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, 2023

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

Eterna 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)**

(212) 582-1199
(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	Nasdaq Capital Market

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, 2023), computed by reference to the closing sale price of the common stock on the Nasdaq Capital Market on such date, was approximately $9.7 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, 2024, the registrant had 5,410,331 shares of common stock outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K, which speak only as of the date of this Annual Report on Form 10-K. 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K to "Eterna" refer to Eterna Therapeutics Inc., references to "Eterna LLC" refer to Eterna Therapeutics LLC, and references to the "Company," "we," "us" or "our" refer to Eterna and its consolidated subsidiaries, including Eterna LLC, 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 Annual Report on Form 10-K, 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 a limited operating history, 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, and in particular on intellectual property we in-license from Factor Limited.
- Our intellectual property rights may not adequately protect our business.
- 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 have identified a material weakness in our internal control over financial reporting, which may adversely affect investor confidence in us, result in litigation and materially and adversely affect our business and operating results.
- Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cyber-security.
- If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Risks Related to New, Cutting Edge Technologies

- Because gene-editing and cell therapy product candidates that may be developed using our mRNA technology platform are based on novel technologies, we cannot assure that such products will be successful.
- We face intense competition and rapid technological change and the possibility that 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 a.
- Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of product candidates that may be developed using our mRNA technology platform or adversely affect our ability to conduct our business.

Risks Related to Ownership of our Common Stock

- A substantial number of shares may be issued upon the exercise and/or conversion of outstanding securities, which would result in substantial dilution to the interests of our existing stockholders.
- The terms of our outstanding convertible notes could limit our growth and our ability to finance our operations, fund our capital needs, respond to changing conditions and engage in other business activities that may be in our best interests.
- The requirement that we redeem our outstanding convertible notes in cash could adversely affect our business plan, liquidity, financial condition, and results of operations.
- 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 potential strategic partners are ultimately unable to obtain regulatory approval for their product candidates, our business will be substantially harmed.
- Healthcare legislative reform measures may have a material and adverse effect on our business, financial condition, results of operations, and prospects.
- 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.
- We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue, or that our issued patents or patents that issue in the future will not be challenged and rendered invalid and/or unenforceable.
- Issued patents covering future products and product candidates that our strategic partners or collaborators may develop could be found invalid or unenforceable if challenged in court or in administrative proceedings.
- Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- 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 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 not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, and our business, financial condition, results of operations, and/or prospects may be materially and adversely effected.
- 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.
- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.
- 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 life science company committed to realizing the potential of mRNA cell engineering to provide patients with transformational new medicines. We have in-licensed a portfolio of over 100 patents covering key mRNA cell engineering technologies, including technologies for mRNA cell reprogramming, mRNA gene editing, the NoveSlice™ and UltraSlice™ gene-editing proteins, and the ToRNAdo™ mRNA delivery system, which we collectively refer to as our "mRNA technology platform." We refer to aspects of our mRNA technology platform as "mRNA delivery," "mRNA gene editing" and "mRNA cell reprogramming." We license our mRNA technology platform from Factor Bioscience Limited ("Factor Limited") under an exclusive license agreement.

Objectives and Business Strategy

We believe that our proprietary technology platform can be used to develop novel pharmaceutical products to treat a broad range of diseases and address unmet medical needs.

In the short term, we are planning to derive revenue by leveraging our core intellectual property ("IP") portfolio by licensing our IP to third parties in out-licensing or co-development arrangements. In addition, we are also planning to enhance our developmental activities through preclinical studies in selected indications.

In the mid-term, we are planning to transform our preclinical stage company into a clinical-stage company through IND-enabling studies, IND approval, and initiation of our first-in-human study. After achieving the initial milestones, we'll seek to diversify our pipeline of product candidates and strengthen the mRNA technology platform with the goal of generating IND applications each year.

In the long term, we aspire to become a therapeutics company with multiple approved gene and cellular therapy products across multiple indications in oncology, autoimmune diseases, and rare diseases.

As discussed in more detail below, following receipt in June 2022 of the results from the INSPIRE phase 2 trial of IRX-2, our only former product candidate, we determined to cease the development of IRX-2. We do not currently plan to develop any product candidates. In the future we may develop and advance product candidates, either internally and/or through strategic partnerships.

mRNA Delivery, Gene-Editing, and Cellular Medicines

mRNA Delivery

Nucleic acids, such as mRNA, can be used to induce cells to express desired proteins, including proteins that are capable of re-writing genetic and epigenetic cellular programs. However, the plasma membrane surrounding cells normally protects cells from exogenous nucleic acids, preventing efficient uptake and protein translation. Delivery systems can be used to enhance the uptake of nucleic acids by cells. Conventional delivery systems, such as lipid nanoparticle ("LNP")-based delivery, often suffer from endosomal entrapment and toxicity, which can limit their therapeutic use. Our mRNA delivery technology is designed to use a novel chemical substance that is designed to deliver nucleic acids, including mRNA, to cells both *ex vivo* and *in vivo*. Our nucleic-acid delivery technology is also designed for *ex vivo* delivery of mRNA encoding gene-editing proteins and reprogramming factors, including to primary cells, insertion of exogenous sequences into genomic safe-harbor loci, and *in vivo* delivery of mRNA to the brain, eye, skin, and lung, which may be useful for the development of mRNA-based therapeutic.

mRNA Gene Editing

Our mRNA gene-editing technology is designed to delete, insert, and repair DNA sequences in living cells, which may be useful for correcting disease-causing mutations, making cells resistant to infection and degenerative disease, modulating the expression of immunoregulatory proteins to enable the generation of durable allogeneic cell therapies, and engineering immune cells to more effectively fight cancer.

