative assessment, we determine that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then no further quantitative testing would be necessary. A quantitative assessment is performed if the qualitative assessment results in a more likely than not determination or if a qualitative assessment is not performed. The quantitative assessment considers whether the carrying amount of a reporting unit exceeds its fair value, in which case an impairment charge is recorded in an amount equal to the excess fair value.

The Company performed its annual qualitative assessments as of December 31, 2025 and 2024, and based on those assessments, the Company was unable to conclude that it was more likely than not that the fair value of the entity exceeded its carrying value as of such date. As a result, the Company performed a step-one quantitative assessment and concluded that the fair value of the reporting unit was greater than the carrying value as of December 31, 2025 and 2024, and the goodwill was considered not impaired. Therefore, the Company did not recognize an impairment charge during the years ended December 31, 2025 and 2024. However, the decline in the Company's stock price during the first quarter of 2026 has increased the likelihood that the fair value of the reporting unit may be below its carrying value as of March 31, 2026, which could result in the recognition of a goodwill impairment charge for the three months ended March 31, 2026.

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

In December 2023, the Financial Accounting Standard Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2023-09, *Improvements to Income Tax Disclosures*, which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and

modifies other income tax-related disclosures. ASU No. 2023-09 was effective for fiscal years beginning after December 15, 2024 and allowed for adoption on a prospective basis, with a retrospective option. We adopted this ASU on a prospective basis, and it did not have an impact to our consolidated financial statements, but it did result in additional disclosures made in the notes to the consolidated financial statements.

Recently Issued Accounting Standards to be Adopted

In October 2023, the FASB issued ASU No. 2023-06, *Disclosure Improvements – Codification Amendment in Response to the SEC's Disclosure Update and Simplification Initiative.* This ASU modified the disclosure and presentation requirements of a variety of codification topics by aligning them with the SEC's regulations. The amendments to the various topics should be applied prospectively, and the effective date will be determined for each individual disclosure based on the effective date of the SEC's removal of the related disclosure. If the SEC has not removed the applicable requirements from Regulation S-X or Regulation S-K by June 30, 2027, then this ASU will not become effective. Early adoption is prohibited. We do not expect the amendments in this ASU to have a material impact on our consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40).* This ASU is intended to improve disclosures about a public business entity's expenses by requiring disaggregated disclosure, in the notes to the financial statements, of prescribed categories of expenses within relevant income statement captions. ASU No. 2024-03 is effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027 (as clarified in ASU No. 2025-01, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date)*. Early adoption is permitted. The new standard may be applied either on a prospective or retrospective basis. We do not expect the adoption of this ASU to have a material impact on our consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-04, *Debt – Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments.* This ASU clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. ASU No. 2024-04 is effective for annual reporting periods beginning after December 15, 2025 and interim reporting periods within those annual reporting periods. Early adoption is permitted, and the amendments may be applied on either a prospective or retrospective basis. We do not expect the amendments in this ASU to have a material impact on our consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software.* This ASU modernizes the accounting for internal-use software costs by removing all references to prescriptive and sequential software development stages and instead requires capitalization when (i) management has authorized and committed to funding the software project and (ii) it is probable that the project will be completed and the software will be used to perform the function intended have both occurred. ASU No. 2025-06 is effective for fiscal years beginning after December 15, 2027, and interim reporting periods, with early adoption permitted. We do not expect the amendments in this ASU to have a material impact on our consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements.* This ASU includes a disclosure principle that requires entities to disclose events since the end of the last reporting period that have a material impact on the entity, which is modeled after the SEC disclosure requirement. This ASU also clarifies the applicability of Topic 270, the types of interim reporting, and the form and content of interim financial statements in accordance with GAAP. For public business entities, this ASU is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. We do not expect the amendments in this ASU to have a material impact on our consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-12, *Codification Improvements.* The amendments in this update represent changes to the Codification that (1) clarify, (2) correct errors, or (3) make minor improvements. The amendments in this ASU are varied in nature and may affect the application of guidance in cases in which the original guidance may have been unclear. This ASU is effective for all entities for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods. We do not expect the amendments in this ASU to have a material impact on our consolidated financial statements.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

Under SEC rules and regulations, as a smaller reporting company we are not required to provide the information otherwise required by this item.

ITEM 8. Financial Statements and Supplementary Data

See "Index to Consolidated Financial Statements" on page F-1 for the consolidated financial statements filed with this report.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

See Item 14, "Principal Accounting Fees and Services" for information related to changes in accountants.

ITEM 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act, designed to ensure that information required to be disclosed in our reports filed pursuant to the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosures.

In designing and evaluating the disclosure controls and procedures, we recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and we were required to apply our judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation as of the end of the period covered by this Annual Report on Form 10-K under the supervision, and with the participation, of our management, including our President and Chief Executive Officer (who serves as our principal executive officer) and our Senior Vice President of Finance (who serves as our principal financial officer) of the effectiveness of the design and operation of our disclosure controls and procedures.

Based on that evaluation, our Chief Executive Officer and Senior Vice President of Finance concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K in providing reasonable assurance of achieving the desired control objectives.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

As of December 31, 2025, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework (2013) (the "2013 Framework"). In adopting the 2013 Framework, management assessed the applicability of the principles within each component of internal control and determined whether they have been adequately addressed within the current system of internal control and adequately documented. Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer and Senior Vice President of Finance, concluded that, as of December 31, 2025, our internal control over financial reporting was effective based on these criteria.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the most recent fiscal quarter that

has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

During the quarter ended December 31, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

On March 10, 2026, the Compensation Committee approved increases to the compensation of our President and Chief Executive Officer, Sanjeev Luther, and our Senior Vice President of Finance, Sandra Gurrola, effective April 1, 2026. Mr. Luther's annual base salary increased from $550,000 to $670,000. Ms. Gurrola's annual base salary increased from $275,000 to $300,000. Additionally, the Committee approved a bonus payment for Ms. Gurrola in the amount of $68,000 and a bonus in the amount of $319,000 for Mr. Luther. There were no other changes to any other component of Mr. Luther's or Ms. Gurrola's executive compensation under our compensation plans and programs as previously disclosed.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

The names of our directors and executive officers and their respective ages, positions, biographies and, in the case of directors, their qualifications to serve as directors, are set forth below as of March 12, 2026.

Name	Age	Position
Sanjeev Luther	64	President and Chief Executive Officer and Director
Sandra Gurrola	59	Senior Vice President, Finance
James Bristol	79	Chairman of the Board
Peter Cicala	64	Director
Elena Ratner	49	Director
William Wexler	66	Director

Sanjeev Luther has served as President, Chief Executive Officer and as a member of our board of directors since January 2024. Prior to that, Mr. Luther served as President, Chief Executive Officer and a board member of Cornerstone Pharmaceuticals from November 2017 to December 2023 and as its Chief Operations Officer and Chief Business Officer from December 2014 to November 2017. Prior to that, Mr. Luther served in various leadership roles at Bristol-Myers Squibb, Novartis, Bausch and Lomb and GE Healthcare. Mr. Luther holds an MBA in Marketing and a B.S. in Marketing and Business Administration from the State University of New York at Buffalo.

Mr. Luther's qualifications to serve on our board of directors include his expertise in the healthcare industry, his business training and education, and his extensive experience managing life science companies.

Sandra Gurrola has served as our Senior Vice President of Finance since May 2023 and served as our Vice President of Finance from June 2021 until May 2023. Prior to that, she served as the Senior Vice President of eGames.com Holdings, LLC from March 2021 to June 2021 and as a consultant to us. Ms. Gurrola served as Senior Vice President of Finance to NTN Buzztime, Inc. from September 2019 to March 2021 and its Vice President of Finance from 2014 until 2019. From 2009 to 2014, Ms. Gurrola served NTN Buzztime, Inc. in various leadership accounting roles, including Controller, Director of Accounting, and Director of Financial Reporting and Compliance. Previously, she was a senior manager of financial reporting for Metabasis Therapeutics, Inc., a biotechnology company. Ms. Gurrola received a B.A. in English from San Diego State University.

James Bristol has served as a member of our board of directors since October 2023. Dr. Bristol worked for 40 years in drug discovery, research and preclinical development at Schering-Plough Corporation, Parke-Davis, and Pfizer Inc. ("Pfizer"), serving in various senior research and development roles. From 2003 until his retirement in 2007, Dr. Bristol served as Senior Vice President of Worldwide Drug Discovery Research at Pfizer Global Research & Development, where he oversaw 3,000 scientists at seven Pfizer sites as they produced an industry-leading number of drug development candidates in 11 therapeutic areas. In 2009, Dr. Bristol joined Frazier Life Sciences as a Senior Advisor. From August 2007 until December 2024, Dr. Bristol has served as a member of the board of directors of Deciphera Pharmaceuticals, and since 2018 he has served as a member of the board of directors of Erasca, Inc., both of which are publicly traded life science companies. He is currently a member of the board of directors of Genuiti. Dr. Bristol also served on the board of directors of Ignyta from 2014 until its acquisition by Roche in 2018, and served on the board of directors of SUDO Biosciences, Inc. from June 2021 until December 2023, and of Cadent Therapeutics, Inc. from 2011 until 2020. Dr. Bristol is the author of over 100 publications, abstracts and patents, and he conducted postdoctoral research at the University of Michigan (NIH Postdoctoral Fellow) and at The Squibb Institute for Medical Research. Dr. Bristol holds a Ph.D. in organic chemistry from the University of New Hampshire and a B.S. in Chemistry from Bates College.

Dr. Bristol's qualifications to serve on our board of directors include his vast experience in the biopharmaceutical industry, including in management and as a director, as well as his expertise in drug discovery and development.

Peter Cicala has served as a member of our board of directors since February 2024. Mr. Cicala currently serves as General Counsel for a private biotechnology company, where he has been since March of 2021. In November of 2019, he co-founded Pretzel Therapeutics, Inc., a biotechnology company, and still serves as an executive advisor. From March 2020 until March 2021, Mr. Cicala served as Chief Intellectual Property Counsel for Intercept Pharmaceuticals, Inc. and from March 2014 until November 2019, he served as Chief Patent Counsel for Celgene Corporation, both publicly traded biopharmaceutical companies. Mr. Cicala has practiced law for over 25 years, and also has over 10 years of experience as a medicinal chemist. He received his B.S. in chemistry from Fairleigh Dickinson University and a J.D. from Seton Hall University School of Law.

Mr. Cicala's qualifications to serve on our board of directors include his expertise in pharmaceutical and biotechnology intellectual property law and in strategic management of proprietary technology and products.

Elena Ratner has served as a member of our board of directors since January 2025. Since July 2019, Dr. Ratner has been serving as a professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at Yale University School of Medicine and also serves as the director of the Discovery to Cure Early Ovarian Detection program. Dr. Ratner's clinical research has focused on new targeted drugs for ovarian cancer and on reversing chemotherapy resistance in ovarian and uterine cancers. She received her B.S. in premedical studies from Barnard College at Columbia University, her MBA at Yale University and her M.D. from the University of Buffalo.

Dr. Ratner's qualifications to serve on our board of directors include her vast expertise in obstetrics, gynecology and reproductive sciences, and specifically in ovarian cancer research and treatment.

William Wexler has served as a member of our board of directors since June 2022. Prior to joining our board of directors, Mr. Wexler worked on over 150 individual projects, serving in various capacities including as Chairman, Chief Executive Officer, Chief Restructuring Officer and other designated roles of senior responsibility. Mr. Wexler has served as the Managing Member of WEXLER Consulting LLC, a management consulting firm, since 2012. From 2012 to 2019, he served in various roles, including as Chairman of the Board, interim Chief Executive Officer, Chief Executive Officer and sole director and stockholder representative of Upstate New York Power Products, Inc., a holding company that owned and operated power plants throughout upstate New York. From 2012 to 2013, Mr. Wexler served as Chief Restructuring Officer of VMR Electronics, LLC, a manufacturer of cable assembly products for the electronics interconnect industry. Prior to that, he served as a Managing Director and national finance practice lead at BBK, Ltd., a turn-around advisory firm, from 2006 to 2011. Mr. Wexler served as group Managing Director of corporate restructuring at Huron Consulting Group, LLC from 2002 to 2005. Previously, he was a Managing Director at Berenson Minella & Co., a boutique investment-banking firm, from 2000 to 2002. Between 1986 and 2000 he served as a Senior Director at BNP Paribas, where he established and led Paribas Properties, Inc., a real estate investment arm of the bank, and also where he was a lead officer of the then newly created U.S. asset workout group. Mr. Wexler started his professional career in 1981 in commercial lease brokerage, asset management and investment sales at Jones Lang Wootton (now Jones Lang LaSalle) where he worked until 1986. He earned a B.A. in Political Science from Johns Hopkins University.

Mr. Wexler's qualifications to serve on our board of directors include his experience in investment and senior management roles, as well as his business training and education.

Family Relationships

There are no family relationships between any of our officers or directors.

Involvement in Certain Legal Proceedings

None of our directors or executive officers is involved in any legal proceeding that requires disclosure under Item 401(f) of Regulation S-K.

Code of Ethics

Our board of directors has adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. A copy of our Code of Business Conduct and Ethics is available under the "Governance" tab of the

"Investor Relations" section of our website located at www.ernexatx.com. We intend to disclose any changes in our Code of Business Conduct and Ethics or waivers from it that apply to our principal executive officer, principal financial officer, or principal accounting officer by posting such information on the same website or by filing with the SEC a Current Report on Form 8-K, in each case if such disclosure is required by SEC or Nasdaq rules. The information on our website is not intended to form a part of or be incorporated by reference into this Proxy Statement.

Audit Committee

We have a standing audit committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Our audit committee consists of William Wexler (Chair), James Bristol and Peter Cicala, all of whom meet the requirements for independence of audit committee members under applicable Nasdaq and SEC rules, including Rule 10A-3 promulgated under the Exchange Act. All of the members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. In addition, Mr. Wexler qualifies as our "audit committee financial expert," as such term is defined in Item 407 of Regulation S-K.

Changes in Stockholder Nomination Procedures

There have been no material changes to the procedures by which stockholders may recommend nominees to our board of directors since such procedures were last described in our proxy statement filed with the SEC on April 14, 2025.

Insider Trading Policy

We have adopted an insider trading policy governing the purchase, sale, and other dispositions of our securities by directors, senior management, and employees. A copy of the Insider Trading Policy has been filed as exhibit 19 to this report.

ITEM 11. Executive Compensation

Overview

When determining executive officer compensation, and the various components that comprise it, our compensation committee evaluates and considers publicly available executive officer compensation survey data to present a competitive compensation package to attract and retain top talent, including an appropriate level of salary, performance-based bonus and equity incentives. Typically, our compensation committee evaluates competitive market benchmark data for a given executive role. Additionally, our compensation committee is authorized to engage outside advisors and experts to assist and advise our compensation committee on matters relating to executive compensation. In 2023, our compensation committee retained the services of Pearl Meyer, an independent compensation consultant, to review the cash and equity compensation package that was offered to Mr. Luther prior to his appointment as our President and Chief Executive Officer.

Our President and Chief Executive Officer presents compensation recommendations to our compensation committee with respect to the executive officers other than himself. Our compensation committee considers such recommendations, in conjunction with possible input from our compensation committee's independent compensation consultant, in making compensation decisions or recommendations to the full board of directors. The full board participates in evaluating the performance of our executive officers, except that our Chief Executive Officer does not participate when our board of directors evaluates his performance and is not present during voting or deliberations regarding his performance or compensation matters.

Compensation-Related Risk Assessment

Our compensation committee assesses and monitors whether any of our compensation policies and programs are reasonably likely to have a material adverse effect on our Company. Our compensation committee and management do not believe that the Company presently maintains compensation policies or practices that are reasonably likely to have a material adverse effect on the Company's risk management or create incentives that could lead to excessive or inappropriate risk taking by employees. In reaching this conclusion, our compensation committee considered all components of our compensation program and assessed any associated risks. Our compensation committee also considered the various strategies and measures employed by the company that mitigate such risk,

including: (i) the overall balance achieved through our use of a mix of cash and equity, annual and long-term incentives and time-and performance-based compensation; (ii) our use of multi-year vesting periods for equity grants; and (ii) the oversight exercised by our compensation committee over performance metrics, if any, established for performance-based bonuses and its administration of our equity incentive plans.

Compensation Recoupment (Clawback) Policy

Our clawback policy provides for the recovery of erroneously awarded incentive-based compensation related to the three fiscal years preceding the date on which the company is required to prepare an accounting restatement. The clawback policy complies with the requirements of Nasdaq's listing rules.

Named Executive Officers

Under applicable SEC rules and regulations, our "named executive officers" are all individuals who served as our principal executive officer during 2025, our two most highly compensated executive officers (other than our principal executive officer) who were serving as executive officers at December 31, 2025, and up to two additional individuals who would have been one of our top two most highly compensated executive officer had they been serving as an executive officer at the end of 2025. Our 2025 named executive officers are identified in the table below:

Name	Title
Sanjeev Luther	President and Chief Executive Officer
Sandra Gurrola	Senior Vice President of Finance

Summary Compensation Table

The following table sets out the compensation for our Named Executive Officers for the years ended December 31, 2025 and December 31, 2024:

2025 Summary Compensation Table

Name and Principal Position	Fiscal Year	Salary (US$)	Bonus (US$)	Stock-Based Awards (US$)[1]	Option-Based Awards (US$)[1]	Non-Equity Incentive Plan Compensation (US$)	Nonqualified deferred compensation earnings (US$)	All Other Compensation (US$)[3]	Total Compensation (US$)
Sanjeev Luther, President and Chief Executive Officer	2025	$ 550,000	$ —	$ —	$ 324,813	$ —	$ —	$ 14,000	$ 888,813
	2024	$ 550,000	$ 75,000[2]	$ —	$ 2,422,818	$ —	$ —	$ 14,000	$ 3,061,818
Sandra Gurrola, Sr. Vice President of Finance	2025	$ 275,000	$ —	$ —	$ 43,372	$ —	$ —	$ 11,000	$ 329,372
	2024	$ 275,000	$ —	$ —	$ 110,198	$ —	$ —	$ 11,000	$ 396,198

1 The amounts reported in this column represent the aggregate grant date fair value of stock options granted during the applicable year. These amounts were calculated in accordance with FASB ASC Topic 718, Compensation – Stock Compensation, except that any estimate of forfeitures was disregarded. For a description of the assumptions used in computing the dollar amount recognized for financial statement reporting purposes, see Note 14, Stock-Based Compensation, in the Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K.

2 Mr. Luther was appointed as our President and Chief Executive Officer effective January 1, 2024 and amount represents a cash signing bonus pursuant to his employment agreement.

3 The amounts reported in this column represent the Company's 401(k) match contribution.

Narrative to Summary Compensation Table

The following is a discussion of each component of our executive compensation program for 2025.

Base Salary

Each of our named executive officers receives a base salary. The base salary is the fixed cash compensation component of our executive compensation program, and it recognizes individual performance, time in role, scope of responsibility, leadership skills and experience. The base salary compensates an executive for performing his or her job responsibilities on a day-to-day basis. Generally, base salaries are reviewed annually company-wide and adjusted (upward or downward) when appropriate based upon individual performance, expanded duties, changes in the competitive marketplace and, with respect to upward adjustments, if we are financially and otherwise able to pay it. We try to offer competitive base salaries to help attract and retain executive talent.

In March 2026, our compensation committee approved (i) an increase to Mr. Luther's annual base salary from $550,000 to $670,000 and (ii) an increase to Ms. Gurrola's annual base salary from $275,000 to $300,000.

Bonus and Incentive Compensation

In addition to base salaries, our compensation committee has the authority to award discretionary annual bonuses to our named executive officers based on corporate and individual performance. Each year, our compensation committee or our board of directors may establish performance goals, which may be based on measures such as revenue, achievement of certain research and development milestones, completion of a strategic transaction, and other metrics the directors and management believe to provide proper incentives for achieving long-term shareholder value. Our board of directors retains full discretion over performance evaluation and the amount of any bonuses to be paid to a named executive officer. Annual bonuses, if any, are intended to reward the individual performance of each named executive officer. In addition to an assessment of corporate and individual performance, the determination of the amount of a named executive officer's bonus may vary from year to year depending on our financial condition and conditions in the industry in which we operate. The amount of such bonuses increase with executive rank so that, as rank increases, a greater portion of total annual cash compensation is based on annual corporate and individual performance.

For the year ended December 31, 2025, no performance goals were established for any named executive officer In March 2026, our compensation committee approved discretionary bonuses to be paid to Mr. Luther and Ms. Gurrola in the amount of $319,000 and $68,000, respectively, to reward their individual performance during the 2025 fiscal year.

Equity-Based Compensation Programs

Historically, we have issued stock options to our employees, including our named executive officers, to provide a means whereby our employees may develop a sense of proprietorship and personal involvement in our development and financial success, and to encourage them to devote their best efforts to us, thereby advancing our interests and the interests of stockholders. Our board of directors believes that the granting of equity awards promotes continuity of management and increases incentive and personal interest in our welfare by those who are primarily responsible for shaping and carrying out our long-range plans and pursuing our growth and financial success.

We do not maintain any written policies on the timing of issuing equity-based incentive awards. Our compensation committee has responsibility for granting equity-based incentive awards to our named executive officers and considers whether there is any material nonpublic information ("MNPI") about the Company when determining the timing and terms of stock option awards. The Compensation Committee generally does not time the grant of stock options in relation to our public disclosure of MNPI. We have not timed the release of MNPI for the purpose of affecting the value of executive compensation. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure.

In February 2025, we granted to Mr. Luther and Ms. Gurrola a time-based non-qualified stock option covering 74,890 shares of common stock and 10,000 shares of common stock, respectively, of which one-third will vest on the one-year anniversary of the grant date and the remaining shares will vest in 24 substantially equal monthly installments thereafter, subject to each of their continuous service.

During fiscal year 2025, no named executive officer received a grant of stock options during the period beginning four business days before, and ending one business day after, the filing of a periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of a current report on Form 8-K that discloses material nonpublic information.

Benefits and Perquisites

Employee Benefit Plans

Named executive officers are eligible to participate in our employee benefit plans, including our medical, disability and life insurance plans, in each case, on the same basis as all of our other employees. Our employee benefit plans are designed to assist in attracting and retaining skilled employees. We also maintain a 401(k) plan for the benefit of our eligible employees, including the named executive officers, as discussed below.

401(k) Plan

We offer to our eligible employees a defined contribution plan, organized under Section 401(k) of the Internal Revenue Code, through our co-employment arrangement with its professional employer organization ("PEO"). Under this arrangement, the PEO serves as the plan sponsor and administrator. Eligible employees may defer up to 100% of their annual compensation or a specific amount imposed by the Internal Revenue Service, whichever is less. We match employees' contributions at a rate of 100% of the first 3% of the employee's contribution and 50% of the next 2% of the employee's contribution, for a maximum Company match of 4%.

Pension Benefits

We do not maintain any pension benefits or retirement plans other than the 401(k) Plan.

Nonqualified Deferred Compensation

We do not maintain any nonqualified deferred compensation plans.

Named Executive Officer Employment Agreements and Change in Control Arrangements

The following descriptions summarize the principal terms of our employment agreements with our named executive officers.

Sanjeev Luther

Sanjeev Luther was appointed as our President and Chief Executive Officer effective January 1, 2024. We entered into an employment agreement, dated as of December 19, 2023, with Mr. Luther, which provides for at-will employment until terminated by us or Mr. Luther. Mr. Luther's employment agreement provides for an annual base salary of $550,000, which amount is subject to periodic review by our board of directors or our compensation committee. Mr. Luther also received a one-time signing bonus of $75,000.

Mr. Luther is eligible to receive an annual cash bonus award in an amount up to 50% of his base salary upon achievement of agreed upon performance targets. The bonus will be determined by our board of directors or our compensation committee and paid annually by March 15 in the year following the performance year on which such bonus is based.

As discussed above, in March 2026, the compensation committee approved an increase to Mr. Luther's base salary to $670,000 and a discretionary bonus of $319,000.

In accordance with the terms of his employment agreement, Mr. Luther was granted an equity award on January 1, 2024 consisting of 112,347 non-qualified stock options, which would vest over a four-year period, with 25% of the options vesting on the first anniversary of the grant date, and the remaining options vesting monthly over the remaining three years. On April 26, 2024, the compensation committee approved a modification to Mr. Luther's stock option award to reduce the vesting term to three years rather than four years, with 25% of the shares subject to the stock option award still vesting on the first anniversary of the grant date, and the balance of the shares vesting monthly over the remaining two years. Vesting generally requires Mr. Luther's continued employment through the relevant vesting date.

If Mr. Luther's employment is terminated by us without Cause (as defined in his employment agreement) or by Mr. Luther for Good Reason (as defined in his employment agreement), we will pay Mr. Luther all amounts accrued but unpaid as of the effective date of such termination, as well as a lump sum payment equal to nine months of his salary, as well as up to nine months of continued benefits. Mr. Luther will also be paid a pro-rata performance bonus equal to (x) the performance bonus Mr. Luther would have received based on actual performance for such fiscal year if Mr. Luther had remained employed for the entire fiscal year multiplied by (y) a fraction, the numerator of which is the number of days Mr. Luther was employed during such fiscal year. Notwithstanding the foregoing, if a termination without Cause or for Good Reason occurs beginning upon the occurrence of a Change in Control (as defined in the employment agreement) and ending on the first anniversary of the occurrence of the Change in Control ("Change in Control Protection Period"), Mr. Luther will receive the benefits described in the preceding sentence, but the lump sum severance payment and the payment of benefits will be for a 12-month period and he will receive 100% of his target bonus. In addition, all outstanding and unvested equity awards granted to Mr. Luther during his employment will become immediately vested and exercisable upon such date of termination during the Change in Control Protection Period and will be exercisable for a period of 12 months following the date of termination during the Change in Control Protection Period. Any such severance benefits under the employment agreement are contingent on Mr. Luther entering into and not revoking a general release of claims in favor of our company.

Sandra Gurrola

We entered into an employment agreement, dated June 16, 2021, with Sandra Gurrola, which provides for our at-will employment of Ms. Gurrola commencing on June 21, 2021 and continuing until terminated by us or Ms. Gurrola. Ms. Gurrola's employment agreement provides for an annual base salary of $220,000, which amount is subject to periodic review by our board of directors or our compensation committee. In December 2023, upon the recommendation of our compensation committee, our board of directors approved an increase to Ms. Gurrola's annual base salary from $220,000 to $275,000.

Ms. Gurrola is also eligible to receive an annual cash bonus award in an amount up to 35% of her base salary upon achievement of agreed upon performance targets. The bonus will be determined by our board of directors or our compensation committee and paid annually by March 15 in the year following the performance year on which such bonus is based.

As discussed above, in March 2026, the compensation committee approved an increase to Ms. Gurrola's base salary to $300,000 and a discretionary bonus of $68,000.

In accordance with her employment agreement, in June 2021, Ms. Gurrola was granted 117 restricted stock units, 25% of which vested on each anniversary of the grant date over four years.

If Ms. Gurrola's employment is terminated by us without Cause (as defined in the employment agreement) or by Ms. Gurrola for Good Reason (as defined in the employment agreement), we will pay Ms. Gurrola all amounts accrued but unpaid as of the effective date of such termination, as well as continuation of her salary and benefits for the following six-month period. Notwithstanding the foregoing, if a termination of employment without Cause or for Good Reason occurs within 90 days before or 12 months after a Change in Control (as defined in the employment agreement), Ms. Gurrola will receive the benefits described in the preceding sentence, but the continuation of her salary and benefits will be for 12-month period, and, in addition, Ms. Gurrola will receive a lump-sum payment of her target bonus and the restricted stock units granted to her in June 2021 will fully vest. Any such severance benefits under the employment agreement are contingent on Ms. Gurrola entering into and not revoking a general release of claims in favor of our company.

Outstanding Equity Awards at 2025 Fiscal Year-End

The following table summarizes the number of shares of our common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2025.

		Option Awards					Stock Awards			
Name	Grant Date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares of units of stock that have not vested ($)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested shares ($)
Sanjeev Luther, President and Chief Executive Officer	2/7/2025[1]	—	74,890	—	5.10	2/07/2035	—	—	—	—
	1/1/2024[2]	66,706	45,641	—	27.00	1/01/2034	—	—	—	—
Sandra Gurrola, Sr. Vice President of Finance	2/7/2025[1]	—	10,000	—	5.10	2/07/2035	—	—	—	—
	3/11/2022[3]	381	—	—	579.00	3/11/2032	—	—	—	—
	4/26/2024[4]	2,962	2,371	—	26.10	4/26/2034	—	—	—	—

1. The stock option vests over three years, with one-third vesting on the one-year anniversary of the grant date, and the remaining stock options vesting in 24 substantially equal monthly installments thereafter.
2. The stock option vests over three years, with 25% vesting on the one-year anniversary of the grant date, and the remaining stock options vesting in 24 substantially equal monthly installments thereafter.
3. The stock option vested in 36 substantially equal monthly installments.
4. The stock option vests over three years, with one-third vesting on the one-year anniversary of the grant date, and the remaining stock options vesting in 24 substantially equal monthly installments thereafter.

Director Compensation

We have a non-employee director compensation program to compensate our non-employee directors for their service in such capacity with annual retainers and equity compensation as described below. However, since August 2022, we have not compensated our non-employee directors in accordance with our non-employee director compensation program.

Our compensation committee and Board continue to assess our non-employee director compensation program, and if and when we restart compensating our non-employee directors for their service in such capacity, the

elements of our non-employee director compensation program may be different from what is described below.

Compensation Element	Amount
Annual Board Member Compensation	Paid in cash or stock options at our board's discretion. Cash paid in quarterly installments or upon the effective date of an earlier resignation of the non-employee director. Stock Options to vest quarterly over one year from grant date: Board Member: $40,000 Board Chair: $70,000
Committee Member Retainers	Paid in cash or stock options at our board's discretion. Cash paid in quarterly installments or upon the effective date of an earlier resignation of the non-employee director. Stock Options to vest quarterly over one year from grant date: Audit Committee: $7,500 Compensation Committee: $5,000 Nominating/Governance Committee: $4,000
Leadership Supplemental Retainer	Paid in cash or stock options, 's discretion. Cash paid in quarterly installments or upon the effective date of an earlier resignation of the non- employee director. Stock Options to vest quarterly over one year from grant date: Audit Committee Chair: $15,000 Compensation Committee Chair: $10,000 Nominating/Governance Committee Chair: $8,000
New Director Equity Award (outside directors)	Option for 553 shares of Common Stock, which option shall have an exercise price equal to the fair market value per share of common stock, as determined under the 2020 Plan, and, subject to continued service on our board of directors, vest in an initial installment of one-third of the shares on the first anniversary of the grant date, with the remaining shares to vest in 24 substantially equal installments thereafter.

Our board of directors and our compensation committee designed our non-employee director compensation program to reward directors for their contributions to our success, align the director compensation program with stockholder interests, and provide competitive compensation necessary to attract and retain high quality non-employee directors. We do not pay fees to any of our directors for meeting attendance.

2025 Director Compensation

The following table sets forth the compensation of each director, who is not a named executive officer, for service during 2025. This table excludes Mr. Luther, who is a named executive officer and does not receive any compensation from us for his service as a director. See the section above entitled "Executive Officer Compensation" for information about Mr. Luther's compensation.

2025 Director Compensation Table

Name	Fees earned or paid in cash ($)	Stock-Awards ($))	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)	Nonqualified deferred compensation earnings ($)	All Other Compensation ($)	Total Compensation ($)
Jame Bristol	$ —	$ —	$ 20,840	$ —	$ —	$ —	$ —
Peter Cicala	$ —	$ —	$ 14,887	$ —	$ —	$ —	$ —
Elena Ratner	$ —	$ —	$ 37,199	$ —	$ —	$ —	$ —
William Wexler	$ —	$ —	$ 36,008	$ —	$ —	$ —	$ —

(1) The amounts reported in this column represent the aggregate grant date fair value of stock options granted during 2025. These amounts were calculated in accordance with FASB ASC Topic 718, Compensation – Stock Compensation, except that any estimate of forfeitures was disregarded. For a description of the assumptions used in computing the dollar amount recognized for financial statement reporting purposes, see Note 14, Stockholders' Equity, in the Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K. The stock options granted during 2025 were as follows:

Name	Options Granted[2]
James Bristol	4,804
Peter Cicala	3,432
Elena Ratner	9,338
William Wexler	8,302

(2) The options granted vest over three years, with one-third vesting on the one-year anniversary of the grant date, and the remaining shares vesting in 24 substantially equal monthly installments thereafter.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information known to us regarding beneficial ownership of common stock as of March 12, 2026 (the "Measurement Date") by:

- each person known by us to be the beneficial owner of more than 5% of outstanding common stock;
- each of our named executive officers and directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including options and warrants that are currently exercisable or exercisable within 60 days after the Measurement Date. In computing the number of shares beneficially owned by a person or entity and the percentage ownership of that person or entity in the table below, all shares subject to options, warrants and restricted stock units held by such person or entity were deemed outstanding if such securities are currently exercisable, or exercisable or would vest based on service-based vesting conditions within 60 days of the Measurement Date, assuming that the liquidity event vesting conditions had been satisfied as of such date. These shares were not deemed outstanding, however, for the purpose of computing the percentage ownership of any other person or entity.

The beneficial ownership of our common stock is based on 29,154,431 shares of our common stock outstanding as of the Measurement Date.

Unless otherwise indicated, we believe that each person named in the table below has sole voting and investment power with respect to all shares of common stock beneficially owned by him.

Unless otherwise noted, the business address of each of these stockholders is c/o Ernexa Therapeutics Inc., 1035 Cambridge Street, Suite 18A, Cambridge, MA 02141.

Name and Address of Beneficial Owner	Common Shares Beneficially Owned	Percentage of Common Shares Beneficially Owned	
Greater than 5% Stockholders:			
Charles Cherington[(1)]	10,791,350	32.54	%
Regolith Capital Investments LP[(2)^]	2,958,531	9.75	%
Freebird Partners LP[(3)^]	3,009,873	9.99	%
John Halpern[(4)^]	1,668,780	5.63	%
Named Executive Officers and Directors:			
Sanjeev Luther[(5)]	115,465	*	%
Sandra Gurrola[(6)]	4,345	*	
James Bristol[(5)]	10,303	*	
Peter Cicala[(5)]	7,359	*	
Elena Ratner[(5)]	3,631	*	
William Wexler[(5)]	4,518	*	
All current directors and executive officers as a group (6 persons)[(7)]	145,622	*	%

Less than 1%

^ The securities beneficially owned by this stockholder include warrants, prefunded warrants or a combination of both securities that include a 9.99% blocker. The number of common shares beneficially owned, the percentage of common shares beneficially owned and the percentage of total voting power shown in the table gives effect to such blocker. Pursuant to the terms of the warrants and prefunded warrants, the number of shares of common stock that may be acquired by the holder thereof upon exercise of the warrants and prefunded warrants is limited, to the extent necessary, to ensure that following such exercise, the number of shares of common stock then beneficially owned by the holder and any other persons or entities whose beneficial ownership of common stock would be attributed to the holder for purposes of Section 13(d) of the Exchange Act does not exceed 9.99% of the total number of shares of our common stock then outstanding. Upon delivery of a written notice to us, the holder may from time-to-time increase (with such increase not effective until the 61st day after delivery of such notice) or decrease the blocker to any other percentage not in excess of 9.99%.

(1) The number of common shares beneficially owned consists of (i) 6,779,440 shares of common stock, (ii) 4,000,000 shares of common stock issuable upon the exercise of warrants and (iii) 11,910 shares of common stock issuable upon the conversion of shares of Series A convertible preferred stock (assuming a conversion rate of 5.987 per share). Mr. Cherington's address is c/o Ara Partners, LLC, 200 Berkeley Street, 26th Floor, Boston, MA, 02116.

(2) The number of common shares beneficially owned consists of (i) 1,747,668 shares of common stock held by Regolith Capital Investments LP ("Regolith") (ii) 10,863 shares of common stock held by Shameek Konar and (iii) 1,200,000 shares of common stock issuable upon the exercise of warrants. Mr. Konar and his spouse are the General Partner of Regolith. By virtue of these relationships, each of Mr. Konar and his spouse may be deemed to share beneficial ownership of the shares held by Regolith. Regolith's address is 10608 Stoppard View Way, Knoxville, TN, 37922.

(3) The number of common shares beneficially owned consists of (i) 2,035,414 shares of common stock, (ii) 599,075 shares of common stock issuable upon the exercise of warrants and (ii) 375,384 shares of common stock issuable upon exercise of prefunded warrants. Freebird Investments LLC serves as the general partner of Freebird Partners LP. Curtis Huff is the sole member and 100% owner of Freebird Investments LLC, the President of Freebird Partners LP and the Managing Member of Freebird Investments LLC. By virtue of these relationships, each of Freebird Investments LLC and Mr. Huff may be deemed to share beneficial ownership of the securities held of record by Freebird Partners LP. The principal business address of Freebird Partners LP is 2800 Post Oak Blvd, Suite 2000, Houston, Texas 77056.