Conventional gene-editing technologies typically employ plasmids or viruses to express gene-editing proteins, which can result in low-efficiency editing and unwanted mutagenesis when an exogenous nucleic acid

fragment is inserted at random locations in the genome. Our mRNA gene-editing technology instead is designed to employ mRNA to express gene-editing proteins, which can potentially enable gene editing without unwanted insertional mutagenesis, because, unlike conventional gene-editing technologies that employ viruses or DNA-based vectors, mRNA does not typically cause unwanted insertional mutagenesis. We believe the efficiency of our mRNA gene-editing technology has the potential to support development of product candidates that could create new therapeutic approaches. For example, we anticipate that our mRNA gene-editing technology can be used to generate allogeneic chimeric antigen receptor T-cell ("CAR-T") therapies for the treatment of cancer. In such allogeneic CAR-T therapies, mRNA encoding gene-editing proteins would be used to inactivate the endogenous T-cell receptor to prevent therapeutic T-cells from causing graft-versus-host disease ("GvHD"). GvHD occurs when transplanted cells view the patient's (i.e. the host's) cells as a threat and attack the host's cells. We expect that this same mechanism of action can generate allogeneic stem cell-derived therapies in which mRNA encoding gene-editing proteins could be used to inactivate one or more components of the human leukocyte antigen ("HLA") complex to render the cells immuno-nonreactive or "stealth," which may be useful for the development of allogeneic cell-based therapies.

mRNA Cell Reprogramming

Our mRNA cell-reprogramming technology is capable of generating clonal lines of pluripotent stem cells that can be expanded and differentiated into many desired cell types that may be useful for the development of regenerative cell therapies.

Conventional cell-reprogramming technologies (e.g., using Sendai virus or episomal vectors) can result in low efficiency reprogramming, can select for cells with abnormal growth characteristics, and can leave traces of the vector in reprogrammed cells. Our mRNA cell-reprogramming technology instead is designed to employ mRNA to express reprogramming factors, which can enable cell reprogramming without leaving traces of the vector in reprogrammed cells, because, unlike conventional cell-reprogramming technologies that employ viruses or DNA-based vectors, mRNA does not typically leave traces of the vector in reprogrammed cells.

Former Product Candidate -- IRX-2

We currently do not have plans to further develop IRX-2, our former clinical product candidate. Results of the 150-patient Phase 2b INSPIRE trial, released in June 2022, showed outcomes favored IRX-2 in certain predefined subgroups but did not meet its primary endpoint of event-free survival at two years of follow up. There were no new safety signals observed with IRX-2. The INSPIRE trial was our only sponsored study of IRX-2. IRX-2 has been studied externally in other clinical settings outside of head and neck cancer in the form of investigator sponsored trials, all of which have either ended or are not currently active. We previously provided IRX-2 as a study drug and financial support to conduct those investigator sponsored trials, but are no longer providing either.

License Agreement

On November 14, 2023, we entered into an amended and restated exclusive license agreement (the "A&R Factor License Agreement") with Factor Limited to replace in its entirety the exclusive license agreement we entered into with Factor dated February 20, 2023, as amended on July 12, 2023. Under the terms of the A&R Factor License Agreement, Factor Limited granted to us an exclusive, sublicensable license under certain patents owned by Factor Limited (the "Factor Patents"). The A&R Factor License Agreement also provides for, among other things, the expansion of our license rights to include (i) the field of use of the Factor Patents to include veterinary uses, (ii) know-how that is necessary or reasonably useful to practice to the licensed patents, (iii) the ability to sublicense through multiple tiers (as opposed to only permitting a direct sublicense), and (iv) the transfer of technology to us, subject to the use restrictions in the Amended and Restated License Agreement. The term of the A&R Factor License Agreement expires on November 22, 2027, but will be automatically extended for an additional five years if we pay at least $6.0 million to Factor Limited from fees from sublicenses to the Factor Patents ("Sublicense Fees"), other cash on hand or a combination of both sources of funds. We will pay to Factor Limited 20% of any Sublicense Fee received by us during the term of the A&R Factor License Agreement. In September 2023, we will also begin paying Factor Limited a monthly maintenance fee of approximately $0.4 million. We may terminate the A&R Factor License Agreement upon 120 days' written notice to Factor Limited, and both parties have additional customary termination rights. Under the A&R Factor License Agreement, we are obligated to pay the expenses incurred by Factor Limited in preparing, filing, prosecuting and maintaining the Factor Patents and we agreed to bear all costs and expenses associated with enforcing and defending the Factor Patents in any action or proceeding arising from pursuit of sublicensing opportunities under the license granted under the A&R Factor License Agreement.