(4) The number of common shares beneficially owned consists of (i) 1,161,113 shares of common stock held by the John D. Halpern Revocable Trust, of which, Mr. Halpern and Katherine H. Halpern are trustees, (ii) 500,000 shares of common stock issuable upon the exercise of warrants and (ii) 7,667 shares of common stock issuable upon exercise of prefunded warrants. Mr. Halpern and Ms. Halpern share voting and dispositive powers. Mr. Halpern's address is PO Box 540 Portsmouth, New Hampshire 03802.

(5) Consists of shares of common stock issuable upon exercise of options.

(6) Includes 4,234 shares of common stock issuable upon exercise of options.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

Except as described in Note 17 (Related Party Transactions) to the consolidated financial statements of this 2025 Annual Report, which is incorporated by reference into this Item 13, since January 1, 2024, there has not been nor are there currently proposed any transactions or series of similar transactions to which we were or are to be a party

in which the amount involved exceeds the lesser of $120,000 or one percent (1%) of the average of our total assets at year-end for the last two completed fiscal years and in which any director, executive officer, holder of more than 5% of the common stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest.

Related Party Transaction Policy

Our audit committee is responsible for the review, approval, or ratification of any potential conflict of interest transaction involving any of our directors or executive officers, director nominees, any person known by us to be the beneficial owner of more than 5% of our outstanding capital stock, or any family member of or related party to such persons, including any transaction required to be reported under Item 404(a) of Regulation S-K promulgated by the SEC.

In reviewing any such proposed transaction, our audit committee is tasked with considering all relevant facts and circumstances, including the commercial reasonableness of the terms, the benefit or perceived benefit, or lack thereof, to us, opportunity costs of alternate transactions, the materiality and character of the related person's direct or indirect interest and the actual or apparent conflict of interest of the related person.

Under our policy, employees are required to report any material transaction or relationship that could result in a conflict of interest to our compliance officer.

All transactions disclosed in Note 17 (Related Party Transactions) to the consolidated financial statements of this Annual Report on Form 10-K were approved by our audit committee in accordance with our related party transaction policy.

Director Independence

Our board of directors undertook a review of the independence of each director. Based on information provided by each director concerning his or her background, employment, and affiliations, our board of directors determined that our board of directors meets independence standards under the applicable rules and regulations of the SEC and the listing standards of Nasdaq. Our board of directors has affirmatively determined that all of our current directors are "independent" as defined in the listing standards of Nasdaq, other than Mr. Luther, who is also an employee. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our Company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

ITEM 14. Principal Accounting Fees and Services

Change in Certifying Accountant

On June 30, 2025, the Company dismissed Grant Thornton as the Company's independent registered public accounting firm effective immediately. The Audit Committee of the Company's board of directors approved Grant Thornton's dismissal on June 30, 2025.

Grant Thornton performed audits of the Company's consolidated financial statements for the years ended December 31, 2024 and 2023. Grant Thornton's reports for such years did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principles, except that, the reports included an explanatory paragraph describing that substantial doubt was raised as to the Company's ability to continue as a going concern.

During the two years ended December 31, 2024 and the subsequent interim period through June 30, 2025, there were no (i) disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K promulgated by the SEC pursuant to the Securities Exchange Act of 1934, as amended) between the Company and Grant Thornton on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to satisfaction of Grant Thornton, would have caused Grant Thornton to make reference to the subject matter of such disagreements in connection with its report, or (ii) "reportable events," as described in Item 304(a)(1)(v) of Regulation S-K, that would require disclosure

under Item 304(a)(1)(v) of Regulation S-K, except for the material weakness in the Company's internal control over financial reporting as of and for the year ended December 31, 2023, stemming from a lack of technical accounting proficiency in complex matters.

The Company previously furnished Grant Thornton with a copy of the disclosure contained in this "Changes In and Disagreements with Accountants on Accounting and Financial Disclosure" section of this annual report.

On July 1, 2025, the Company engaged Haskell & White LLP as the Company's independent registered public accounting firm. The decision to engage Haskell & White was approved by the Audit Committee of the Company's board of directors.

During the two years ended December 31, 2024 and the subsequent interim period through June 30, 2025, neither the Company nor anyone acting on its behalf has consulted Haskell & White regarding either: (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on the Company's financial statements, and no written report or oral advice was provided to the Company by Haskell & White that Haskell & White concluded was an important factor considered by the Company in reaching a decision as to an accounting, auditing or financial reporting issue; or (ii) any matter that was either subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K, or a "reportable event," as that term is described in Item 304(a)(1)(v) of Regulation S-K.

Fees and Services of Independent Registered Public Accounting Firm

The table below summarizes the fees billed to us by Haskell & White and Grant Thornton for the years ended December 31, 2025 and 2024.

Year	Audit Fees	Audit-Related Fees	Tax Fees	All Other Fees	Total
2025	$ 188,000	$ —	$ —	$ —	$ 188,000
2024	$ 399,130	$ —	$ —	$ —	$ 399,130

Audit Fees. Audit fees consist of fees for professional services rendered for the audit of our consolidated financial statements (including tax services performed to fulfill the auditor's responsibility under generally accepted auditing standards), reviews of the interim financial statements included in Forms 10-Q and for services that are normally provided by the auditor in connection with statutory and regulatory filings or engagements.

Audit-Related Fees. Audit-related fees consist of fees for assurance and related services (e.g., due diligence) that are reasonably related to the performance of the audit or review of our financial statements and are not reported under audit fees. The nature of those services is comprised of services for employee benefit plan audits, due diligence related to mergers and acquisitions, accounting consultations and audits in connection with proposed or consummated acquisitions, internal control reviews, attest services related to financial reporting that are not required by statute or regulation, and consultation concerning financial accounting and reporting standards.

Tax Fees. Tax fees consist of fees for professional services rendered for tax compliance, tax consulting and tax planning.

All Other Fees. All other fees are fees for products and services other than services in respect of which the fees are reported as audit, audit-related or tax fees.

Policy for Approval of Audit and Permitted Non-Audit Services

All audit and permissible non-audit services provided by the independent auditors are pre-approved by the Audit Committee (or the Chair of the Audit Committee, pursuant to a delegation of authority). These services may include audit services, audit-related services, tax services and other services. Pre-approval is generally provided for up to one year and any pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. The independent auditors and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent auditors in accordance with this pre-approval,

and the fees for the services performed to date. The Audit Committee may also pre-approve particular services on a case-by-case basis.

PART IV

ITEM 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as a part of this Annual Report on Form 10-K:

(1) Consolidated Financial Statements. The consolidated financial statements of the Company and its consolidated subsidiaries are set forth in the "Index to Consolidated Financial Statements" on page F-1.

(2) Financial Statement Schedules. None

(3) Exhibits. The following exhibits are submitted with this Annual Report on Form 10-K or, where indicated, incorporated by reference to other filings.

Exhibit	Description	Incorporated By Reference
Articles of Incorporation and Bylaws		
3.1	Composite Restated Certificate of Incorporation of the Company	Filed herewith
3.2	Third Amended and Restated Bylaws of the Company	Exhibit 3.2 to Form 8-K filed on March 26, 2025
3.3	Certificate of Validation of Eterna Therapeutics Inc., as filed with the Secretary of State of the State of Delaware on September 3, 2021	Exhibit 3.1 to Form 8-K filed on September 13, 2021
Instruments Defining Rights of Security Holders		
4.1	Form of Pre-Funded Warrant (Feb 2026)	Exhibit 4.1 to Form 8-K filed on February 11, 2026
4.2	Form of Common Warrant (Feb 2026)	Exhibit 4.2 to Form 8-K filed on February 11, 2026
4.3	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	Filed herewith
4.4	Form of Common Stock Warrant (March 2022)	Exhibit 10.3 to Form 8-K filed on March 9, 2022
4.5	Form of Warrant (December 2022)	Exhibit 10.1 to Form 8-K filed on December 5, 2022
4.6	Form of Warrant (December 2023 and January 2024)	Exhibit 4.2 to Form 8-K filed on December 20, 2023
Material Contracts		
10.1	Placement Agency Agreement by and between Ernexa Therapeutics Inc. and Brookline Capital Markets, a division of Arcadia Securities, LLC, dated as of February 6, 2026.	Exhibit 1.1 to Form 8-K filed on February 11, 2026

10.2	Form of Securities Purchase Agreement by and between Ernexa Therapeutics Inc. and certain investors, dated as of February 6, 2026.	Exhibit 10.1 to Form 8-K filed on February 11, 2026
10.3	Warrant Agent Agreement, by and among Ernexa Therapeutics Inc., Computershare Inc. and Computershare Trust Company, N.A., dated as of February 10, 2026.	Exhibit 10.2 to Form 8-K filed on February 11, 2026
10.5(a)	Securities purchase agreement, dated as of September 24, 2024, between Eterna Therapeutics Inc. and the purchaser parties thereto	Exhibit 10.1 to Form 8k filed on September 25, 2024
10.5(b)	Form of pre-funded warrant issuable under the securities purchase agreement, dated as of September 24, 2024, between Eterna Therapeutics Inc. and the purchaser parties thereto	Exhibit 10.2 to Form 8k filed on October 29, 2024
10.5(c)	Form of exchange agreement, dated as of September 24, 2024, between Eterna Therapeutics Inc. and the parties thereto	Exhibit 10.3 to Form 8k filed on September 25, 2024
10.5(d)	Note purchase agreement, dated as of September 24, 2024, between Eterna Therapeutics Inc. and the purchaser parties thereto	Exhibit 10.4 to Form 8k filed on September 25, 2024
10.5(e)	Form of 12.0% senior convertible note issued under the note purchase agreement, dated as of September 24, 2024, between Eterna Therapeutics Inc. and the purchaser parties thereto	Exhibit 10.5 to Form 8k filed on September 24, 2024
10.5(f)	Form of pre-funded warrant issuable upon conversion of 12.0% senior convertible notes issued under the note purchase agreement, dated as of September 24, 2024, between Eterna Therapeutics Inc. and the purchaser parties thereto	Exhibit 10.3 to Form 8k filed on October 29, 2024
10.5(g)	Form of support agreement, dated as of September 24, 2024, between Eterna Therapeutics Inc. and the stockholder parties thereto	Exhibit 10.7 to Form 8k filed on September 24, 2024
10.5(h)	Form of lock-up agreement, dated as of September 24, 2024, between Eterna Therapeutics Inc. and the stockholder parties thereto	Exhibit 10.8 to Form 8k filed on September 24, 2024
10.5(i)	Registration Rights Agreement, dated October 29, 2024, between Eterna Therapeutics Inc. and the purchaser parties thereto	Exhibit 10.1 to Form 8-K filed on November 25, 2022
10.6	Exclusive License and Collaboration Agreement, effective as of September 9, 2024, with Factor Bioscience Limited	Exhibit 10.10 to Form 10-Q filed on August 13, 2024
10.7	Sublease Agreement, dated October 18, 2022, by and between E.R. Squibb & Sons, LLC and Eterna Therapeutics Inc.	Exhibit 10.16 to Form 10-K filed on March 20, 2023
10.8	Sublease Termination Agreement, dated August 9, 2024, between Eterna Therapeutics Inc. and E.R. Squibb & Sons, L.L.C.	Exhibit 10.11 to Form 10-Q filed on August 13, 2024

10.9*	Employment Agreement, dated as of December 19, 2023, by and among Eterna Therapeutics Inc. and Sanjeev Luther.	Exhibit 10.3 to Form 8-K filed on December 20, 2023
10.10(a)*	Eterna Therapeutics Inc. 2021 Inducement Stock Incentive Plan (the "2021 Inducement Plan")	Exhibit 10.3 to Form 8-K filed on May 26, 2021
10.10(b)*	Form of Stock Option Inducement Award for issuances under the 2021 Inducement Plan	Exhibit 10.13(b) to Form 10-K filed on March 14, 2024
10.10(c)*	Form of Restricted Stock Unit Inducement Award for issuances under the 2021 Inducement Plan	Exhibit 10.13(c) to Form 10-K filed on March 14, 2024
10.11(a)*	Eterna Therapeutics Inc. Restated 2020 Stock Incentive Plan (the "Restated 2020 Plan")	Exhibit 99.1 to Form 8-K filed on September 13, 2021
10.11(b)*	Form of Stock Option Inducement Award for issuances under the Restated 2020 Plan	Exhibit 10.14(b) to Form 10-K filed on March 14, 2024
10.11(c)*	Form of Restricted Stock Unit Inducement Award for issuances under the Restated 2020 Plan	Exhibit 10.14(c) to Form 10-K filed on March 14, 2024
10.11(d)*	Form of Restricted Award Agreement for issuances under the Restated 2020 Plan	Exhibit 10.1 to Form 10-Q filed on August 13, 2024
10.12*	Inducement Stock Option Award Agreement entered into with Sanjeev Luther	Exhibit 99.1 to Form S-8 filed on January 16, 2024
10.13*	Employment Agreement, dated June 16, 2021, by and among Eterna Therapeutics Inc. and Sandra Gurrola.	Exhibit 10.1 to Form 8-K filed on June 21, 2021
10.14	Form of indemnification agreement for directors and officers	Exhibit 10.1 to Form 8-K filed on April 16, 2021
19	Insider Trading Policy	Filed herewith
23.1	Consent of the Independent Registered Accounting Firm, Haskell & White LLP	Filed herewith
23.2	Consent of the Independent Registered Accounting Firm, Grant Thornton LLP	Filed herewith
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith

97	Eterna Therapeutics Inc. Clawback Policy	Exhibit 97 to Form 10-K filed on March 14, 2024
101	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)	Filed herewith
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)	

* Indicates management contract or compensatory plan.

** Pursuant to Item 601(a)(5) of Regulation S-K, schedules and similar attachments to this exhibit have been omitted because they do not contain information material to an investment or voting decision and such information is not otherwise disclosed in such exhibit. The Company will supplementally provide a copy of any omitted schedule or similar attachment to the U.S. Securities and Exchange Commission or its staff upon request.

Pursuant to Regulation S-K Item 601(b)(2), certain exhibits and schedules to this exhibit have been omitted. The Company agrees to furnish supplementally a copy of any omitted exhibit or schedule to the SEC upon its request.

^ Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because such information is both not material and is the type that the Company treats as private or confidential.

ITEM 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ERNEXA THERAPEUTICS INC.

Date: March 13, 2026

By: */s/ Sanjeev Luther*
Sanjeev Luther
President, Chief Executive Officer, and Director
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Sanjeev Luther **Sanjeev Luther**	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 13, 2026
/s/ Sandra Gurrola **Sandra Gurrola**	Senior Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)	March 13, 2026
/s/ *James Bristol* **James Bristol**	Chairman of the Board	March 13, 2026
/s/ Peter Cicala **Peter Cicala**	Director	March 13, 2026
/s/ Elena Ratner **Elena Ratner**	Director	March 13, 2026
/s/ William Wexler **William Wexler**	Director	March 13, 2026

ERNEXA THERAPEUTICS INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Ernexa Therapeutics, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Ernexa Therapeutics, Inc. (the "Company") as of December 31, 2025, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2025, and the consolidated results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has recurring losses from operations, an accumulated deficit, and requires additional working capital to achieve its operating plans. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Haskell & White LLP

HASKELL & WHITE LLP

We have served as the Company's auditor since 2025.

Irvine, California
March 13, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Ernexa Therapeutics Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheet of Ernexa Therapeutics Inc. (formerly known as "Eterna Therapeutics Inc.") (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2024, the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Going concern

The accompanying 2024 consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the 2024 consolidated financial statements, the Company incurred a net loss of approximately $44.5 million during the year ended December 31, 2024, and had an accumulated deficit of approximately $231.5 million as of December 31, 2024. These conditions, along with other matters as set forth in Note 2 to the 2024 consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2 to the 2024 consolidated financial statements. The 2024 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We served as the Company's auditor from 2022 to 2025.

Iselin, New Jersey
March 12, 2025 (except for Note 3B, as to which the date is February 2, 2026)

ERNEXA THERAPEUTICS INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value amounts)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash	$ 1,884	$ 1,729
Other receivables	95	437
Due from related party	750	-
Prepaid expenses and other current assets	404	186
Total current assets	3,133	2,352
Property and equipment, net	94	85
Right-of-use assets - operating leases, net	453	670
Goodwill	2,044	2,044
Other assets	110	118
Total assets	$ 5,834	$ 5,269
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,125	$ 1,721
Accrued expenses	898	1,007
Income taxes payable	3	3
Due to related party	750	-
Operating lease liabilities, current	213	207
Contingent consideration liability, current	41	-
Other current liabilities	83	-
Total current liabilities	3,113	2,938
Warrant liabilities	-	1
Operating lease liabilities, non-current	277	477
Contingent consideration liability, non-current	-	41
Other liabilities	43	111
Total liabilities	3,433	3,568
Stockholders' equity:		
Preferred stock, $0.005 par value, 1,000 shares authorized, 156 designated and outstanding of Series A convertible preferred stock at December 31, 2025 and 2024, $156 liquidation preference	1	1
Common stock, $0.005 par value, 150,000 and 100,000 shares authorized at December 31, 2025 and 2024, respectively, 7,854 and 3,426 issued and outstanding at December 31, 2025 and 2024, respectively	39	17
Additional paid-in capital	247,997	233,219
Accumulated deficit	(245,636)	(231,536)
Total stockholders' equity	2,401	1,701
Total liabilities and stockholders' equity	$ 5,834	$ 5,269

The accompanying notes are an integral part of these consolidated financial statements.

ERNEXA THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Years ended December 31,	
	2025	**2024**
Revenue	$ -	$ 582
Cost of revenues	-	96
Gross profit	-	486
Operating expenses:		
Research and development	4,156	4,604
General and administrative	5,163	13,132
Gain on lease termination	-	(1,576)
Total operating expenses	9,319	16,160
Loss from operations	(9,319)	(15,674)
Other expense, net:		
Forward sales contract expense	(5,847)	-
Gain (loss) on extinguishment of debt	765	(22,440)
Change in fair value of convertible notes	-	1,017
Change in fair value to bridge notes derivative liability	-	(1,459)
Change in fair value of warrant liabilities	1	414
Change in fair value of contingent consideration	-	66
Interest income	83	249
Interest expense	(27)	(6,752)
Other income, net	215	70
Total other expense, net	(4,810)	(28,835)
Loss before income taxes	(14,129)	(44,509)
Benefit (provision) for income taxes	45	(30)
Net loss	(14,084)	(44,539)
Series A preferred stock dividend	(16)	(16)
Net loss attributable to common stockholders	$ (14,100)	$ (44,555)
Net loss per common share - basic and diluted	$ (2.24)	$ (48.96)
Weighted average shares outstanding - basic and diluted	6,307	910

The accompanying notes are an integral part of these consolidated financial statements.