Patent Portfolio

Our strategy is to develop and advance a pipeline of therapeutic products both internally and through strategic partnerships, leveraging our in-licensed mRNA technology platform, with the near-term focus on deploying our mRNA technology platform through strategic partnerships. As of February 06, 2024, we had in-licensed 16 patent families filed in the United States and other major markets worldwide, including 138 granted patents, 5 allowed patent applications, 11 nationalized PCT applications, 100 pending non-provisional patent applications or provisional patent applications, and 1 pre-nationalization PCT application. Patent protection for the mRNA 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. 9,422,577, 9,605,277, 9,605,278, 10,472,611, 10,662,410, 10,829,738, 10,982,229, ,11,466,293, 11,692,203 and 11,708,586), EP (CH, DE, FR, GB, IE), EP (BE, CH, DE, DK, FR, GB, IE, NL), AU (6X), CA, CN (4X), HK (5X), JP (2X), KR (2X), MX(2X), RU **Nationalized PCT**: (1X) **Pending**: US (4X), AU, BR (4X), CA, CN, EP, HK (2X), KR, MX (3X), RU	12/05/2011
FAB-003: "Methods and Products for Transfection"	**Granted**: US (Nos. 8,497,124, 9,127,248, 9,399,761, 9,562,218, 9,695,401, 9,879,228, 9,969,983, 10,131,882, 10,301,599, 10,443,045, 11,492,600) **Pending**: US	5/07/2012
FAB-005: "Methods and Products for Expressing Proteins in Cells"	**Granted**: US (Nos. 9,447,395, 9,376,669, 9,464,285, 9,487,768, 9,657,282, 9,758,797, 10,415,060, 10,590,437, 11,339,409, 10,752,917, 11,339,410 ,10,724,053, 11,332,758, 10,767,195, 11,332,759, 10,752,918 and 10,752,919), EP (CH, DE, FR, GB, IE), AU (2X), BR (3X), CA, HK, JP (3X), KR (3X), MX, RU **Nationalized PCT**: (1X) **Allowed:** BR, JP, MX and US	11/01/2012

Family Number and Title	United States or Foreign Jurisdiction	Earliest Effective Date of Patent Application
	Pending: AU, CA, CN, EU, HK, KR and US	
FAB-008: "Methods and Products for Nucleic Acid Production and Delivery"	**Granted**: US (Nos. 9,770,489 and 10,124,042), EP (DE, FR, GB, CH, ES, IE), EP (BE; DK; FI; FR; DE; IE; NL; NO; ES; SE; CH; GB), AU, HK, JP, KR, MX, RU **Nationalized PCT**: (1X) **Pending**: AU, BR, CA, CN, EP, JP, KR, MX and US (2X)	08/18/2014
FAB-009: "Nucleic Acid Products and Methods of Administration Thereof"	**Granted**: US (No. 11,241,505), AU, JP **Nationalized PCT**: (1X) **Pending**: AU, CA, CN, EP, HK (2X), JP, NZ and US	02/16/2016
FAB-010: "Nucleic Acid Products and Methods of Administration Thereof"	**Granted**: US (Nos. 10,576,167, 10,137,206, 10,350,304, 10,363,321, 10,369,233, 10,888,627, and 10,894,092), AU, CN **Nationalized PCT**: (1X) **Issue Fees Paid:** US **Pending**: US (3X), AU, CN, EP, HK, IL (2X), JP (2X), NZ (2X)	08/17/2017
FAB-011: "Nucleic Acid-Based Therapeutics"	**Nationalized PCT: (1X)** **Pending:** US, AU, CA, EP and HK	03/27/2019
FAB-012: "Cationic Lipids and Transfection Methods"	**Granted**: US (Nos. 10,501,404, 10,556,855, 10,611,722, 10,752,576, 11,242,311 and 11,814,333) **Nationalized PCT: (1X)** **Pending**: US (2X), AU, CA, CN, EP, HK, JP, KR, MX, NZ	US: 07/30/2019 Foreign: 07/03/2019

Family Number and Title	United States or Foreign Jurisdiction	Earliest Effective Date of Patent Application
FAB-013: “Engineered Gene-Editing Proteins”	**Pending**: US, EP **Nationalized PCT: (1X)**	05/12/2021
FAB-016: “Mesenchymal Stem Cell Therapies”	**Nationalized PCT: (1X)** **Pending**: US, AU, CN, EP, HK and JP	04/28/2021
FAB-017: “Engineered Immune Cell Therapies”	**Nationalized PCT: (1X)** **Pending:** US, AU, CA, CN, EP and JP	03/04/2022
FAB-018: “Circular RNA”	**Nationalized PCT: (1X)** **Pending:** US, AU, CA, CN, EP and JP	04/27/2022
FAB-019: “Methods for reprogramming and gene editing cells”	**Pre-nationalization PCT: (1X)**	01/05/2022

US – United States of America
EP – European Patent Convention
PCT – Patent Cooperation Treaty
AU – Australia
BE – Belgium
BR – Brazil
CA – Canada
CH – Switzerland
CN – Peoples’ Republic of China
DE – Germany
DK – Denmark
ES – Spain
FI – Finland
FR – France
GB – Great Britain
HK – Hong Kong
IE – Ireland
IL – Israel
IN – India
JP – Japan
KR – Republic of Korea (South Korea)
MX – Mexico
NL – Netherlands
NO – Norway
NZ – New Zealand
RU – Russian Federation
SE – Sweden

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-008: “Methods and Products for Nucleic Acid Production and Delivery” - 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. 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, including cells present in vivo. 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-012: “Cationic Lipids and Transfection Methods” - The present invention relates in part to novel cationic lipids and their use, e.g., in delivering nucleic acids to cells.
- 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 mesenchymal stem cells (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 complimentary 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.

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 United States 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 United States 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 Item 1A “Risk Factors-Risks Related to Our Intellectual Property” contained in this Annual Report on Form 10-K.

Supply and Manufacturing

We currently do not have any agreements for the supply or manufacturing of cell lines. However, together with our licensor, Factor Limited, we believe that we have considerable experience in developing engineered cell lines. Pursuant to a Master Services Agreement, dated as of September 9, 2022 (the “MSA”), by and between us and Factor Bioscience Inc. (“Factor Bioscience”), the parent company of Factor Limited, Factor Bioscience has agreed to provide us with certain mRNA cell engineering research support services, including (i) access to Factor Bioscience’s research laboratory facilities located in Cambridge, Massachusetts, (ii) access to Factor Bioscience’s scientific equipment, (iii) training of our research staff in certain mRNA, iPSC, and gene editing technologies, (iv) copies of protocols, formulations, and sequences that may be useful for the development of mRNA cell engineering products and (v) in vitro transcription templates, mRNA constructs, and iPS cells that may be useful for the development of mRNA cell engineering products. To the extent that we need to obtain a supply of cell lines or manufacture them, we expect to contract with a contract manufacturing organization or to enter into a new work order under the MSA.