ERNEXA THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

For the years December 31, 2025 and 2024

(In thousands)

	Series A Preferred Stock		Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balances at January 1, 2025	156	$ 1	3,426	$ 17	$ 233,219	$ (231,536)	$ 1,701
Issuance of common stock to Series A preferred stockholders in lieu of cash dividends	-	-	7	-	16	(16)	-
Issuance of common stock in connection with exercise of prefunded warrants	-	-	398	2	28	-	30
Issuance of common stock to consultant for services	-	-	38	-	141	-	141
Issuance of common stock in connection with settlement	-	-	20	-	69	-	69
Issuance of common stock and prefunded warrants in connection with private placement	-	-	3,965	20	13,028	-	13,048
Stock-based compensation	-	-	-	-	1,496	-	1,496
Net loss	-	-	-	-	-	(14,084)	(14,084)
Balances at December 31, 2025	156	$ 1	7,854	$ 39	$ 247,997	$ (245,636)	$ 2,401

	Series A Preferred Stock		Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balances at January 1, 2024	156	$ 1	361	$ 2	$ 189,211	$ (186,981)	$ 2,233
Issuance of note warrants	-	-	-	-	720	-	720
Fair value of forward sale contract pursuant to common stock offering	-	-	-	-	576	-	576
Reclassification of warrants to liability	-	-	-	-	(11,244)	-	(11,244)
Issuance of common stock in exchange of Convertible Notes	-	-	1,891	10	31,177	-	31,187
Issuance of common stock in exchange of warrants	-	-	663	3	10,942	-	10,945
Issuance of common stock and prefunded warrants upon the conversion of Bridge Notes	-	-	416	2	9,276	-	9,278
Issuance of common stock and prefunded warrants in connection with private placement, net	-	-	93	-	1,002	-	1,002
Issuance of common stock to consultant for services	-	-	1	-	23	-	23
Stock-based compensation	-	-	-	-	1,520	-	1,520
Issuance of common stock to Series A preferred stockholders in lieu of cash dividends	-	-	1	-	16	(16)	-
Net loss	-	-	-	-	-	(44,539)	(44,539)
Balances at December 31, 2024	156	$ 1	3,426	$ 17	$ 233,219	$ (231,536)	$ 1,701

The accompanying notes are an integral part of these consolidated financial statements.

ERNEXA THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the years ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (14,084)	$ (44,539)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	65	139
Stock-based compensation	1,496	1,520
Amortization of right-of-use asset	198	1,499
Impairment of right-of-use asset	33	-
Gain on lease termination	-	(1,576)
Loss on disposal of fixed assets	13	-
Accrued interest expense	22	174
Paid-in-kind interest expense	-	1,261
Amortization of debt discount and debt issuance costs	-	5,259
Forward sales contract expense	5,847	-
(Gain) loss on extinguishment of debt	(765)	22,440
Change in fair value of convertible notes	-	(1,017)
Fair value adjustments to bridge notes derivative liability	-	1,459
Issuance of common stock in connection with settlement	69	-
Issuance of common stock to consultant for services	141	-
Change in fair value of warrant liabilities	(1)	(414)
Change in fair value of contingent consideration liability	-	(66)
Changes in operating assets and liabilities:		
Other receivables	342	(12)
Prepaid expenses and other current assets	(268)	1,319
Other non-current assets	8	2
Accounts payable and accrued expenses	60	183
Operating lease liability	(208)	(1,707)
Due from related party	(750)	-
Due to related party	750	(1,205)
Deferred revenue	-	(582)
Other liabilities	15	27
Net cash used in operating activities	(7,017)	(15,836)
Cash flows from investing activities:		
Purchase of property and equipment	(37)	(369)
Proceeds received from the sale of fixed assets	-	4
Net cash used in investing activities	(37)	(365)

The accompanying notes are an integral part of these consolidated financial statements.

ERNEXA THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)
(In thousands)

	For the years ended December 31,	
	2025	**2024**
Cash flows from financing activities:		
Proceeds received from notes payable	2,250	-
Proceeds received from issuance of common stock and prefunded warrants	4,929	1,137
Fees paid related to the common stock and prefunded warrant offering	-	(135)
Proceeds received from exercise of prefunded warrants	30	-
Proceeds received from the convertible notes financing	-	1,405
Fees paid related to the convertible notes financing	-	(34)
Proceeds received from bridge notes financing	-	3,887
Net cash provided by financing activities	7,209	6,260
Net increase (decrease) in cash	155	(9,941)
Cash at beginning of period	1,729	11,670
Cash at end of period	$ 1,884	$ 1,729
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ 6	$ 48
Income taxes	$ 3	$ 3
Supplemental disclosure of non-cash investing and financing activities:		
Offset of related party notes payable principal with related party receivable related to issuance of common stock and prefunded warrants	$ 2,250	$ -
Reclassification of forward sales contract to equity upon issuance of common stock	$ 5,847	$ -
Issuance of common stock to Series A preferred stockholders in lieu of cash dividends	$ 16	$ 16
Adjustment to lease liability and ROU asset due to remeasurement	$ 14	$ 4,245
Leasehold improvements funded by tenant improvement allowance	$ 50	$ -
Note warrants issued	$ -	$ 755
Unpaid fees incurred in connection with the convertible note financing	$ -	$ 32
Paid in-kind interest added to convertible notes principal	$ -	$ 1,447
Reclassification of warrants to liability	$ -	$ 11,244
Exchange of warrants for common stock	$ -	$ 10,945
Exchange of convertible notes for common stock	$ -	$ 31,187
Conversion of bridge notes for common stock	$ -	$ 9,278

The accompanying notes are an integral part of these consolidated financial statements.

ERNEXA THERAPEUTICS INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
For the Years Ended December 31, 2025 and 2024

1. Organization and Description of Business Operations

Ernexa Therapeutics Inc. (the "Company") is a preclinical-stage synthetic allogeneic iMSC therapy company. iMSCs are induced pluripotent stem cell ("iPSC")-derived mesenchymal stem cells. The Company envisions a future where cell therapies powered by synthetic iMSCs can offer new options for patients with limited treatment paths and its mission is to transform the treatment of cancer and autoimmune disease by developing scalable, affordable, off-the-shelf cell therapies that restore hope.

As used herein, the "Company" or "Ernexa" refers collectively to Ernexa and its consolidated subsidiaries (Ernexa TX2, Inc., Novellus, Inc., Novellus Therapeutics Limited and Eterna Therapeutics LLC) unless otherwise stated or the context otherwise requires. In April 2025, the Company dissolved Eterna Therapeutics LLC, which was a single-member limited liability company and had no operations.

2. Liquidity and Capital Resources

The Company has incurred significant operating losses and has an accumulated deficit as a result of its efforts to develop product candidates and provide general and administrative support for operations. As of December 31, 2025, the Company had a cash balance of approximately $1.9 million and an accumulated deficit of approximately $245.6 million. For the year ended December 31, 2025, the Company incurred a net loss of $14.1 million, which includes a non-cash charge of $5.8 million related to a forward sales contract the Company entered into on March 31, 2025. During the year ended December 31, 2025, the Company used cash of $7.0 million in operating activities.

On September 24, 2024, the Company entered into certain financing agreements for the September 2024 Transactions (as discussed more fully in Note 15), which included (in) the private placement of $3.9 million of convertible Bridge Notes (as defined in Note 11), (ii) the Common Stock Private Placement of $1.1 million in shares of the Company's common stock or pre-funded warrants, as well as (iii) the Exchange Transaction, which provided for the exchange of convertible notes and warrants into shares of the Company's common stock. The September 2024 Transactions were subject to shareholder approval, and on October 29, 2024, the shareholders approved the issuance of common stock under the September 2024 Transactions. Following the conversions of the convertible notes, the Company had no convertible notes outstanding.

On March 11, 2025 and March 20, 2025, the Company received $1.5 million and $0.8 million, respectively, in exchange for the issuance of two promissory notes with aggregate principal amounts of $2.3 million to an investor. During the year ended December 31, 2025, the Company repaid the notes in full for $2.3 million, including accrued interest. See Note 11 for more information on the promissory notes.

On May 1, 2025, the $10.0 million Standby equity purchase agreement ("SEPA") the Company entered into with Lincoln Park Capital Fund, LLC ("Lincoln Park") expired. The Company did not sell any shares under the SEPA during the year ended December 31, 2025. The Company does not have a new SEPA in place at this time.

During the year ended December 31, 2025, the Company raised $7.2 million in gross proceeds from the sale of shares of the Company's common stock and prefunded warrants (the "2025 Private Placement"). See Note 15 for additional information regarding this financing.

On February 10, 2026, the Company received approximately $9.6 million in net proceeds from a public offering (the "2026 Offering") of (i) 21.0 million shares of the Company's common stock or pre-funded warrants and (ii) accompanying warrants to purchase 21.0 million shares of the Company's common stock (the "Milestone Warrants"). See Note 18 for more information regarding the 2026 Offering.

In connection with preparing the accompanying consolidated financial statements as of and for the year ended, the Company's management concluded that there is substantial doubt regarding the Company's ability to continue as a going concern because it does not expect to have sufficient cash or working capital resources to fund operations for the twelve-month period subsequent to the issuance date of these consolidated financial statements. The Company will need to raise additional capital, which could be through public or private equity offerings, grants, debt financings, out-licensing the Company's intellectual property, strategic partnerships or other means. The Company currently has no arrangements for capital, and no assurances can be given that it will be able to raise capital when

needed, on acceptable terms, or at all. The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

3. Basis of Accounting Presentation and Summary of Significant Accounting Policies

3A) Basis of Accounting Presentation

The consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). All significant intercompany balances and transactions have been eliminated in consolidation.

3B) Reverse Stock Split

As approved by the Company's stockholders at the Company's Annual Meeting of Stockholders held on June 2, 2025 (the "2025 Annual Meeting"), the Company effected a reverse stock split of its common stock at a ratio of 1-for-15, as determined by the Company's Board of Directors within the parameters approved by the Company's stockholders (the "Reverse Stock Split"). The Reverse Stock Split became effective under Delaware law at 12:01 a.m. Eastern time on June 12, 2025.

Upon the effectiveness of the Reverse Stock Split, every fifteen shares of the issued and outstanding common stock were automatically combined and reclassified into one issued and outstanding share of common stock. The Reverse Stock Split did not alter the par value of the common stock, and the number of authorized shares of common stock remains unchanged, after giving effect to the increase in the authorized shares of the Company's common stock from 100,000,000 to 150,000,000 shares, which occurred on June 2, 2025 following stockholder approval at the 2025 Annual Meeting. No fractional shares were issued in connection with the Reverse Stock Split, and no cash or other consideration was paid in connection with any fractional shares. Stockholders who otherwise would have held a fractional share after giving effect to the Reverse Stock Split instead owned one whole share of the post-reverse stock split common stock. The Company issued an aggregate of 153 shares for rounding up fractional shares to whole shares.

All share and per share data in this Annual Report on Form 10-K have been adjusted for all periods presented to reflect the Reverse Stock Split.

3C) Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect: (a) the reported amounts of assets and liabilities; (b) disclosure of contingent assets and liabilities at the date of the consolidated financial statements; (c) the reported amounts of expenses during the reporting period; and (d) the reported amount of the fair value of assets acquired in connection with business combinations. On an ongoing basis, the Company evaluates its estimates, including those related to the recoverability and useful lives of long-lived assets; stock-based compensation assumptions; valuation assumptions of warrants and liabilities associated with the 2025 Private Placement and the September 2024 Transactions; contingencies; contingent consideration and the provision for income taxes, including the valuation allowance. The Company bases its estimates on a combination of historical experience and various other assumptions that it believes are reasonable under the circumstances. Actual results may differ materially from these estimates.

Cash and Cash Equivalents

The Company classifies highly liquid investments with a remaining contractual maturity at the date of purchase of three months or less as cash equivalents. The Company had no cash equivalents as of December 31, 2025 or 2024.

Property and Equipment

Property and equipment are recorded at cost and are depreciated over their estimated useful lives using the straight-line method. Laboratory and manufacturing equipment are depreciated over an estimated useful life of seven

years. Leasehold improvements are depreciated over the shorter of their estimated useful life, or the lease term. Furniture and fixtures are depreciated over an estimated useful life of five years. Computer equipment are depreciated over an estimated useful life of three years. Upon retirement or other disposition of these assets, the cost and related accumulated depreciation of these assets are removed from the accounts and the resulting gain or losses are reflected in the results of operations. Expenditures for maintenance and repairs are charged to operations. Renewals and betterments are capitalized.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of identifiable assets acquired and liabilities assumed. Goodwill is not amortized but is tested for impairment annually or more frequently if events occur or circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that would indicate impairment and trigger an interim impairment assessment include, but are not limited to, macroeconomic conditions, industry and market considerations, cost factors, overall financial performance and other relevant events. Management evaluates the Company as a single reporting unit, therefore, goodwill is tested for impairment at the entity level. Goodwill is tested for impairment as of December 31st of each year, or more frequently as warranted by events or changes in circumstances mentioned above. Accounting guidance also permits an optional qualitative assessment for goodwill to determine whether it is more likely than not that the carrying value of a reporting unit exceeds its fair value. If, after this qualitative assessment, the Company determines that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then no further quantitative testing will be necessary. A quantitative assessment is performed if the qualitative assessment results in a more likely than not determination or if a qualitative assessment is not performed. The quantitative assessment considers whether the carrying amount of a reporting unit exceeds its fair value, in which case an impairment charge is in an amount equal to the excess fair value..

Revenue Recognition

The Company recognizes revenue under ASC 606, *Revenue from Contracts with Customers* ("ASC 606") when a customer obtains control of promised services or goods in an amount that reflects the consideration to which the Company expects to receive in exchange for those goods or services.

In general, the Company applies the following steps when recognizing revenue from contracts with customers: (i) identify the contract, (ii) identify the performance obligations, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations and (v) recognize revenue when a performance obligation is satisfied. Recognition of revenue is driven by satisfaction of the performance obligations using one of two methods: revenue is either recognized over time or at a point in time. Contracts containing multiple performance obligations classify those performance obligations into separate units of account either as standalone or combined units of account. Allocation of revenue to individual elements that qualify for separate accounting is based on the separate selling prices determined for each component, and total contract consideration is then allocated across the components of the arrangement. If separate selling prices are not available, the Company will use its best estimate of such selling prices, consistent with the overall pricing strategy and after consideration of relevant market factors.

The Company estimates the amount of consideration it expects to recognize as revenue that is not probable of having a significant reversal of such recognized revenue, and it places a constraint on the remaining contractual consideration. As it becomes evident that the constrained amounts are no longer at risk of a significant reversal of revenue, the Company will remove the constraint from the related revenue and recognize a cumulative catch-up adjustment to revenue in the period in which the constraint was removed.

The Company had one revenue-generating contract during the year ended December 31, 2024, relating to an option and license agreement as well as certain development activities. This contract was assigned to a third party in September 2024, and the Company had no further performance obligations under the contract. See Note 4 for more information. The Company did not have any revenue generating contracts during the year ended December 31, 2025.

Contract Assets:

A contract asset is an entity's right to payment for goods and services already transferred to a customer if that right to payment is conditional on something other than the passage of time. Generally, an entity will recognize a contract asset when it has fulfilled a contract obligation but must perform other obligations before being entitled to payment. Contract assets consist primarily of the cost of project contract work performed by third parties whereby the Company expects to recognize any related revenue at a later date, upon satisfaction of the contract obligations. The Company had no contract assets as of December 31, 2024. There were no revenue generating contracts during the

year ended December 31, 2025.

Contract Liabilities:

Contract liabilities consist primarily of consideration received, usually in the form of payment, on project work to be performed, whereby the Company expects to recognize the related revenue at a later date, upon satisfaction of the contract obligations. The Company recognized $0.6 million of revenue during the year ended December 31, 2024 from contract liabilities that arose in a prior year. There were no contract liabilities that arose during the year ended December 31, 2024, and there was no contract liabilities balance as of December 31, 2024. There were no revenue generating contracts during the year ended December 31, 2025.

Research and Development

The Company expenses its research and development costs as incurred. Research and development expenses consist of costs incurred for company-sponsored research and development activities. Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred if the technology is not expected to have any alternative future uses other than the specific research and development project for which it was intended.

The major components of research and development costs include salaries and employee benefits, stock-based compensation expense, supplies and materials, preclinical study costs, expensed licensed technology, consulting, scientific advisors and other third-party costs, as well as allocations of various overhead costs related to our product development efforts.

The Company has contracted with third parties to perform various studies. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. The Company accrues for third party expenses based on estimates of the services received and efforts expended during the reporting period. If the actual timing of the performance of the services or the level of effort varies from the estimate, the accrual is adjusted accordingly. The expenses for some third-party services may be recognized on a straight-line basis if the expected costs are expected to be incurred ratably during the period. Payments under the contracts depend on factors such as the achievement of certain events or milestones, the allocation of responsibilities among the parties to the agreement, and the completion of portions of the preclinical study or similar conditions.

Income Taxes

The Company records deferred tax liabilities and assets based on the differences between the consolidated financial statements carrying amounts and the tax basis of assets and liabilities, using enacted tax rates in effect in the years the differences are expected to reverse and establishing a valuation allowance when it was more likely than not that some portion or all of the deferred tax assets would not be realized. Income tax expense consists of the tax payable for the period and the change during the period in deferred tax assets and liabilities.

Tax benefits from uncertain tax positions are recognized only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution. The Company has no material uncertain tax positions for any of the reporting periods presented.

Loss Per Share

The Company calculates basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for participating securities. The Company's convertible notes contractually entitled the holders of such notes to participate in dividends but did not contractually require the holders to participate in the Company's losses. As such, the two-class method is not applicable during periods with a net loss.

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, including the weighted average effect of prefunded warrants the Company issued in connection with the 2025 Private Placement and September 2024 Transactions (see Note 15), and without consideration for potentially dilutive securities. The Company determined that the exercise of prefunded warrants requires nominal consideration for the delivery of shares of common stock, and as a result, has considered the shares underlying prefunded warrants to be outstanding effective on the issuance date of the prefunded warrants for purposes of calculated basic net loss per share.

Diluted net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding, including the weighted average effect of the prefunded warrants, plus dilutive securities. Shares of common stock issuable upon exercise, conversion or vesting of stock options, restricted stock units, warrants and the outstanding Series A convertible preferred stock are considered potential shares of common stock and are included in the calculation of diluted net loss per share using the treasury method when their effect is dilutive. The Company did not have any convertible notes outstanding as of December 31, 2025 or 2024, therefore, there were no potential shares of common stock related to convertible notes included in the calculation of diluted net loss per share. Diluted net loss per share is the same as basic net loss per share for periods in which the effect of potentially dilutive shares of common stock is antidilutive.

Segment Reporting

The Company operates within a single reportable operating segment being the research and development of cellular therapies. The Company has identified its president and chief executive officer as its chief operating decision maker ("CODM"), who regularly reviews the Company's performance and allocates resources based on information reported at the consolidated entity level.