Regulatory Matters

As discussed above, our near-term focus is on entering into strategic partnerships to deploy our mRNA

technology platform, and we expect that potential strategic partners will use our mRNA technology platform for preclinical and eventual clinical development of product candidates for a variety of clinical indications. To the extent we enter into agreements with strategic partners, the fees, payments or other compensation we may be eligible to receive may be based on or related to the clinical, regulatory or commercial development of their product candidates, which development we expect will be largely out of our control.

In addition, as discussed in this section, government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, record-keeping, promotion, storage, advertising, distribution, marketing and export and import of product candidates and products that potential strategic partners may seek to develop. Accordingly, although we do not currently plan to directly develop any product candidates, the regulatory framework related to products and the development of product candidates may continue to impact our operations and financial condition.

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 United States. 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 United States, 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 require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States 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 United States 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 require 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 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 use 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 where 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 Gene 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 gene therapy. The FDA has issued various guidance documents regarding gene 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 gene 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 gene therapies when the risk of such effects is high. Further, the FDA usually recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by 10 years of annual queries, either in person or by questionnaire. The NIH and the FDA have a publicly accessible database, the Genetic Modification Clinical Research Information System, which includes information on gene therapy trials and serves as an electronic tool to facilitate the reporting and analysis of adverse events on these trials.

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 United States 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 United States. 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 United States, 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 United States 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 United States, 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 United States 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 "Affordable Care Act").

In the United States, 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 United States drugs to non-United States 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

In the United States and internationally, major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions have intellectual property and other technology that is competitive with our mRNA technology platform and the aspects thereof. The gene therapy market is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. 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 discovery and development of technology that could make our mRNA technology platform or 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 mRNA technology platform.

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, 2024, we had eight full-time employees, which includes four research and development positions and four 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 (212) 582-1199. We maintain a website at www.eternatx.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 at www.eternatx.com, 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 Annual Report on Form 10-K.

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 Annual Report on Form 10-K, 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:

- our ability to enter into strategic partnerships to deploy our mRNA technology platform, and the terms of such strategic partnerships, including the economic terms and the proceeds we receive, if any, thereunder;
- the pace and success of our potential strategic partners in developing and commercializing their product candidates and/or products that deploy our mRNA technology platform 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 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. We expect that our ability to raise additional capital and the amount of capital available to us will depend not only on progress we make toward entering into strategic partnerships to deploy our mRNA technology platform and the terms thereof, but also on factors outside of our control, such as the pace and success of our potential strategic partners in developing and commercializing their product candidates and/or products that deploy our mRNA technology platform and the proceeds to us, if any, as a result, macroeconomic and financial market conditions.

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 our outstanding convertible notes and under any other debt we incur will divert funds that might otherwise be available to support our operations. In addition, debt financing involves 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 a limited operating history, 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 a limited operating history upon which to evaluate our business and prospects. We were formed in September 2018, for the purpose of consummating a business combination with IRX Therapeutics, Inc., which business combination was consummated in November 2018. Since inception, we have incurred significant net losses. As of December 31, 2023, we had an accumulated deficit of approximately $187.0 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. We devoted significant resources to the development of our former product candidate, IRX-2, and in 2022 we determined to cease the development of IRX-2. Our near-term focus is now on entering into strategic partnerships to deploy our mRNA technology platform. As discussed above, we must raise additional capital to finance our operations and remain a going concern and adequate additional capital may not be available to us on a timely basis, or at all.

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 A&R Factor License Agreement. We may in the future become party to additional license agreements pursuant to which we in-license key intellectual property. The A&R Factor License Agreement imposes various sublicense fees and other obligations on us. For example, we are obligated to pay the expenses incurred by Factor Limited in preparing, filing, prosecuting and maintaining the Factor Patents and have agreed to bear all costs and expenses associated with enforcing and defending the Factor Patents in any action or proceeding arising from pursuit of sublicensing opportunities under the license granted under the A&R Factor License Agreement. Factor Limited has customary termination rights under the A&R Factor License Agreement, including in connection with certain uncured material breaches of the A&R Factor License 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 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 mRNA technology platform and any other in-licensed intellectual property, our ability to enter into 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 are substantially dependent on intellectual property we have in-licensed from Factor Limited, and if we lose the license to such intellectual property or the A&R Factor License Agreement is terminated for any reason, our ability to enter into strategic partnerships would be harmed, and our business, financial condition and results of operations would be materially and adversely affected.

Our business is substantially dependent upon the mRNA technology platform licensed from Factor Limited. Pursuant to the A&R Factor License Agreement, Factor Limited has customary termination rights, including in connection with certain uncured material breaches of the A&R Factor License Agreement, failure to make payments and specified bankruptcy events. Our ability to enter into strategic partnerships or develop therapeutics products using the Factor Patents depends entirely on the effectiveness and continuation of the A&R Factor License Agreement. If we lose the right to license any of the mRNA technology platform, our ability to enter into strategic would be harmed. Further, if the A&R Factor License 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.

We have identified a material weakness in our internal control over financial reporting. If we are unable to develop and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner, which may adversely affect investor confidence in us, and materially and adversely affect our business and operating results.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud.

In prior periods, we identified a material weakness as discussed below. We were unable to timely file our Quarterly Report on Form 10-Q for the three months ended March 31, 2022 with the SEC due to identifying errors in our financial statements reported in the Annual Report on Form 10-K for the years ended December 31, 2021 and 2020 during our preparation of the financial statements for the quarter ended March 31, 2022. On June 30, 2022, we filed an amendment to our Annual Report on Form 10-K for the years ended December 31, 2021 and 2020 to correct the errors in our financial statements for the years ended December 31, 2021 and 2020 and for the quarters ended June 30, 2020, September 30, 2020, March 31, 2021, June 30, 2021 and September 30, 2021. Management concluded that the errors were the result of accounting personnel's lack of technical proficiency in the accounting for complex matters. This material weakness remained unremediated as of December 31, 2023.

As disclosed in Part II, Item 9A to this Annual Report on Form 10-K, our Chief Executive Officer and Senior Vice President of Finance concluded that, as of December 31, 2023, our disclosure controls and procedures were not effective and did not provide reasonable assurance of achieving the desired control objectives. For a discussion of management's consideration of its material weaknesses and plans for remediation, see Part II, Item 9A: Controls and Procedures included in this Annual Report on Form 10-K.

Management has implemented measures designed to ensure that the deficiencies contributing to the ineffectiveness of our internal control over financial reporting are remediated, such that the internal controls are designed, implemented and operating effectively. The remediation actions implemented to date include: enhancing the business process controls related to reviews over technical, complex, and non-recurring transactions; providing additional training to accounting personnel and using an external accounting advisor to review management's conclusions on certain technical, complex and non-recurring matters. We will continue to season and further enhance the controls to ensure that they will continue to operate effectively for a sufficient period of time before management can make conclusions on the operating effectiveness. These remediation measures may be costly and there is no assurance that these initiatives will ultimately have the intended effects.

If we identify any additional material weaknesses in the future, any such newly identified material weakness could limit our ability to prevent or detect a misstatement of our accounts or disclosures and could result in a material misstatement of our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, investors may lose confidence in our financial reporting and our stock price may decline as a result. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to avoid potential future material weaknesses.

We may face litigation and other risks as a result of the material weaknesses in our internal control over financial reporting.

We identified a material weakness in our internal controls over financial reporting. As a result of the material weakness, restating our previously issued financial statements, and other matters that may in the future be raised by the SEC, we may face the potential for litigation or other disputes which may include, among others, claims invoking

the federal and state securities laws, contractual claims or other claims arising from the material weakness in our internal control over financial reporting and the preparation of our financial statements. As of the date of this Annual Report on Form 10-K, we have no knowledge of any such litigation or dispute. However, we can provide no assurance that such litigation or dispute will not arise in the future. Any such litigation or dispute, whether successful or not, could have a material adverse effect on our business, results of operations and financial condition or our ability to complete a business combination.

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 that it will not be able to 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

Because gene-editing and cell therapy product candidates that may be developed using our mRNA technology platform are based on novel technologies, we cannot assure that such products will be successful.

Cellular immunotherapies, stem cell therapies, gene-edited, 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 a gene-editing or 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 potential strategic partners may confront in developing and advancing a pipeline of iPSC-derived therapeutic products. We and our strategic partners 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 successful commercialization of 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- and gene-based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates using our mRNA 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 and genetic technologies, regulatory processes and requirements in the United States and in other jurisdictions governing cellular and gene 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 and gene therapy products. In addition, adverse developments in clinical trials of cellular gene 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 strategic partners' 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 BCMA-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 and gene therapies in the EU and may issue new guidelines concerning the development and marketing authorization for cellular or gene 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 strategic partnerships or adversely affect the commercialization of any future therapeutic products they may develop.

Accordingly, our strategic partners may be required to change regulatory strategies or to modify applications for clinical investigations or regulatory approval, which could delay and impair their ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, their product candidates. Changes in regulatory authorities and advisory groups, or any new regulations, requirements or guidelines they 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 developed through our strategic partners or lead to significant post-approval limitations or restrictions that may reduce the anticipated benefits of our strategic partnerships.

Likewise, gene editing technology is relatively new, with the first cell-based gene therapy product incorporating such technology having been approved by the FDA in December 2023. In addition, only a limited number of clinical trials of product candidates based on gene-editing technologies have been commenced. It is therefore difficult to accurately predict the developmental challenges we may incur pursuing our business strategy. There may be long-term effects from treatment with any product candidates that our strategic partners may develop that we cannot predict at this time. Any such product candidates may interact with genetic material (RNA/DNA) and because animal genetic materials differ from human genetic material, past testing of any such product candidates in animal models may not be predictive of results in human clinical trials designed to demonstrate safety or efficacy. As a result of these factors, it is more difficult to predict the time and cost of such product candidate development, and we cannot predict whether the application of gene editing technology, or other similar or competitive gene editing technologies, will result in the identification, development or regulatory approval of any products.

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 gene-edited 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 how long it will take or how much it will cost to obtain regulatory approvals for product candidates using this technology in either the United States 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 face intense competition and rapid technological change and the possibility that 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 United States 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 of gene therapy and genetic research may damage public perception of our future product candidates or adversely affect our ability to conduct our business or obtain and maintain marketing approvals for our future product candidates.

Public perception may be influenced by claims that gene therapy, including gene editing technologies, is unsafe or unethical, and research activities and adverse events in the field, even if not ultimately attributable to us or our future product candidates, could result in increased governmental regulation, unfavorable public perception, challenges in recruiting patients to participate in future clinical studies involving product candidates using our mRNA technology platform, potential regulatory delays in the testing or approval of product candidates using our mRNA technology platform, labeling restrictions for any future approved products, and a decrease in demand for any such product. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of future product candidates using our mRNA technology platform or demand for any approved 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 generally complex and requires significant expertise and capital investment. Manufacturers for any product candidates developed using our mRNA 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

Six stockholders collectively own a significant percentage of our outstanding common stock, and as a result of such ownership, such stockholders may influence the election of directors and other matters submitted to stockholders.