Concentration of Credit Risk

The Company maintains its cash balances in financial institutions located in the United States (the "U.S."). Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. The Company's cash balances are uninsured for deposit accounts that exceed the FDIC insurance limit.

In the Company's business, vendor concentrations could be indicative of vulnerabilities in the Company's supply chain, which could ultimately impact the Company's ability to continue its research and development activities. For the years ended December 31, 2025 and 2024, there was no vendor concentration related to the Company's research and development activities.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset, or paid to transfer a liability, in an orderly transaction between willing market participants. A fair value hierarchy has been established for valuation inputs that gives the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. The fair value hierarchy is as follows:

- Level 1 Inputs – Valued based on quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- Level 2 Inputs – Valued based on inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (such as interest rates, volatilities, prepayment speeds, credit risks, etc.) or inputs that are derived principally from or corroborated by market data by correlation or other means.
- Level 3 Inputs – Valued based on inputs for which there is little or no market value, which require the reporting entity to develop its own assumptions.
- The carrying amounts reported on the consolidated balance sheet for cash, other receivables, prepaid assets and other current assets, accounts payable and accrued expenses, other current liabilities and other liabilities approximate fair value due to their short maturities.

Leases

The Company accounts for its leases under ASC Topic 842, *Leases.* Operating lease liabilities represent the present value of lease payments not yet paid. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset and are based upon the operating lease liabilities adjusted for prepaid or accrued lease payments, initial direct costs, lease incentives and impairment of operating lease assets. If the interest rate implicit in the lease is not readily determinable, the Company uses the incremental borrowing rates for collateralized borrowings in an amount equal to the lease payments under similar terms.

The Company has elected the practical expedient to not separate non-lease components from the lease components to which they relate and instead account for each as a single lease component for all underlying asset

classes. Some leasing arrangements require variable payments that are dependent on usage or may vary for other reasons, such as payments for insurance, tax payments and other miscellaneous costs. The variable portion of payments contemplated in the lease that do not depend on an index or rate are not included in the ROU assets or lease liabilities. Rather, variable payments that do not depend on an index or rate are expensed when the obligation for those payments is incurred and are included in lease expenses. Accordingly, all expenses associated with a lease contract are accounted for as lease expenses.

The Company has also elected not to recognize ROU and lease liabilities for short-term leases that have a term of 12 months or less.

The Company accounts for lease modifications as a separate contract when the modification (i) grants the lessee an additional right of use not included in the original lease contract, and (ii) increases the lease payments commensurate with the stand-alone price for the additional right of use. In this case, the lease modification would be treated as a new lease and measured in accordance with ASC 842 at the commencement date of the new lease without any impact on the existing lease. Otherwise, the Company accounts for lease modifications as a continuance of the existing lease, in which case, the Company reassesses the lease classification, remeasures the lease liability using an updated discount rate, and unless there is a full or partial termination of the lease, adjusts the ROU asset by the amount of change to the lease liability. For a full or partial lease termination, the lessee reduces the carrying amount of the ROU asset on a basis proportionate to the full or partial termination of the lease, and any difference between the adjustment to the ROU asset and the lease liability is recognized as a gain or loss in the current period.

Commitment and Contingencies

The Company follows ASC 450-20, *Loss Contingencies*, to report accounting for contingencies. Liabilities for loss contingencies arising from claims, assessments, litigation, fines and penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment can be reasonably estimated.

Stock-Based Compensation

The Company recognizes stock-based compensation expense for equity awards granted to employees, directors and certain consultants. The Company estimates the fair value of stock options using the Black-Scholes option pricing model. The fair value of stock options granted is recognized as expense over the requisite service period on a straight-line basis.

Warrants

The Company accounts for common stock warrants as either equity-classified or liability-classified instruments based on an assessment of the specific terms of the warrants and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815*, Derivatives and Hedging*. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, or meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own stock and whether the holders of the warrants could potentially require net cash settlement in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

Convertible Notes

The Company accounts for its convertible notes as a liability equal to the proceeds received from issuance, including the embedded conversion feature, plus any interest paid-in-kind, net of the unamortized debt issuance costs and debt discount on the consolidated balance sheets. The Company evaluates all embedded features contained in the convertible notes, such as the conversion feature, the paid-in-kind feature and the redemption feature in the event of a default, to determine if such features require bifurcation as a derivative. The conversion feature included in the convertible notes is not required to be accounted for separately as an embedded derivative because the conversion feature is considered both indexed to the Company's own stock and qualifies to be classified in stockholders' equity. The paid-in-kind feature is considered to be a commitment to originate a loan, and the terms of the additional loans have the same terms as the original debt instrument. Therefore, the paid-in-kind feature qualifies for the scope exception under the applicable accounting guidance and is not required to be bifurcated as a derivative. The redemption feature in the event of a default was determined to be clearly and closely related to the convertible notes and not required to be bifurcated as a derivative.

Proceeds from the sale of convertible notes with stock purchase warrants are allocated to the two elements based on their relative fair values. The portion of the proceeds allocated to warrants are recorded as a debt discount to the convertible note proceeds and presented on a net basis in the consolidated balance sheet. Debt issuance costs directly attributable to the transaction are capitalized and allocated to the convertible notes and warrants in the same manner as the proceeds. The amount of debt issuance costs allocated to the convertible notes represent a reduction of the face value of the convertible note proceeds. The Company amortizes debt issuance costs and debt discounts over the contractual term of the convertible notes, using the effective interest method, as interest expense on the consolidated statements of operations.

Recent Accounting Standards

Recently Adopted Accounting Standards

In December 2023, the Financial Accounting Standard Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2023-09, *Improvements to Income Tax Disclosures*, which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. ASU No. 2023-09 was effective for fiscal years beginning after December 15, 2024 and allowed for adoption on a prospective basis, with a retrospective option. The Company adopted this ASU on a prospective basis, and it did not have an impact to the Company's consolidated financial statements, but it did result in additional disclosures made in the notes to the consolidated financial statements.

Recently Issued Accounting Standards to be Adopted

In October 2023, the FASB issued ASU No. 2023-06, *Disclosure Improvements – Codification Amendment in Response to the SEC's Disclosure Update and Simplification Initiative.* This ASU modified the disclosure and presentation requirements of a variety of codification topics by aligning them with the SEC's regulations. The amendments to the various topics should be applied prospectively, and the effective date will be determined for each individual disclosure based on the effective date of the SEC's removal of the related disclosure. If the SEC has not removed the applicable requirements from Regulation S-X or Regulation S-K by June 30, 2027, then this ASU will not become effective. Early adoption is prohibited. The Company does not expect the amendments in this ASU to have a material impact on its consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40).* This ASU is intended to improve disclosures about a public business entity's expenses by requiring disaggregated disclosure, in the notes to the financial statements, of prescribed categories of expenses within relevant income statement captions. ASU No. 2024-03 is effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027 (as clarified in ASU No. 2025-01, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date)*. Early adoption is permitted. The new standard may be applied either on a prospective or retrospective basis. The Company does not expect the adoption of this ASU to have a material impact on its consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-04, *Debt – Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments.* This ASU clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. ASU No. 2024-04 is effective for annual reporting periods beginning after December 15, 2025 and interim reporting periods within those annual reporting periods. Early adoption is permitted, and the amendments may be applied on either a prospective or retrospective basis. The Company does not expect the amendments in this ASU to have a material impact on its consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software.* This ASU modernizes the accounting for internal-use software costs by removing all references to prescriptive and sequential software development stages and instead requires capitalization when (i) management has authorized and committed to funding the software project and (ii) it is probable that the project will be completed and the software will be used to perform the function intended have both occurred. ASU No. 2025-06 is effective for fiscal years beginning after December 15, 2027, and interim reporting periods, with early adoption permitted. The Company does not expect the amendments in this ASU to have a material impact on its consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements.* This ASU includes a disclosure principle that requires entities to disclose events since the end of the

last reporting period that have a material impact on the entity, which is modeled after the SEC disclosure requirement. This ASU also clarifies the applicability of Topic 270, the types of interim reporting, and the form and content of interim financial statements in accordance with GAAP. For public business entities, this ASU is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company does not expect the amendments in this ASU to have a material impact on its consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-12, *Codification Improvements.* The amendments in this update represent changes to the Codification that (1) clarify, (2) correct errors, or (3) make minor improvements. The amendments in this ASU are varied in nature and may affect the application of guidance in cases in which the original guidance may have been unclear. This ASU is effective for all entities for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods. The Company does not expect the amendments in this ASU to have a material impact on its consolidated financial statements.

4. Contract with Customer

During the year ended December 31, 2024, the Company had one contract with a customer that was accounted for under ASC 606 related to an exclusive option and license agreement it entered into in February 2023, and amended in August 2023, with a customer, which provided the customer with the option (the "Option Right") to obtain an exclusive sublicense of intellectual property from the Company and to request to have the Company develop a customized cell line. The customer paid the Company a $0.3 million non-refundable up-front payment (the "Option Fee") for the Option Right and paid an initial payment of $0.4 million to commence the cell line customization activities.

In September 2024, the Company assigned this customer contract to Factor Bioscience Limited ("Factor Limited") whereby all the Company's rights and obligations under the customer contract are now Factor Limited's. Factor Limited will pay the Company thirty percent (30%) of all amounts it receives from the customer under the contract in the event that the customer exercises its Option Right, and Factor Limited will pay the Company twenty percent (20%) of all amounts it receives from the customer for the customization activities set forth in the contract. During the year ended December 31, 2025, Factor Limited paid the Company approximately $0.5 million, which was 20% of what Factor Limited received from the customer customization activities. Factor Limited did not pay the Company anything during the year ended December 31, 2024.

Prior to assigning the contract to Factor Limited, the Company recognized the $0.4 million received from the customer equally over the development period. However, as a result of assigning the customer contract to Factor Limited, and there being no further obligations the Company needed to fulfill for the customization activities, the Company accelerated the recognition of the remaining $0.2 million in deferred revenue during the year ended December 31, 2024. Likewise, there being no further obligations regarding the non-refundable payment related to the Option Right, the Company also recognized the $0.3 million Option Right payment in full as revenue during the year ended December 31, 2024. During the year ended December 31, 2024, the Company recognized approximately $0.6 million in revenue related to this customer contract for the customization activities and Option Right, including the accelerations of revenue recognition discussed above. There was no such revenue recognized during the year ended December 31, 2025.

The Company recognized direct labor and supplies used in the customization activities as incurred, which were recorded as a cost of revenue. The Company was also obligated to pay Factor Limited 20% of any amounts the Company received from a customer that was related to the licensed technology under a previous license agreement the Company had with Factor Limited, which has since been terminated. During the year ended December 31, 2024, the Company recognized approximately $0.1 million in fees to Factor Limited, which was recorded as a cost of revenue. There were no direct labor, supplies or license fee recognized during the year ended December 31, 2025.

5. Segment Reporting

The CODM uses consolidated net loss as a measure of profit and loss and assesses Company performance through the achievement of its business strategy goals. The CODM is regularly provided with forecasted expense information that is used to determine the Company's liquidity needs and cash allocation to execute its business strategy, and he uses cash as a measure of segment assets in managing the Company. The Company operates in the U.S., and all of its assets are located in the U.S.

The table below provides a breakdown of the Company's significant operating expenses for the years ended December 31, 2025 and 2024 with a reconciliation to net loss for each of those years.

The Company's revenue, the total of which was generated in the U.S., and its cost of revenues for the year ended December 31, 2024 relate to a customer contract that was assigned to Factor Limited in September 2024. The Company did not have any revenue generating contracts during the year ended December 31, 2025. The Company's purchases of property and equipment were less than $0.1 million for the year ended December 31, 2025 and approximately $0.4 million for the year ended December 31, 2024. Depreciation and amortization expense was $0.1 million for each of the years ended December 31, 2025 and 2024. During the year ended December 31, 2025, the Company recognized $5.8 million in other expense for the 2025 Private Placement and $0.8 million in other income for time-barred liabilities. During the year ended December 31, 2024, the Company recognized $22.6 million in other expense, net, related to the September 2024 Transactions. The Company recognized $0.1 million and $0.2 million in interest income for the years ended December 31 2025 and 2024, respectively, and it recognized interest expense of less than $0.1 million and approximately $6.8 million during the years ended December 31, 2025 and 2024, respectively.

	Years ended December 31,	
	2025	2024
Revenue	$ -	$ 582
Cost of revenues	-	96
Gross profit	-	486
Operating expenses:		
Research and development by significant expense:		
MSA/license fees	1,847	3,017
Study fees	667	468
Professional fees	812	291
Payroll and related	502	591
Other[1]	328	237
Research and development	4,156	4,604
General and administrative by significant expense:		
Stock-based compensation	1,433	1,431
Payroll and related	1,431	1,607
Professional fees	1,668	4,168
Occupancy expense	29	5,074
Other[2]	602	852
General and administrative	5,163	13,132
Gain on lease termination	-	(1,576)
Total operating expenses	9,319	16,160
Loss from operations	(9,319)	(15,674)
Other expense, net:		
Forward sales contract expense	(5,847)	-
Gain (loss) on extinguishment of debt	765	(22,440)
Change in fair value of convertible notes	-	1,017
Change in fair value to bridge notes derivative liability	-	(1,459)
Change in fair value of warrant liabilities	1	414
Change in fair value of contingent consideration	-	66
Interest income	83	249
Interest expense	(27)	(6,752)
Other income, net	215	70
Total other expense, net	(4,810)	(28,835)
Loss before income taxes	(14,129)	(44,509)
Benefit (provision) for income taxes	45	(30)
Net loss	$ (14,084)	$ (44,539)

	At December 31,	
	2025	2024
Cash	$ 1,884	$ 1,729
Total assets	$ 5,834	$ 5,269

[1]Other includes certain lab supply expenses, amounts related to the close out of a former clinical trial, allocated occupancy costs, stock-based compensation, and depreciation.

[2]Other includes expenses related to insurance, information technology, travel, banking, depreciation and other miscellaneous expenses.

6. Basic and Diluted Net Loss per Common Share

The following table sets forth the computation of the net loss per share attributable to common stockholders, basic and diluted (in thousands, except per share data):

	Years ended December 31,	
	2025	2024
Numerator:		
Net loss attributable to common stockholders	$ (14,100)	$ (44,555)
Denominator:		
Weighted average shares outstanding - basic and diluted	6,307	910
Net loss per common share - basic and diluted	$ (2.24)	$ (48.96)

Since the Company was in a net loss position for all periods presented, the net loss per share attributable to common stockholders was the same on a basic and diluted basis, as the inclusion of all potential common equivalent shares outstanding would have been anti-dilutive.

The following table presents the amount of stock options, warrants, convertible preferred stock, convertible notes and restricted stock units ("RSUs") that were excluded from the computation of diluted net loss per share of common stock for the years ended December 31, 2025 and 2024, as their effect was anti-dilutive (in thousands):

	Years ended December 31,	
	2025	2024
Stock options	326	175
Warrants	32	32
Preferred stock converted into common stock	5	2
Total potential common shares excluded from computation	363	209

7. Property and Equipment

Property and equipment consist of the following (in thousands):

	As of December 31,	
	2025	2024
Laboratory and manufacturing equipment	$ 5	$ 28
Furniture and fixtures	34	19
Leasehold improvements	68	-
Computer equipment and programs	184	210
	291	257
Less accumulated depreciation and amortization	(197)	(172)
Property and equipment, net	$ 94	$ 85

During the year ended December 31, 2024, the Company recognized a loss on disposal of assets of approximately $0.5 million in connection with the sublease termination agreement related to the Somerville, Massachusetts lease, which is recorded as part of the gain on lease termination on the accompanying consolidated statement of operations for the year ended December 31, 2024 (See Note 12 for more details on the sublease termination agreement). During the year ended December 31, 2025, the Company recognized a de minimis loss on disposal of fixed assets.

Depreciation expense was approximately $0.1 million for each of the years ended December 31, 2025 and

2024. No depreciation expense is recorded on fixed assets in process until such time as the assets are completed and are placed into service.

8. Goodwill

The Company recorded goodwill in the amount of $2.0 million related to a 2018 acquisition that was accounted for as a business combination. The Company performed its annual qualitative assessments as of December 31, 2025 and 2024, and based on those assessments, the Company was unable to conclude that it was more likely than not that the fair value of the entity exceeded its carrying value as of such date. As a result, the Company performed a step-one quantitative assessment and concluded that the fair value of the reporting unit was greater than the carrying value as of December 31, 2025 and 2024, and the goodwill was considered not impaired. Therefore, the Company did not recognize an impairment charge during the years ended December 31, 2025 and 2024.

9. Fair Value of Financial Instruments

In connection with the Bridge Notes (as defined in Note 11) on September 24, 2024, the Company recorded a derivative liability of approximately $5.5 million, with a corresponding $3.9 million reduction in the carrying value of the Bridge Notes recorded as a debt discount and a $1.6 million charge to expense for the incremental fair value of the derivative liability. The Company determined the fair value of the derivative liability by taking the difference between the fair value of the Bridge Notes with the conversion feature and without the conversion feature. The Company remeasured the fair value of the Bridge Notes at each reporting period or immediately prior to converting the Bridge Notes to shares of common stock and recorded changes in fair value of approximately $0.2 million. Pursuant to the approval of the September 2024 Transactions by the Company's stockholders at the 2024 Annual Meeting, the Bridge Notes were converted to shares of the Company's common stock, and the outstanding principal and interest of the Bridge Notes, as well as the derivative liability of approximately $5.3 million, were reclassified to equity. As of December 31, 2024, there was no derivative liability balance.

In connection with the Exchanged Warrants (as defined in Note 15), the Company reclassified the fair value of the Exchanged Warrants of approximately $11.2 million from equity to a liability. The Company determined the fair value of the Exchanged Warrants as of September 24, 2024 by taking the number of shares of common stock issuable from the Exchanged Warrants multiplied by the closing stock price of $16.95 and reclassified approximately $11.2 million from equity to warrant liabilities. The Company remeasured the fair value of the Exchanged Warrants at each reporting period or immediately prior to exchanging the Exchanged Warrants to shares of common stock and recorded a change in fair value of approximately $0.3 million. Upon approval of the September 2024 Transactions at the 2024 Annual Meeting, the Company exchanged the Exchanged Warrants for shares of common stock and reclassified the $10.4 million fair value of the Exchanged Warrants from liabilities to equity. There was no remaining Exchanged Warrants liability as of December 31, 2024.

The Company issued approximately 23,000 warrants in connection with a private placement during the first quarter of 2022 (the "Q1-22 warrants"), which were determined to be classified as a liability. The Company has also recorded a three-year contingent consideration liability related to an asset acquisition in April 2023, which is recorded in current liabilities at December 31, 2025 due to the Company's obligation for this liability terminating in April 2026.

The Company uses a Black-Scholes option pricing model to estimate the fair value of the Q1-22 warrant liabilities and a Monte Carlo simulation model to estimate the fair value of the contingent consideration liability, both of which are considered a Level 3 fair value measurement. The Company remeasures these liabilities at each reporting period and recognizes changes in their respective fair value in the accompanying consolidated statements of operations.

In connection with the 2025 Private Placement, the Company recorded a forward sales contract liability at fair value and recognized $5.3 million of expense because the fair value of the expected shares to be purchased by the investors exceeded the proceeds under the 2025 Private Placement. The Company determined the expense related to the forward sales contract by taking the difference between (I) the fair value of the expected shares to be purchased by the investors as of the March 31, 2025 date the Company entered into the 2025 Private Placement and (ii) the discounted purchase price of the shares. The Company remeasured the fair value of the forward sales contract liability at each reporting period or immediately prior to the settlement of the shares purchased under the 2025 Private Placement and recognized approximately $0.2 million for the changes in the fair value in the accompanying consolidated statement of operations. During the year ended December 31, 2025, the Company completed the sale of the shares under the 2025 Private Placement, and as a result, the forward sales contract liability was reclassified to equity. There was no remaining forward sales contract liability balance as of December 31, 2025.

The following table summarizes the liabilities that are measured at fair value as of December 31, 2025 and 2024 (in thousands):

Description	Level	December 31, 2025	December 31, 2024
Liabilities:			
Warrant liabilities - Q1-22 warrants	3	$ -	$ 1
Contingent consideration	3	$ 41	$ 41

Certain inputs used in Black-Scholes and Monte Carlo models may fluctuate in future periods based upon factors that are outside of the Company's control. A significant change in one or more of these inputs used in the calculation of the fair value may cause a significant change to the fair value of the Company's warrant liabilities or contingent consideration liabilities, which could also result in material non-cash gains or losses being reported in the Company's consolidated statements of operations.

The following table presents the changes in the liabilities measured at fair value from January 1, 2025 through December 31, 2025 (in thousands):

	Warrant Liabilities	Contingent Consideration	Forward Sales Contract
Fair value at January 1, 2025	$ 1	$ 41	$ -
Initial measurement	-	-	5,335
Change in fair value	(1)	-	512
Reclassification of forward sales contract liability to equity	-	-	(5,847)
Fair value at December 31, 2025	$ -	$ 41	$ -

The Company remeasured the fair value of the Q1-22 warrants at December 31, 2025, and the result of the remeasurement was *de minimis.* The Company assessed the fair value of the contingent consideration liability at each reporting period through December 31, 2025 and determined that there were no material changes to the inputs used in the December 31, 2024 remeasurement that would have resulted in a material change to the liability at December 31, 2025. Therefore, the Company did not recognize a change in fair value of the contingent consideration liability for the year ended December 31, 2025.

10. Accounts Payable and Accrued Expenses

During the year ended December 31, 2025, the Company requested its legal counsel to provide guidance with respect to vendor collectability of various accounts payable and accrued expenses carried on its balance sheet from 2020 and prior. Based on the review of the statute of limitations for the various jurisdictions by which the liabilities were governed, legal counsel provided a conclusion as to whether such statute of limitation had expired in the respective jurisdiction. The statute of limitations is an affirmative defense in which the defendant introduces evidence, which, if found to be credible, will negate criminal or civil liability, even if it is proven the defendant committed the alleged acts. The party raising the affirmative defense has the burden of proof on establishing that it applies. In a civil action in which a creditor demands payment on a written instrument evidencing a debt, the successful assertion of the statute of limitations defense will bar collection of the debt. In order to assert the statute of limitations as a defense, a defendant must specifically assert the defense is the answer. If a defendant fails to specifically plead the defense, it will be deemed to be waived. Since no action to enforce such liabilities was brought before December 31, 2025, it is our legal counsel's opinion that the liabilities are time-barred from collection under the respective state laws and should be removed from the Company's balance sheet. Therefore, the Company wrote off approximately $0.6 million of accounts payable and approximately $0.2 million of accrued expenses, which resulted in a gain on extinguishment of debt of $0.8 million report in the accompanying consolidated statement of operations for the year ended December 31, 2025. The Company did not write off any time-barred liabilities for the year ended December 31, 2024.

Accrued expenses at December 31, 2025 and 2024 consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Professional fees	$ 535	$ 446
Legal matters	336	323
Accrued compensation	12	12
Other	15	226
Total accrued expenses	$ 898	$ 1,007

11. Promissory Notes and Bridge Notes

Promissory Notes

On March 11, 2025, the Company received $1.5 million for the issuance of a promissory note in the principal amount of $1.5 million to Charles Cherington, and on March 21, 2025 the Company received $0.8 million for the issuance of a second promissory note in the principal amount of $0.8 million to Mr. Cherington. The promissory notes had a maturity date of the earlier of (i) June 15, 2025 or (ii) upon the Company receiving $5.0 million in gross proceeds from a subsequent capital raise. Each of the promissory notes accrued interest at a rate of 5.0% per annum, payable at maturity.

As a result of completing the 2025 Private Placement discussed in Note 15, the Company offset the outstanding principal plus accrued interest on the notes in full in the aggregate amount of $2.3 million with the receivable due to the Company from Mr. Cherington for his purchase of shares in the 2025 Private Placement, and as of December 31, 2025, there were no outstanding balances on the notes.

Bridge Notes Financing

On September 24, 2024, the Company entered into a purchase agreement with certain purchasers for the private placement of $3.9 million of convertible notes (the "Bridge Notes"). The interest rate on the Bridge Notes was 12% per year, payable quarterly in arrears. At the Company's election, it may pay interest either in cash or in-kind by increasing the outstanding principal amount of the Bridge Notes. The Bridge Notes were to mature on the one-year anniversary of the date of their issuance, unless earlier converted or repurchased. The Company did not have the option to redeem any of the Bridge Notes prior to maturity. The Bridge Notes financing closed on September 24, 2024.

The only conversion event for the Bridge Notes was upon stockholder approval at the Company's annual meeting of stockholders on October 29, 2024 (the "2024 Annual Meeting"), in which case, 100% of the principal amount of the Bridge Notes plus all accrued and unpaid interest thereon, and interest that would have accrued on the principal amount through December 24, 2024, would automatically convert into shares of the Company's common stock at a conversion price of $7.50. Otherwise, the Bridge Notes could only be paid in cash upon maturity.

The Company was required to bifurcate the conversion feature from the Bridge Notes and record it as a derivative liability at its fair value. The Company determined the fair value of the derivative liability by taking the difference between the fair value of the Bridge Notes with the conversion feature and without the conversion feature, which resulted in the Company recording a $5.5 million derivative liability, with a corresponding $3.9 million reduction in the carrying value of the Bridge Notes recorded as a debt discount and a $1.6 million charge to expense for the incremental fair value of the derivative liability as of September 24, 2024. The debt discount was amortized as a component of interest expense.

During the year ended December 31, 2024, the Company remeasured the fair value of the Bridge Notes derivative liability and recorded a reduction in the liability of $0.2 million. The corresponding credit of $0.2 million was recorded as a component of the fair value adjustments to Bridge Notes derivative liability on the accompanying consolidated statement of operations for the year ended December 31, 2024, which also includes the $1.6 million incremental expense noted above. See Note 9 for more information on the fair value of the Bridge Notes.

On October 29, 2024, all of the Bridge Notes were converted to common stock as part of the September 2024 Transactions (as defined in Note 15) that the Company's stockholders approved at the 2024 Annual Meeting. As of December 31, 2025 and 2024, there were no liabilities remaining on the Bridge Notes.

12. Leases

Operating Leases

As of December 31, 2025, the Company had operating leases for offices in the Borough of Manhattan in New York, New York (the "Manhattan Lease"), and Cambridge, Massachusetts (the "Cambridge Lease"), which expire in 2027 and 2028, respectively.

During the year ended December 31, 2024, the Company entered into a sublease termination agreement with a sublessor related to a sublease of office, laboratory, and research and development space in Somerville, Massachusetts (the "Somerville Sublease Termination Agreement"), which was effective on August 31, 2024. Prior to the Somerville Sublease Termination Agreement, the Company was paying approximately $0.6 million per month in base rent, parking, common area maintenance costs and taxes under the Somerville Sublease, which was originally scheduled to expire in 2033.

Pursuant to the Somerville Sublease Termination Agreement, the Company agreed to the following: to surrender and vacate the premises; that the Company's right, title and interest in all furniture, fixtures and laboratory equipment at the premises will become the property of the sublessor; and that both parties will be released of their obligations under the sublease. As a result of the sublease termination, the Company recognized a gain on lease termination of approximately $1.6 million for the year ended December 31, 2024, which includes a loss on disposal of fixed assets of approximately $0.5 million.

For the years ended December 31, 2025 and 2024, the net operating lease expenses were as follows (in thousands):

	Years ended December 31,	
	2025	2024
Operating lease expense	$ 271	$ 4,447
Sublease income	(84)	(84)
Variable lease expense	21	893
Total lease expense	$ 208	$ 5,256

The tables below show the beginning balances of the operating ROU assets and lease liabilities as of January 1, 2025 and the ending balances as of December 31, 2025, including the changes during the period (in thousands).

	Operating Lease ROU Assets
Operating lease ROU assets at January 1, 2025	$ 670
Amortization of operating lease ROU assets	(198)
Remeasurment of ROU asset	14
Impairment of ROU asset	(33)
Operating lease ROU assets at December 31, 2025	$ 453

	Operating Lease Liabilities
Operating lease liabilities at January 1, 2025	$ 684
Principal payments on operating lease liabilities	(208)
Remeasurment of lease liability	14
Operating lease liabilities at December 31, 2025	490
Less non-current portion	(277)
Current portion at December 31, 2025	$ 213

The Cambridge Lease, which commenced in June 2021, included a tenant improvement allowance of up to $50,000 (the "TI Allowance"), which was not paid or payable at lease commencement, and the amount of payment from the lessor was contingent on future events (e.g., the timing and the amount of qualified costs the Company incurs

to construct leasehold improvements). Therefore, the TI Allowance was not previously included in the consideration of the contract when the Company measured the lease liability and ROU asset.

During the year ended December 31 2025, the Company made some leasehold improvements to the Cambridge office space of approximately $0.1 million, of which $50,000 qualified to be reimbursed under the TI Allowance. As a result, the contingent aspects of the TI Allowance were resolved and became fixed, which resulted in the Company remeasuring the lease liability. The TI Allowance of $50,000 was deducted from the ROU asset balance immediately prior to the re-measurement. The remaining unpaid lease payments, including the reimbursement of the TI Allowance, which is considered a reduction in the consideration of the contract, were then remeasured using the current index and interest rate and resulted in an approximately $14,000 increase to the lease liability, with a corresponding adjustment to the ROU asset. The $0.1 million of leasehold improvements was recorded as a fixed asset and is being depreciated over the remaining lease term.

During the year ended December 31, 2025, the Company tested the Manhattan Lease ROU asset for recoverability and determined that the carrying value of the ROU asset was more than its fair value. As a result, the Company recognized an impairment loss of approximately $33,000 during the year ended December 31, 2025, which was recorded in general and administrative expense in the accompanying consolidated statement of operations. There were no impairment losses recognized for the year ended December 31, 2024.

As of December 31, 2025, the Company's operating leases had a weighted-average remaining life of 2.2 years with a weighted-average discount rate of 11.93%. The maturities of the operating lease liabilities are as follows (in thousands):

	As of December 31, 2025
2026	$ 254
2027	200
2028	95
Total payments	549
Less imputed interest	(59)
Total operating lease liabilities	$ 490

In February 2026, the Company entered into a lease termination agreement related to the Manhattan Lease. See Note 18 for more information on this agreement.

Manhattan Sublease

In April 2019, the Company entered into a sublease with an unaffiliated third party (the "Subtenant"), whereby the Subtenant agreed to sublease the space rented by the Company under the Manhattan Lease. The term of this sublease expires on October 31, 2026 with no option to extend. Rent payments by the Subtenant under the sublease began on September 1, 2019. The sublease stipulates an annual rent increase of 2.25%. The Subtenant is also responsible for paying to the Company all tenant energy costs, annual operating costs, and annual tax costs attributable to the subleased space during the term of the sublease.

The Company received sublease payments of approximately $0.1 million for each of the years ended December 31, 2025 and 2024, respectively. The Company treats the sublease as a separate lease, as the Company was not relieved of the primary obligation under the related lease. The Company continues to account for the related lease as a lessee and in the same manner as prior to the commencement date of the sublease. The Company accounts for the sublease as a lessor of the lease. The sublease is classified as an operating lease, as it does not meet the criteria of a sale-type or direct financing lease.

In February 2026, the Company entered into a sublease termination agreement with the Subtenant. See Note 18 for more information on this agreement.

13. Commitments and Contingencies

Litigation Matters

The Company is involved in litigation and arbitrations from time to time in the ordinary course of business.

Legal fees and other costs associated with such actions are expensed as incurred. In addition, the Company assesses the need to record a liability for litigation and contingencies. The Company reserves for costs relating to these matters when a loss is probable, and the amount can be reasonably estimated.

Donoghue v. Cherington and Ernexa

Dennis J. Donoghue, a security owner of the Company, initiated a lawsuit against the Company as a nominal defendant, and Charles Cherington as defendant, on October 20, 2025 in the Southern District of New York (Case No. 25-cv-8653) alleging a violation of Section 16(b) of the Securities Exchange Act of 1934, 15 U.S.C. Section 78p(b) and seeking recovery of alleged short swing profits by Mr. Cherington (the "Donoghue Matter").

On December 19, 2025, Mr. Donoghue, the Company and Mr. Cherington entered into a settlement agreement.

Novellus, Inc. v. Sowyrda et al., C.A. No. 2184CV02436-BLS2

On October 25, 2021 Novellus, Inc. filed a complaint in the Superior Court of Massachusetts, Suffolk County, against former Novellus, Inc. employees Paul Sowyrda and John Westman and certain other former investors in Novellus LLC (Novellus, Inc.'s former parent company prior to our acquisition of Novellus, Inc.), alleging breach of fiduciary duty, breach of contract and civil conspiracy. The Company acquired Novellus, Inc. on July 16, 2021. On May 27, 2022 Novellus, Inc. amended the complaint to withdraw all claims against all defendants except Paul Sowyrda and John Westman. Since 2022, the parties have engaged in legal proceedings relating to alleged conduct that took place before the Company acquired Novellus, Inc., including certain counterclaims against Novellus LLC, Novellus Inc., Factor Bioscience Inc., Christopher Rohde, Matthew Angel and the Company (the "Counterclaim Defendants").

On July 31, 2024, Counterclaim Defendants and Sowyrda informed the Court that they had reached a settlement and requested that all claims pending between them be dismissed with prejudice, and on August 9, 2024, the Court approved the motion for approval of dismissal of all such claims with prejudice. On April 22, 2025, Counterclaim Defendants and Westman reached a confidential settlement with an effective date of April 30, 2025. Such settlement included the issuance of 20,000 shares of the Company's common stock and a cash payment of less than $0.1 million. On May 27, 2025, Counterclaim Defendants and Westman filed stipulation of dismissal with prejudice with the Court.

Licensing Agreements

On September 24, 2024, the Company entered into the Exclusive License and Collaboration Agreement ("the Factor L&C Agreement") with Factor Limited. The Factor L&C Agreement terminated a previous license agreement, as well as a license that the Company acquired from a third party pursuant to an asset purchase agreement in April 2023.

Under the Factor L&C Agreement, the Company has obtained exclusive licenses in the fields of cancer, autoimmune disorders, and rare diseases with respect to certain licensed technology and has the right to develop the licensed technology directly or enter into co-development agreements with partners who can help bring such technology to market. The Factor L&C Agreement also provides for certain services and materials to be provided by Factor Limited to facilitate the development of the licensed technology and to enable the Company to scale up production at third party facilities.

The initial term of the Factor L&C Agreement is one year after the effective date, and it automatically renews yearly thereafter. The Company may terminate the Factor L&C Agreement for any reason upon 90 days' written notice to Factor Limited, and the parties otherwise have customary termination rights, including in connection with certain uncured material breaches and specified bankruptcy events.

Pursuant to the Factor L&C Agreement, the Company will pay Factor Limited approximately $0.2 million per month for the first twelve months, approximately $0.1 million per month for the first nine months toward patent costs, certain milestone payments, royalty payments on net sales of commercialized products and sublicensing fee payments.

Contingent Consideration

The Company has recorded a three-year contingent consideration liability related to an asset acquisition in April 2023. If during the three-year period since April 26, 2023, the Company's market cap equals or exceeds $100 million for at least ten consecutive trading days, then the Company will issue to the seller shares of the Company's

common stock equal to (a) $2.0 million divided by (b) the quotient of $100 million divided by the number of the Company's then issued and outstanding shares of common stock. If during that three-year period, the Company's market cap equals or exceeds $200 million for at least ten consecutive trading days, then the Company will issue to the seller additional shares of the Company's common stock equal to (a) $2.0 million divided by (b) the quotient of $200 million dividend by the number of the Company's then issued and outstanding shares of common stock. As discussed in Note 9, the Company records the contingent consideration liability at its fair value, and as of December 31, 2025 the fair value of the liability was approximately $41,000. The contingent consideration obligation will expire on April 26,2026.

Retirement Savings Plan

The Company offers to its eligible employees a defined contribution plan, organized under Section 401(k) of the Internal Revenue Code, through its co-employment arrangement with its professional employer organization ("PEO"). Under this arrangement, the PEO serves as the plan sponsor and administrator. Eligible employees may defer up to 100% of their annual compensation or a specific amount imposed by the Internal Revenue Service, whichever is less. The Company matches employees' contributions at a rate of 100% of the first 3% of the employee's contribution and 50% of the next 2% of the employee's contribution, for a maximum Company match of 4%. The Company matched less than $0.1 million towards employees' 401k contributions for each of the years ended December 31, 2025 and 2024.

14. Stock-Based Compensation

Equity Incentive Plans

The Company's stock-based compensation plans consist of the Restated 2020 Equity Incentive Plan (the "Restated 2020 Plan") and the 2021 Inducement Equity Incentive Plan (the "2021 Inducement Plan"). The Company's board of directors has designated its compensation committee as the administrator of the foregoing plans (the "Plan Administrator"). Among other things, the Plan Administrator selects persons to receive awards under the foregoing plans and determines the number of shares subject to each award and the terms, conditions, performance measures, if any, and other provisions of the award.