According to their most recent Schedule 13G filings and/or our corporate records, six stockholders—Charles Cherington, Nicholas Singer, John D. Halpern, George P. Denny III, Freebird Partners LP and IAF, LLC—collectively own approximately 43% of our outstanding shares of common stock. Although, to our knowledge, such stockholders are not a "group" or "acting in concert," they have and are expected to continue to have, individually and/or collectively, the ability to influence the election of our board of directors and the outcome of other matters submitted to our stockholders. In addition, each of those stockholders own note warrants and convertible notes, which if exercised and/or converted would increase their ownership percentage of our outstanding common stock. Pursuant to the terms of the note warrants and convertible notes, the number of shares of common stock that may be acquired by a particular holder upon exercise of the note warrants and/or conversion of the convertible notes is limited, to the extent necessary, to ensure that following such exercise and/or conversion, 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% (for Messrs. Singer and Halpern and IAF, LLC) or 19.99% (for Messrs. Cherington and Denny and Freebird Partners LLP) of the total number of shares of our common stock then outstanding. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders, and such stockholders, individually or collectively, may act in a manner that advances their best interests and not necessarily those of other stockholders. One consequence to this substantial influence is that it may be difficult for investors to remove our management and it could also deter unsolicited takeovers, including transactions in which stockholders might otherwise receive a premium for their shares over then current market prices.

The sale of our common stock to Lincoln Park Capital Fund LLC ("Lincoln Park") may cause dilution to our other stockholders and the subsequent sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

Lincoln Park committed to purchase up to $10.0 million of our common stock under a standby equity purchase agreement ("SEPA"). Through December 31, 2023, we have issued and sold approximately 214,000 shares of our common stock to Lincoln Park for approximately $0.3 million in gross proceeds under the SEPA, leaving an approximately $9.7 million balance of the $10.0 million total commitment. The purchase price for the shares that we may sell to Lincoln Park under the SEPA is subject to a pricing formula in the SEPA and will vary based on the price of our common stock at the time we initiate the sale. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park under the SEPA. Sales of shares of our common stock to Lincoln Park under the SEPA, if any, will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the shares of our common stock that may be available for us to sell pursuant to the SEPA. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

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 the asset purchase agreement pursuant to which we acquired assets from Exacis Biotherapeutics Inc. ("Exacis"), we agreed to issue to Exacis shares of our common stock as contingent consideration. If our market capitalization equals or exceeds $100.0 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 $200.0 million during the same three-year period, we agreed to issue to Exacis additional shares of our common stock determined by a formula specified in the asset purchase agreement. See Note 4 to the accompanying consolidated financial statements for additional information.

In addition to the shares that may be sold to Lincoln Park under the SEPA, a large number of shares may be issued and subsequently sold upon the exercise of outstanding options and warrants and upon the conversion of our outstanding convertible notes.

As of March 12, 2024, there were approximately 5.4 million shares of our common stock outstanding. In addition, there were approximately 2.2 million shares of common stock issuable under outstanding options with a weighted average exercise price of $9.29 per share, 20.4 million shares of common stock issuable upon exercise of

outstanding warrants with a weighted average exercise price of $2.05 per share, 3.1 million shares of common stock issuable upon conversion of our outstanding July 2023 convertible notes (assuming all principal and accrued interest is converted at a conversion rate of $2.86 per share) and 4.8 million shares of common stock issuable upon conversion of our outstanding December 2023 convertible notes (assuming all principal and accrued interest is converted at a conversion rate of $1.9194 per share). To the extent that holders of such securities sell the shares of common stock issued upon the exercise or conversion of such securities, the market price of our common stock may decrease due to the additional selling pressure in the market. In addition to the risk of dilution from the sale of shares of our common stock to Lincoln Park described above, the risk of dilution from issuances of shares of common stock underlying outstanding securities and/or to Exacis described above may cause stockholders to sell their common stock, which could further decline in the market price.

The terms of our convertible notes could limit our growth and our ability to finance our operations, fund our capital needs, respond to changing conditions and engage in other business activities that may be in our best interests.

Our convertible notes contain a number of restrictive covenants that, among other things, generally limit our ability to create liens, pay dividends, acquire shares of capital stock and make payments on subordinated debt, incur indebtedness, or enter into transactions with affiliates. Our ability to comply with these covenants may be adversely affected by events beyond our control, and we cannot assure you that we can comply with these covenants. The financial covenants could limit our ability to make needed expenditures or otherwise conduct necessary or desirable business activities.

The requirement that we redeem our convertible notes in cash could adversely affect our business plan, liquidity, financial condition, and results of operations.

If not converted, we are required to redeem some or all of the principal of our convertible notes for cash under certain circumstances. These obligations could have important consequences on our business. In particular, they could:

- limit our flexibility in planning for, or reacting to, changes in our businesses and the industries in which we operate;
- increase our vulnerability to general adverse economic and industry conditions; and
- place us at a competitive disadvantage compared to our competitors.

No assurances can be given that we will be successful in making the required payments to the holders of our convertible notes or that we will be able to comply with the financial or other covenants in our convertible notes. If we are unable to make the required cash payments or otherwise comply with the covenants in our convertible notes:

- the holders of our convertible notes may require us to repurchase some or all of their convertible notes at a price equal to 100% of the principal amount being repurchased, plus accrued and unpaid interest;
- the holders of our convertible notes could foreclose against our assets; and/or
- we could be forced into bankruptcy or liquidation.