The Restated 2020 Plan provides for (a) approximately 48,000 shares of common stock that can be issued under the Restated 2020 Plan, which includes an increase to the Restated 2020 Plan of 20,000 that was approved by the Company's stockholders at the 2023 annual meeting of stockholders in June 2023, and (b) an annual increase in the number of shares reserved for issuance on January 1 of each year from 2022 through 2031 equal to the lesser of (i) 5% of the number of shares of common stock outstanding on the immediately preceding December 31 and (ii) such smaller number of shares of common stock as may be determine by the board of directors (the provision providing for the increase described in clause (b) is referred to as the "evergreen provision"). Pursuant to the evergreen provision, shares issuable under the Restated 2020 Plan was increased by approximately 206,000 in the aggregate.

Awards under the Restated 2020 Plan may be granted to officers, directors, employees and consultants of the Company. Stock options granted under the Restated 2020 Plan may either be incentive stock options or nonqualified stock options, may have a term of up to ten years, and are exercisable at a price per share not less than the fair market value, as defined in the Restated 2020 Plan, on the date of grant.

As of December 31, 2025, there were approximately 326,000 stock options outstanding and no RSUs outstanding under the Restated 2020 Plan. As of December 31, 2025, there were approximately 2,000 shares of common stock remaining to be issued under the Restated 2020 Plan.

The 2021 Inducement Plan provides for the grant of up to 5,000 share-based awards as material inducement awards to new employees in accordance with the employment inducement grant rules set forth in Section 711(a) of the NYSE American LLC Company Guide (the Company's common stock was listed on the NYSE American at the time the 2021 Inducement Plan was adopted). The 2021 Inducement Plan expires in May 2031. As of December 31, 2025, there were approximately 5,000 shares of common stock remaining to be issued under the 2021 Inducement Plan. As of December 31, 2025, there were no stock options outstanding and or RSUs outstanding under the 2021 Inducement Plan.

Equity Awards

Stock Options

The following weighted-average assumptions were used for stock options granted during the years ended December 31, 2025 and 2024:

	Year ended December 31,	
	2025	2024
Weighted average risk-free rate	4.34%	4.44%
Weighted average volatility	118.75%	98.09%
Dividend yield	0%	0.00%
Expected term	7.11 years	6.04 years

The risk-free rate is based on the observed interest rates appropriate for the expected term. The expected term (estimated period of time outstanding) of the stock options granted is estimated using the "simplified" method as permitted by the SEC's Staff Accounting Bulletin No. 110, *Share-Based Payment*. Expected volatility is based on the volatility of the Company's peer group over the expected term of the stock option granted, and the Company assumes no dividends. Forfeitures are recognized as incurred.

The following table summarizes stock option activity for the years ended December 31, 2025 and 2024 (in thousands except for per-share and remaining contractual life data):

	Outstanding Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding January 1, 2024	26	$ 675	7.04	$ -
Granted	166	26		
Cancelled	(17)	120		
Outstanding December 31, 2024	175	113	8.77	-
Granted	160	4		
Cancelled	(9)	1,636		
Outstanding December 31, 2025	326	$ 18	8.67	$ -
Options vested and exercisable at December 31, 2025	137	$ 27	8.45	$ -

The per-share weighted average grant-date fair value of stock options granted during the year ended December 31, 2025 and 2024 was $3.68 and $20.77, respectively.

As of December 31, 2025, the unamortized stock-based compensation expense related to outstanding unvested options was approximately $1.4 million with a weighted average remaining requisite service period of 1.37 years. The Company expects to amortize this expense over the remaining requisite service period of these stock options.

Vesting of all stock options is subject to continuous service with the Company through their applicable vesting dates.

On January 1, 2024, Sanjeev Luther was appointed as President, Chief Executive Officer and a director of the Company. Upon his appointment, he was granted a non-qualified stock option to purchase approximately 112,000 shares of the Company's common stock. The stock option has an exercise price of $27 per share, which was equal to the fair market value (as defined in the 2020 Restated Equity Incentive Plan) of the Company's common stock on the date of grant, will vest over four years, with 25% of the shares vesting on the first anniversary of the grant date and the remaining 75% of the shares vesting in equal monthly installments over the three years thereafter, in each case, subject to continued service. The stock option was granted pursuant to the terms of Mr. Luther's employment agreement and as a material inducement to his joining the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

On April 26, 2024, the vesting terms of Mr. Luther's stock option award were amended so that the option vests over three years, with 25% of the shares vesting on the first anniversary of the grant date and the remaining 75% of the shares will vest in equal monthly installments over the remaining two years, in each case, subject to continued service.

Since the only modification to Mr. Luther's stock option award was to the vesting terms, there was no change

to the fair value of the stock option and the total compensation cost was unchanged. However, the total compensation cost will be recognized over three years rather than four years, and as a result, the Company recognized approximately $0.1 million in additional stock-based compensation expense during the year ended December 31, 2024 as a result of the modification. There was no modification expense recorded during the year ended December 31, 2025.

Restricted Stock Units

The following table summarizes RSU activity for the years ended December 31, 2025 and 2024 :

	Outstanding Restricted Stock Units	Weighted Average Fair Value per Share
January 1, 2024	59	$ 4,830
Released	(29)	$ 4,830
December 31, 2024	30	$ 4,830
Released	(30)	4,816
December 31, 2025	-	$ -

The Company recognizes the fair value of RSUs granted as expense on a straight-line basis over the requisite service period. For performance based RSUs, the Company begins recognizing the expense once the achievement of the related performance goal is determined to be probable.

Outstanding RSUs are settled in an equal number of shares of common stock on the vesting date of the award. An RSU award is settled only to the extent vested. Vesting generally requires the continued employment or service by the award recipient through the respective vesting date. Because RSUs are settled in an equal number of shares of common stock without any offsetting payment by the recipient, the measurement of cost is based on the quoted market price of the stock at the measurement date, which is the grant date.

In lieu of paying cash to satisfy withholding taxes due upon the settlement of vested RSUs, at the Company's discretion, an employee may elect to have shares of common stock withheld that would otherwise be issued at settlement, the value of which is equal to the amount of withholding taxes payable. During the years ended December 31, 2025 and 2024, less than 1,000 RSUs vested in each year, and as of December 31, 2025, there are no RSUs outstanding.

Stock-Based Compensation Expense

For the years ended December 31, 2025 and 2024, the Company recognized stock-based compensation expense as follows (in thousands):

	Years ended December 31, 2025	2024
Research and development	$ 63	$ 89
General and administrative	1,433	1,431
Total	$ 1,496	$ 1,520

15. Stockholders' Equity and Warrants

2025 Private Placement

On March 31, 2025, the Company entered into a securities purchase agreement (the "2025 SPA") with certain accredited investors to sell in a private placement an aggregate of approximately 4,621,000 shares of common stock at a purchase price of $1.569 per share (or pre-funded warrants in lieu of common stock at a purchase price of $1.494 per pre-funded warrant). The pre-funded warrants will be exercisable until exercised in full at a nominal exercise of $0.075 per share and may not be exercised to the extent such exercise would cause the holder to beneficially own more than 4.99% or 9.99%, as applicable, of the Company's outstanding common stock.

The 2025 SPA represented a forward sale contract obligating the Company to sell a fixed number of shares of its common stock at a fixed price per share and contained an adjustment to the settlement amount based on shareholder approval, which is not an input into the pricing of a fixed-for-fixed forward on equity shares. The

Company measured the fair value of the forward sale contract as the difference between (i) the fair value of the expected shares to be purchased by the investors as of the date the Company entered into the 2025 SPA and (ii) the discounted purchase price of the shares and recorded a liability of approximately $5.3 million at the contract inception date. The Company also recognized a corresponding $5.3 million charge to expense on the contract inception date because the fair value of the expected shares to be purchased by the investors exceeded the expected proceeds under the 2025 SPA.

During the year ended December 31, 2025, the Company sold the following shares of common stock and pre-funded warrants under the 2025 SPA (in thousands):

Date	Common Stock	Pre-funded Warrants	Gross Proceeds
April 2, 2025	662	34	$ 1,090
June 9, 2025	3,182	622	5,921
June 27, 2025	121	-	190
	3,965	656	$ 7,201

The shares sold on April 2, 2025 (the "First Closing") represented 19.99% of the Company's outstanding shares of common stock as of March 31, 2025. The shares sold in June 2025 (the "Second Closing") were subject to satisfaction or waiver of certain conditions, including without limitation, receipt of stockholder approval for such issuance as required under applicable Nasdaq listing rules, which the Company received at the 2025 Annual Meeting.

Immediately before each settlement date, the Company remeasured the fair value of the respective forward sales contract liability and recognized changes in fair value of approximately $0.5 million in the accompanying consolidated statement of operations. Upon settlement, the Company then reclassified the respective forward sales contract liability to equity. For the year ended December 31, 2025, the Company recognized $5.8 million of forward sales contract expense. During the year ended December 31, 2025, the Company reclassified the $5.8 million forward sales contract liability to equity, and at December 31, 2025, there was no forward sales contract liability balance.

September 2024 Transactions

2024 Exchange Transaction

On September 24, 2024, the Company entered into exchange agreements (the "Exchange Agreements") with (i) the holders of all convertible notes issued in convertible note financings during 2023 (the "2023 Convertible Notes), (ii) all holders of warrants issued in connection with the 2023 Convertible Notes and (iii) substantially all of the holders of warrants issued in December 2022 (the "December 2022 Warrants"). One holder of a December 2022 Warrants to purchase approximately 9,000 shares of our common stock did not enter into the Exchange Agreement.

Subject to approval by the Company's stockholders at the 2024 Annual Meeting, under the Exchange Agreements (i) the holders of the warrants agreed to exchange all their warrants for shares of the Company's common stock at an exchange ratio of 0.50 shares of a share of common stock for every one share of common stock issuable upon exercise of the applicable warrant (rounded up to the nearest whole number), and (ii) the holders of the convertible notes agreed to exchange all their convertible notes for shares of the Company's common stock at an exchange ratio equal to (A) the sum expressed in U.S. dollars of (1) the principal amount of the applicable convertible note, plus (2) all accrued and unpaid interest thereon through the date the applicable convertible note is exchanged plus (3) all interest that would have accrued through, but not including, the maturity date of applicable convertible note if it was outstanding from the date such convertible note is exchanged through its maturity date (the sum of (A) totaling approximately $28.4 million), divided by (B) $15.00 (rounded up to the nearest whole number) (the "Exchange Transactions").

The Company determined that the modifications to the convertible notes should be accounted for as an extinguishment of debt because there was at least a 10% change in the cash flows of the modified debt instrument compared to the carrying amount of the original debt instrument, and as such, the difference between the reacquisition price (which includes any premium) and the net carrying amount of the debt being extinguished (which includes any deferred debt issuance costs) should be recognized as a gain or loss when the debt is extinguished.

As of September 24, 2024, prior to entering into the Exchange Agreements, there was approximately $10.1 million of net carrying amount of the 2023 Convertible Notes, which was comprised of $19.4 million of principal and accrued interest through such date, offset by approximately $9.3 million of unamortized debt issuance costs. Upon

entering into the Exchange Agreements, the fair value of the 2023 Convertible Notes was $32.0 million and was determined by multiplying approximately 1,890,000 shares the Company would be issuing on October 29, 2024 by the closing stock price of $16.95 per share on September 24, 2024. The difference between the reacquisition price and the net carrying amount of the 2023 Convertible Notes being extinguished was approximately $21.9 million. Accordingly, the Company increased the carrying value of the 2023 Convertible Notes to $32.0 million and recognized a loss on extinguishment of debt of approximately $21.9 million during the year ended December 31, 2024. As discussed further below, upon conversion of the Convertible Notes to shares of common stock on October 29, 2024, the Company recorded $1.0 million in income for the change in fair value of the shares of common stock being issued.

Because shareholder approval was required for the Exchange Transactions to occur, the Company determined that the modifications to the Exchanged Warrants resulted in a change in classification from equity to liability. A provision that requires shareholder approval precludes equity classification because such approval is not an input into a fixed-for-fixed valuation model. As a result, the Company recorded the Exchanged Warrants at fair value as of September 24, 2024 by taking the number of shares of common stock issuable from the exchanged warrants multiplied by the closing stock price of $16.95 and reclassified approximately $11.2 million from equity to warrant liabilities. The Company remeasured the fair value of the Exchanged Warrants at each reporting period or immediately prior to exchanging the Exchanged Warrants to shares of common stock and recorded a change in fair value of approximately $0.3 million. A corresponding credit of $0.3 million was recognized as a change in fair value of warrant liabilities for the year ended December 31, 2024 on the accompanying consolidated statement of operations.

2024 Private Placement

On September 24, 2024, the Company entered into a securities purchase agreement (the "2024 SPA") with certain accredited investors to sell in a private placement an aggregate of approximately 101,000 shares of the Company's common stock (or, in lieu thereof, pre-funded warrants to purchase one share of our common stock) for a purchase price of $11.25 per share of common stock and $11.175 per pre-funded warrant (the "2024 Private Placement" and together with the Bridge Notes and the Exchange Transactions, the "September 2024 Transactions"). The closing of the 2024 Private Placement was conditioned upon receiving stockholder approval at the 2024 Annual Meeting.

The 2024 SPA represented a forward sale contract obligating the Company to sell a fixed number of shares of its common stock at a fixed price per share upon obtaining shareholder approval at the 2024 Annual Meeting. The Company measured the fair value of the forward sale contract as the difference between (A) the fair value of the expected shares to be purchased by the investors as of the date the Company entered into the 2024 SPA and (B) the purchase price of the shares and recorded approximately $0.6 million to additional paid-in capital as of September 24, 2024. Because of the concurrent execution of the 2024 SPA and the Exchange Agreements, and because the investors in the 2024 SPA were also parties to the Exchange Transactions, the $0.6 million was added to the $21.9 million loss on extinguishment of debt discussed above for a total loss of $22.4 million during the year ended December 31, 2024 in the accompanying consolidated statement of operations.

Summary of Shares Issued in the September 2024 Transactions

On October 29, 2024, the Company held the 2024 Annual Meeting, the Company's stockholders approved the September 2024 Transactions, and as a result, the following occurred on October 29, 2024:

- Under the 2024 Private Placement, the Company issued approximately 93,000 shares of common stock and pre-funded warrants to purchase approximately 8,000 shares of common stock and received approximately $1.1 million in gross proceeds from the issuance of such securities. The pre-funded warrants have an exercise price of $0.075 per share, are exercisable at any time and will not expire until exercised in full.
- Under the Bridge Notes, approximately $3.0 million of the principal amount of the Bridge Notes plus all accrued and unpaid interest thereon, plus such amount of interest that would have accrued on the principal amount through December 24, 2024, was automatically converted at a conversion price of $7.50 into approximately 416,000 shares of the Company's common stock and approximately $0.9 million of the principal amount of the Bridge Notes plus all accrued and unpaid interest thereon, plus such amount of interest that would have accrued on the principal amount through December 24, 2024, was automatically converted at a conversion price of $7.50 into pre-funded warrants to purchase approximately 118,000 shares of common stock. The pre-funded

warrants have an exercise price of $0.075 per share, are exercisable at any time and will not expire until exercised in full. As of October 29, 2024, there were no Bridge Notes outstanding.

- Under the Exchange Transactions, (i) the holders of the Exchanged Warrants exchanged approximately 1,327,000 warrants for approximately 663,000 shares of the Company's common stock, and (ii) the holders of the Convertible Notes exchanged all their Convertible Notes for approximately 1,890,000 shares of our common stock for a total of 2,553,000 shares of our common stock under the Exchange Transactions. As of October 29, 2024, there were no Convertible Notes outstanding.

Warrants

As of December 31, 2025, the Company had the following common warrants outstanding:

	Warrants Outstanding (in thousands)	Exercise Price	Issuance Date	Expiration Date	Classification
Q1-22 Warrants	23	$ 572.98	03/09/22	09/09/27	Liability
December 2022 Warrants	9	$ 21.45	12/02/22	06/02/28	Equity
Prefunded warrants	75	$ 0.075	10/29/24	None	Equity
Prefunded warrants	34	$ 0.075	04/02/25	None	Equity
Prefunded warrants	274	$ 0.075	06/09/25	None	Equity
	415				

As of December 31, 2025, the weighted average remaining contractual life of expiring warrants outstanding was 1.90 years and the weighted average exercise price for the expiring warrants was $411.74. The prefunded warrants do not expire and have a weighted average exercise price of $0.075.

The following table shows the warrant activity for the years ended December 31, 2025 and 2024 (in thousands):

	Outstanding January 1, 2024	Granted	Exchanged	Outstanding December 31, 2024	Granted	Exercised	Outstanding December 31, 2025
Q1-22 Warrants	23	-	-	23	-	-	23
December 2022 Warrants	9	-	-	9	-	-	9
Exchanged Warrants	1,229	98	(1,327)	-			-
Prefunded warrants	-	125	-	125	656	(398)	383
Total	1,261	223	(1,327)	157	656	(398)	415

Stock Repurchase Program

In November 2024, the Company's Board of Directors authorized a stock repurchase program (the "Repurchase Program") of up to $1.0 million of the Company's outstanding common stock. Under the Repurchase Program, the repurchases may be made by the Company from time to time through open-market purchases, privately negotiated transactions or other means in accordance with applicable securities laws. The timing and amount of repurchases will be determined by the Company, taking into consideration market conditions, stock price, and other factors. The Repurchase Program does not have a set expiration date and may be suspended, modified or discontinued at any time without prior notice. The Company did not repurchase any of its shares under the Repurchase Program during the years ended December 31, 2025 or 2024.

Cumulative Convertible Preferred Stock

The Company has authorized 156,000 shares of preferred stock, all of which is designated as Series A Cumulative Convertible Preferred Stock (the "Series A Preferred Stock"), and all of which were issued and outstanding as of December 31, 2025 and 2024.

The Series A Preferred Stock provides for a cumulative annual dividend of $0.10 per share, payable in semi-annual installments in June and December. Dividends may be paid in cash or with shares of common stock. The Company issued approximately 7,000 shares of common stock for the payment of dividends during the year ended

December 31, 2025. The Company paid approximately $8,000 in cash and issued approximately 1,000 shares of common stock for payment of dividends during the year ended December 31, 2024.

The Series A Preferred Stock has no voting rights and has a $1.00 per share liquidation preference over the Company's common stock. The holder of shares of Series A Preferred Stock has the right at any time to convert such shares into that number of shares of common stock that equals the number of shares of Series A Preferred Stock divided by the conversion rate. At December 31, 2025, the conversion rate was 32.3618 and, based on that conversion rate, one share of Series A Preferred Stock would have converted into approximately 0.03 shares of common stock, and all the outstanding shares of the Series A Preferred Stock would have converted into approximately 5,000 shares of common stock in the aggregate. There were no conversions during the years ended December 31, 2025 and 2024. There is no mandatory conversion term, date or any redemption features associated with the Series A Preferred Stock. The conversion rate will adjust under the following circumstances:

(i) If the Company (a) pays a dividend or makes a distribution in shares of its common stock, (b) subdivides its outstanding shares of common stock into a greater number of shares, (c) combines its outstanding shares of common stock into a smaller number of shares, or (d) issues by reclassification of its shares of common stock any shares of its common stock (other than a change in par value, or from par value to no par value, or from no par value to par value), then the conversion rate in effect immediately prior to the applicable event will be adjusted so that the holders of the Series A Preferred Stock will be entitled to receive the number of shares of common stock which they would have owned or have been entitled to receive immediately following the happening of the event, had the Series A Preferred Stock been converted immediately prior to the record or effective date of the applicable event.