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. The Nasdaq Capital Market requires that listed companies satisfy continued listing requirements, one of which that listed companies have: (x) stockholders' equity of at least $2.5 million; (y) a market value of listed securities of at least $35 million; or (z) 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. Our stockholders’ equity at December 31, 2023 was approximately $2.2 million and we do not currently meet either of the two alternative compliance standards described in clause (y) and (z). Accordingly, we expect to receive a notice from Nasdaq informing us that we do not meet the foregoing continued listing requirements. If we receive such a notice, we expect to be afforded 45 days to submit a plan to regain compliance with the stockholders’ equity requirement for Nasdaq’s consideration, and if the plan is accepted, to be granted an extension period of up to 180 calendar days from the date of the deficiency notice to regain compliance. If the plan is not accepted or if we are unable to regain compliance within any extension period granted by Nasdaq, Nasdaq would be required to issue a delisting determination, which we expect we would be entitled to request a hearing before a Nasdaq Hearings Panel to present a plan to regain compliance and to request a further extension period to regain compliance.

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 United States Department of Health and Human Services, the United States 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 United States 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 our potential strategic partners are ultimately unable to obtain regulatory approval for their product candidates, we may be unable to product revenue and our business will be substantially harmed.

We cannot commercialize a product 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.

The results of non-clinical studies and early-stage clinical trials of our future therapeutic candidates may not be predictive of the results of later stage clinical trials.

Success in non-clinical studies and early clinical trials does not ensure that later and pivotal clinical trials will generate the same results, or otherwise provide adequate data to demonstrate the safety and efficacy of a therapeutic candidate. Frequently, therapeutic candidates that have shown promising results in non-clinical studies or early clinical trials have subsequently suffered significant setbacks in later clinical trials. There can be no assurance that any of our non-clinical and preclinical programs will ultimately be successful or support initiating clinical development of any of our future therapeutic candidates. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier non-clinical studies or clinical trials, and any such setbacks in our development pipeline could have a material adverse effect on our business and operating results.

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 United States 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 Affordable Care Act of 2010 ("ACA") includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers in the United States. 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 United States'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 United States. 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 United States 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 United States 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 Eterna's Intellectual Property

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 competitors could develop and commercialize products similar or identical to those derived from our intellectual property, and our ability to achieve profitability may be adversely affected.

Our ability to compete effectively will depend, in part, on our ability to maintain the proprietary nature of our 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.

In certain situations, and as considered appropriate, we have sought, and we intend to continue to seek to protect our proprietary position by filing patent applications in the United States and, in at least some cases, one or more countries outside the United States relating to future products and product candidates that we or our strategic partners or collaborators may develop that are important to our business. However, we cannot predict whether the patent applications currently being pursued will issue as patents, or whether the claims of any resulting patents will provide us with a competitive advantage or whether we 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. We 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 to seek additional patent protection. It is possible that 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 we fail 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 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 we hold or pursue with respect to such product candidates 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 United States. As a result, any patents we may obtain 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 United States 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 our patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our 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 our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, we cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents 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.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue, or that our issued patents or patents that issue in the future will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our drug candidates by obtaining and defending patents. We have pending and issued U.S. and foreign patents and patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any issued patent will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications will result in issued patents with claims that cover each of our drug candidates or uses thereof in the United States or in other foreign countries.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenge may result in loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from

using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

We may rely on more than one patent to provide multiple layers of patent protection for our drug candidates. If the latest-expiring patent is invalidated or held unenforceable, in whole or in part, the overall protection for the drug candidate may be adversely affected. For example, if the latest-expiring patent is invalidated, the overall patent term for our drug candidate could be adversely affected.

Issued patents covering future products and product candidates that we or our strategic partners or collaborators may develop could be found invalid or unenforceable if challenged in court or in administrative proceedings. We may not be able to protect our trade secrets in court.

If we initiate legal proceedings against a third-party to enforce a patent covering future products and product candidates that we or our strategic partners or collaborators may develop, the defendant could counterclaim that the patent covering such products or product candidates is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions. An adverse determination in any of the foregoing proceedings could result in the revocation or cancellation of, or amendment to, our patents in such a way that they no longer cover future products and product candidates that we or our strategic partners or collaborators may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we were unaware during prosecution. If a defendant or third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of the future products and product candidates that we or our strategic partners or collaborators may develop. Such a loss of patent protection could have a material adverse impact on our business.

In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Competitors and other third parties could purchase future products and product candidates that we or our strategic partners or collaborators may develop and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or otherwise violate our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedurals, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which

non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. The terms of one or more licenses that we enter into the future may not provide us with the ability to maintain or prosecute patents in the portfolio and must therefore rely on third parties to do so. If we fail to obtain and maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as our product candidates, which could have a material adverse effect on our business.

If we do not obtain patent term extension for future products that we or our strategic partners or collaborators may successfully develop, our business may be materially harmed.

Patents have a limited lifespan. In the United States, 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, we 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 United States 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 United States 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 United States 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, and 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 United States could be less extensive than those in the United States. 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 United States 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 United States. Consequently, we may not be able to prevent third parties from utilizing our inventions in all countries outside the United States, even in jurisdictions where we pursue patent protection, or from selling or importing products made using our inventions in and into the United States 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 United States. 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 United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States 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 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 United States 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, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could 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 United States 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 United States 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 United States 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, 2023 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 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 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 Chief Executive Officer and Senior Vice President of Finance have assistance from consultants.