(ii) If the outstanding shares of the Company's common stock are reclassified (other than a change in par value, or from par value to no par value, or from no par value to par value, or as a result of a subdivision, combination or stock dividend), or if the Company consolidates with or merge into another corporation and the Company is not the surviving entity, or if the Company sells all or substantially all of its property, assets, business and goodwill, then the holders of the Series A Preferred Stock will thereafter be entitled upon conversion to the kind and amount of shares of stock or other equity securities, or other property or assets which would have been receivable by such holders upon such reclassification, consolidation, merger or sale, if the Series A Preferred Stock had been converted immediately prior thereto.

(iii) If the Company issues common stock without consideration or for a consideration per share less than the then applicable Equivalent Preference Amount (as defined below), then the Equivalent Preference Amount will immediately be reduced to the amount determined by dividing (A) an amount equal to the sum of (1) the number of shares of common stock outstanding immediately prior to such issuance multiplied by the Equivalent Preference Amount in effect immediately prior to such issuance and (2) the consideration, if any, received by the Company upon such issuance, by (B) the total number of shares of common stock outstanding immediately after such issuance. The "Equivalent Preference Amount" is the value that results when the liquidation preference of one share of Series A Preferred Stock (which is $1.00) is multiplied by the conversion rate in effect at that time; thus the conversion rate applicable after the adjustment in the Equivalent Preference Amount as described herein will be the figure that results when the adjusted Equivalent Preference Amount is divided by the liquidation preference of one share of Series A Preferred Stock.

SEPA

On May 1, 2025, the Company's $10.0 million SEPA with Lincoln Park expired in accordance with its terms. The Company did not sell any shares under the SEPA during the years ended December 31, 2025 or 2024.

16. Income Taxes

Loss before income taxes consist of the following (in thousands):

	Years ended December 31,	
	2025	2024
(in thousands)		
Domestic	$ (14,129)	$ (44,529)
Foreign	-	20
Total loss before income taxes	$ (14,129)	$ (44,509)

For each of the years ended December 31, 2025 and 2024, current tax provisions and current deferred tax

provisions were recorded as follows (in thousands):

	Years ended December 31,	
	2025	2024
Current Tax Provision		
Federal	$ -	$ -
State	3	3
Foreign	-	-
	3	3
Deferred Tax Provision		
Federal	19	-
State	(67)	27
Foreign	-	-
	(48)	27
Total tax provision (benefit) for income taxes	$ (45)	$ 30

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of net deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. The table below consists of the Company's net deferred tax assets and liabilities as of December 31, 2025 and December 31, 2024 (in thousands). Deferred tax assets have been substantially reserved for by a valuation allowance since it is more likely than not that such tax benefits will not be realized.

	As of December 31,	
	2025	2024
Deferred Tax Assets:		
Net operating losses	$ 19,420	$ 16,496
Foreign net operating losses	-	782
Stock compensation	2,325	2,646
In-process research and development	704	1,030
Capitalized research and development expenses	3,336	4,548
Accrued expenses	52	192
R&D credit carryforwards	437	437
ROU Liabilities	103	187
Other	27	29
Total gross deferred tax assets	26,404	26,347
Valuation allowance	(26,145)	(26,023)
Net deferred tax assets	259	324
Deferred Tax Liabilities:		
ROU Assets	(95)	(183)
Intangibles - goodwill	(205)	(229)
Total deferred tax liabilities	(300)	(412)
Net deferred taxes	$ (41)	$ (88)

The reconciliation between the Company's effective tax rate on income from continuing operations and the federal statutory tax rate of 21% for the years ended December 31, 2025 and 2024 is as follows (in thousands, except for percentages):

	As of December 31,			
	2025		2024	
	$	%	$	%
Current tax at federal statutory rate	$ (2,967)	21.00%	$ (9,347)	21.00%
State income tax, net of federal tax (a)	(51)	0.36%	(1,315)	2.95%
Foreign tax differential	-	0.00%	-	0.00%
Non-deductible expenses/excludable items	21	(0.15%)	24	(0.05%)
Financing costs	1,022	(7.23%)	-	0.00%
Convertible debt	-	0.00%	4,079	(9.16%)
Credits	-	0.00%	79	(0.18%)
Other	12	(0.09%)	(1,210)	2.72%
Change in valuation allowance	1,918	(13.58%)	7,720	(17.35%)
(Provision) benefit for income taxes	$ (45)	0.31%	$ 30	(0.07%)

(a) For the years ended December 31, 2025, state taxes in Massachusetts made up the majority (greater than 50%) of the tax effect in this category.

The net change in the total valuation allowance for the year ended December 31, 2025 was an increase of approximately $0.1 million. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. Management considered the scheduled reversal of deferred tax liabilities, projected future taxable income and planning strategies in making this assessment. Based on the level of historical operating results and projections for the taxable income for the future, management has determined that it is more likely than not that the deferred taxes assets will not be utilized. Accordingly, the Company has recorded a full valuation allowance. The net deferred tax liability represents an indefinite life intangible liability related to tax deductible goodwill, partially offset by an indefinite life deferred tax asset.

At December 31, 2025 and 2024, the Company has available net operating loss ("NOL") carryforwards of approximately $71.5 million and $62.1 million for federal income tax purposes, respectively, of which approximately $70.8 million can be carried forward indefinitely. Federal NOL carryforwards generated after tax year 2021 are subject to an 80% limitation on taxable income, do not expire and will carryforward indefinitely. The Company has available $55.2 million and $52.6 million state NOLs for the years ended December 31, 2025 and 2024, respectively, which begin to expire in 2041. The Company also has foreign NOL carryforwards of approximately $6.3 million for each of the years ended December 31, 2025 and 2024, which carry forward indefinitely.

Section 382 of the Internal Revenue Code ("IRC") imposes limits on the ability to use NOL carryforwards that existed prior to a change in control to offset future taxable income. Such limitations would reduce, potentially significantly, the gross deferred tax assets disclosed in the table above related to the NOL carryforwards. The Company continues to disclose the NOL carryforwards at their original amount in the table above as no potential limitation has been quantified. The Company has also established a full valuation allowance for all deferred tax assets, including the NOL carryforwards, since the Company could not conclude that it was more likely than not able to generate future taxable income to realize these assets.

The Company has federal and state income tax credit carryforwards of approximately $0.4 million at both December 31, 2025 and 2024. The credits begin to expire in 2041.

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The following table summarizes amounts the Company recorded for uncertain tax positions as of December 31, 2025 and 2024 (in thousands):

	As of December 31,	
	2025	2024
Beginning balance of uncertain tax positions	$ 393	$ 393
Additions based on current year's tax positions	-	-
Net changes based on prior year's tax positions	-	-
Ending balance of uncertain tax positions	$ 393	$ 393

It is reasonably possible that unrecognized tax benefits may increase or decrease within the next twelve months due to tax examination changes, expiration of statute of limitations, or changes in tax law. The Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months.

The Company recognizes interest and penalties related to unrecognized tax positions within the income tax expense line in the accompanying consolidated statements of operations. There were no accrued interest and penalties associated with uncertain tax positions as of December 31, 2025 or December 31, 2024.

The Company is also subject to certain non-income taxes such as value added taxes, sales taxes and property taxes. The Company has taken certain positions that management feels, although not free from doubt, should not result in a successful challenge by certain tax authorities.

The Company is subject to U.S. federal, state, and foreign income tax. The Company's income tax returns are subject to examination by the relevant taxing authorities. As of December 31, 2025, the 2022 – 2025 tax years remain subject to examination in the U.S. federal tax, various state, and foreign tax jurisdictions. The Company is not currently under examination by federal state, or foreign jurisdictions.

For the years ended December 31, 2025, the components of total income taxes paid, net of refunds, by jurisdiction were as follows (in thousands):

	Year ended December 31, 2025
Federal	$ -
State:	
California	2
Massachusetts	1
Total state	3
Total cash paid for income taxes (net of refunds)	$ 3

The table above excludes jurisdictions that do not meet the 5% of total taxes paid reporting threshold for the respective periods.

On July 4, 2025, the One Big Beautiful Bill ("OBBBA") was enacted, introducing significant and wide-ranging changes to the U.S. federal tax system. Significant components include restoration of 100% accelerated tax depreciation on qualifying property including expansion to cover qualified production property. Another major aspect includes the return to immediate expensing of domestic research and experimental expenditures ("R&E"), which in some cases may include retroactive application back to 2021 for businesses with gross receipts of less than $31 million or accelerated tax deductions of R&E that was previously capitalized for larger businesses. The legislation also reinstates EBITDA-based interest deductions for tax purposes and makes several business tax incentives permanent. Less favorable business provisions include limitations on tax deductions for charitable contributions.

The OBBBA modified the U.S. International Tax provisions for Global Intangible Low-Taxed Income ("GILTI"), Foreign-Derived Intangible Income ("FDII"), and the Base-erosion Anti-abuse Tax ("BEAT") effective for tax years starting after December 31, 2025. The tax rate on GILTI, now renamed to Net CFC Tested Income ("NCTI"), is now 12.6%. The FDII rules, now renamed to Foreign Derived Deduction Eligible Income ("FDDEI"), now carry a 14% tax rate on FDDEI eligible income. The OBBB Act increases the BEAT rate from 10% to 10.5%.

17. Related Party Transactions

Recent Financings

Investors who participated in the September 2024 Transactions and the 2025 Private Placement that are discussed in Note 15 and in the 2026 Offering discussed in Note 18 included Charles Cherington. Mr. Cherington participated in the applicable financing under the same terms and subject to the same conditions as all the other investors. Mr. Cherington served on the Company's board of directors from March 2021 to July 6, 2023. As of December 31, 2025, Mr. Cherington owned approximately 35% of the Company's outstanding common stock, and after the 2026 Offering and exercise of the related prefunded warrants, he owned approximately 23%.

March 2025 Promissory Notes

On March 11, 2025, the Company received $1.5 million for the issuance of a promissory note in the principal amount of $1.5 million to Mr. Cherington, and on March 21, 2025 the Company received $0.8 million for the issuance of a second promissory note in the principal amount of $0.8 million to Mr. Cherington. The promissory notes had a maturity date of the earlier of (i) June 15, 2025 or (ii) upon us receiving $5 million in gross proceeds from a subsequent capital raise. Each of the promissory notes accrued interest at a rate of 5.0% per annum, payable at maturity. Upon issuance of the notes, Mr. Cherington owned approximately 32% of our outstanding common stock and currently owns approximately 25% of our outstanding common stock.

As a result of completing the 2025 Private Placement discussed in Note 15, the Company repaid the outstanding principal plus accrued interest on the notes in full in the aggregate amount of $2.3 million, and as of September 30, 2025, there were no outstanding balances on the notes.

18. Subsequent Events

2026 Offering

On February 6, 2026, the Company entered into a placement agency agreement (the "Placement Agency Agreement") with Brookline Capital Markets, a division of Arcadia Securities, LLC (the "Placement Agent"), pursuant to which the Company engaged the Placement Agent for the 2026 Offering, which included the public offering of (i) 19.0 million shares (the "Shares") of the Company's common stock, par value $0.005 per share ("Common Stock") and accompanying Milestone Warrants to purchase 19.0 million shares of Common Stock, at a combined offering price of $0.50 per share of Common Stock and accompanying Milestone Warrant and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase 2.0 million shares of Common Stock and accompanying Milestone Warrants to purchase 2.0 million shares of Common Stock, at a combined offering price of $0.49 per Pre-Funded Warrant and accompanying Milestone Warrant. In connection with the 2026 Offering, the Company also entered into a securities purchase agreement (each, a "Purchase Agreement") with certain investors who purchased Shares, Pre-Funded Warrants and Milestone Warrants in the 2026 Offering.

The Pre-Funded Warrants are immediately exercisable subject to certain ownership limitations, have an exercise price of $0.01 per share, and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. On February 11, 2026 and February 18, 2026, the holder of the Pre-Funded Warrants exercised 1.3 million and 0.7 million Pre-Funded Warrants, respectively, for a total exercise price of approximately $20,000. There are no remaining Pre-Funded Warrants related to the 2026 Offering outstanding.

On February 6, 2026, the Milestone Warrants commenced trading on The Nasdaq Capital Market under the symbol "ERNAW." The Milestone Warrants are immediately exercisable subject to certain ownership limitations, have an exercise price of $0.68 per share, and expire on the earlier of (i) the five (5)-year anniversary of the original issuance date or (ii) the 180th calendar day following the public release by the Company of clinical trial data from the first cohort of the Phase 1 study of ERNA-101.

Pursuant to the Placement Agency Agreement, the Company paid the Placement Agent an aggregate cash fee of approximately $0.5 million, which was equal to 6.5% of the aggregate purchase price paid by investors in the Offering (or 1.5% with respect to certain existing investors). The Company will also pay the Placement Agent a cash fee as compensation for gross proceeds the Company receives from any exercise of any Milestone Warrants sold in connection with the 2026 Offering, payable quarterly on each January 1, April 1, July 1 and October 1 following the closing of the 2026 Offering (or the following business day if such day is not a business day), at the same percentage and as calculated in the manner as set forth above. The Company also issued approximately 0.2 million shares of Common Stock to the Placement Agent (the "Agent's Shares"), which was equal to 1.5% of the aggregate number of Shares and Pre-Funded Warrants sold in the Offering (or 0.5% with respect to sales to certain existing investors). In addition, the Company reimbursed the Placement Agent for its accountable offering-related legal expenses in an amount of $125,000.

The 2026 Offering closed on February 10, 2026, for aggregate gross proceeds of approximately $10.5 million before deducting Placement Agent fees and other offering expenses payable by the Company. The Company intends to use the net proceeds from the 2026 Offering to support the advancement of its development programs, working capital and general corporate purposes.

The Placement Agency Agreement and the Purchase Agreements contain customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the

Company, the Placement Agent, or the investors, as the case may be, and other obligations of the parties.

Pursuant to the terms of the Purchase Agreements and the Placement Agency Agreement, the Company has agreed that for a period of ninety (90) days from the closing of the 2026 Offering, that neither the Company nor any subsidiary may (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock equivalents or (ii) file any registration statement or prospectus, or any amendment or supplement thereto, in each case, subject to certain exceptions. The Company has also agreed not to effect or enter into an agreement to effect any issuance of Common Stock or Common Stock equivalents involving a Variable Rate Transaction, as defined in the Purchase Agreements, for a period of ninety (90) days following the closing of the 2026 Offering, subject to certain exceptions, unless waived by the Placement Agent. In addition, as part of the Purchase Agreement, subject to certain exceptions, the Company's officers and directors entered into lock-up agreements, pursuant to which they agreed not to sell or otherwise dispose of any of the Common Stock for a period of ninety (90) days following the date of closing of the 2026 Offering.

On February 10, 2026, the Company also entered into a Warrant Agent Agreement (the "Warrant Agent Agreement") with it transfer agent pursuant to which the transfer agent agreed to act as warrant agent with respect to the Milestone Warrants.

Lease and Sublease Termination Agreements

On February 16, 2026, the Company entered into a sublease termination agreement with the Subtenant of the Manhattan Lease (the "Manhattan Sublease Termination Agreement") effective March 13, 2026. Pursuant to the Manhattan Sublease Termination Agreement, the Subtenant agreed to surrender and vacate the premises in exchange for a sublease termination payment of approximately $0.1 million to the Company.

On February 18, 2026, the Company entered into a lease termination agreement with the lessor of the Manhattan Lease (the "Manhattan Lease Termination Agreement") effective March 13, 2026. Pursuant to the Manhattan Lease Termination Agreement, the Company agreed to surrender and vacate the premises in exchange for a lease termination payment of approximately $0.1 million to the lessor.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-256760, 333-260200, 333-276521, and 333-287955), Form S-1 (File Nos. 333-261185, 333-283003, and 333-293150), and Form S-3 (File Nos. 333-264585, 333-286581, and 333-287954) of Ernexa Therapeutics, Inc. (the "Company") of our report dated March 13, 2026, relating to the consolidated financial statements as of December 31, 2025 and for the year then ended, which appears in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025. Our report includes an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern.

/s/ *Haskell & White LLP*

HASKELL & WHITE LLP

Irvine, California
March 13, 2026

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 12, 2025 (except for Note 3B, as to which the date is February 2, 2026), with respect to the consolidated financial statements included in the Annual Report of Ernexa Therapeutics Inc. on Form 10-K for the year ended December 31, 2025. We consent to the incorporation by reference of said report in the Registration Statements of Ernexa Therapeutics Inc. on Forms S-8 (File Nos. 333-256760, 333-260200, 333-276521, and 333-287955), on Forms S-1 (File Nos. 333-261185, 333-283003, and 333-293150), and on Forms S-3 (File Nos. 333-264585, 333-286581, and 333-287954).

/s/ GRANT THORNTON LLP

New York, New York
March 13, 2026

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15(d)-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sanjeev Luther, certify that:

1. I have reviewed this annual report on Form 10-K of Ernexa Therapeutics Inc. (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 13, 2025

/s/ SANJEEV LUTHER

Sanjeev Luther
President and Chief Executive Officer
Eterna Therapeutics Inc.

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15(d)-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sandra Gurrola, certify that:

1. I have reviewed this annual report on Form 10-K of Eterna Therapeutics Inc. (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 13, 2026

/s/ *SANDRA GURROLA*

Sandra Gurrola
Senior Vice President of Finance
Eterna Therapeutics Inc.

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Eterna Therapeutics Inc. (the "Registrant") on Form 10-K for the year ended December 31, 2025 (the "Report"), I, Sanjeev Luther, President and Chief Executive Officer of the Registrant, do hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report, as filed with the Securities and Exchange Commission, fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: March 13, 2026

/s/ *SANJEEV LUTHER*

Sanjeev Luther
President and Chief Executive Officer
Eterna Therapeutics Inc.

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Eterna Therapeutics Inc. (the "Registrant") on Form 10-K for the year ended December 31, 2025 (the "Report"), I, Sandra Gurrola, Senior Vice President of Finance of the Registrant, do hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report, as filed with the Securities and Exchange Commission, fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: March 13, 2026

/s/ SANDRA GURROLA

Sandra Gurrola
Senior Vice President of Finance
Eterna Therapeutics Inc.