Our 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 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 49,000 square feet of office and laboratory space in the aggregate in New York and Massachusetts, of which, approximately 45,000 square feet is new office and laboratory space in Somerville, Massachusetts that we subleased in October 2022. The terms of our leases expire from December 2026 through approximately November 2033. We believe that our leased properties are generally well maintained, in good operating condition and meet 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 is listed on The Nasdaq Capital Market under the symbol "ERNA."

Holders of Common Stock

As of March 12, 2024, there were approximately 155 stockholders of record. 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 2023, we paid approximately $16,000 in cash 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 life science company committed to realizing the potential of mRNA cell engineering to provide patients with transformational new medicines. We have in-licensed a portfolio of over 100 patents covering key mRNA cell engineering technologies, including technologies for mRNA cell reprogramming, mRNA gene editing, the NoveSlice™ and UltraSlice™ gene-editing proteins, and the ToRNAdo™ mRNA delivery system, which we collectively refer to as our "mRNA technology platform." We refer to aspects of our mRNA technology platform as

"mRNA delivery," "mRNA gene editing" and "mRNA cell reprogramming." We license our mRNA technology platform from Factor Bioscience Limited ("Factor Limited") under an exclusive license agreement.

Our near-term focus is on entering into strategic partnerships to deploy our mRNA technology platform. We expect that potential strategic partners will use our mRNA technology platform for preclinical and eventual clinical development of product candidates for a variety of clinical indications.

Following receipt of the results from the INSPIRE phase 2 trial of IRX-2, our only product candidate, in June 2022, we determined to cease the development of IRX-2. We do not currently plan to develop any product candidates. In the future we may develop and advance product candidates, either internally and/or through strategic partnerships.

Recent Financings

In July 2023, we received $8.7 million from a private placement in which we issued $8.7 million in aggregate principal amount of convertible notes (the "July 2023 convertible notes") and warrants to purchase an aggregate of approximately 6.1 million shares of our common stock (the "July 2023 warrants").

On December 8, 2023, we received $1.5 million in exchange for a 6% promissory note with an aggregate principal amount of $1.5 million we issued to Charles Cherington. The promissory note was to mature on January 8, 2024, and interest accrued at a rate of 6.0% per annum, payable at maturity. On December 14, 2023, we repaid the $1.5 million of principal and $1,500 of accrued interest due under the promissory note. There are no further obligations under the promissory note.

On December 14, 2023, we entered into a purchase agreement with certain purchasers for the private placement of $9.2 million of convertible notes (the "December 2023 convertible notes" and together with the July 2023 convertible notes, the "convertible notes") and warrants to purchase an aggregate of approximately 9.6 million shares of our common stock (the "December 2023 warrants" and together with the July 2023 warrants, the "note warrants"). There were two closings under this purchase agreement: on December 15, 2023, we received $7.8 million and issued $7.8 million in December 2023 convertible notes and December 2023 warrants to purchase approximately 8.1 million shares of our common stock, and on January 11, 2024, we received the remaining $1.4 million and issued an aggregate of $1.4 million in December 2023 convertible notes and December 2023 warrants to purchase approximately 1.5 million shares of our common stock.

The July 2023 convertible notes bear interest at 6% per annum, and the December 2023 convertible notes bear interest at 12% per annum, both of which are payable quarterly in arrears. At our election, we may pay interest either in cash or in-kind by increasing the outstanding principal amount of the applicable notes. The July 2023 convertible notes mature on July 14, 2028, and the December 2023 convertible notes mature on December 15, 2028 and January 11, 2029, depending on the issuance date of such notes, unless earlier converted or repurchased. We may not redeem any of the convertible notes prior to maturity.

At the option of the holder, the July 2023 convertible notes and the December 2023 convertible notes may be converted from time-to-time in whole or in part into shares of our common stock at a conversion rate of $2.86 per share and $1.9194 per share, respectively, subject to customary adjustments for stock splits, stock dividends, recapitalization and the like. The convertible notes contain conversion limitations such that no conversion may be made if the aggregate number of shares of common stock beneficially owned by the holder thereof would exceed 4.99%, 9.99% or 19.99% immediately after conversion thereof, subject to certain increases not in excess of either 9.99% or 19.99% at the option of the holder.

The convertible notes provide for customary events of default (subject in certain cases to customary grace and cure periods), which include, among others: nonpayment of principal or interest; breach of covenants or other agreements in the convertible notes; the occurrence of a material adverse effect event and certain events of bankruptcy. Generally, if an event of default occurs and is continuing under the convertible notes, the holder thereof may require us to repurchase some or all of their convertible notes at a repurchase price equal to 100% of the principal amount of the convertible notes being repurchased, plus accrued and unpaid interest thereon.

In connection with the issuance of the December 2023 convertible notes, we agreed to reduce the exercise price of the warrants we issued in a private placement in December 2022 to purchase an aggregate of approximately 4.4 million shares of our common stock from $3.28 to $1.43 per share and of the July 2023 warrants from $2.61 to $1.43 per share.

Basis of Presentation

Revenue

Our near-term focus is on deploying our mRNA technology platform through strategic partnerships. We are not currently developing any product candidates. Our future revenue, if any, is primarily expected to come from out-licensing our mRNA technology platform and/or aspects thereof.

In February 2023, we entered into an exclusive option and license agreement with a third party, under which we granted such third party 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. In August 2023, that third party requested that we begin developing certain induced pluripotent stem cell lines in exchange for a cell line customization fee. The third party paid us $0.4 million towards the customization fee, which we are recognizing ratably over the customization period, which is expected to be approximately 20 to 25 months. We will only earn the remaining amount of the customization fee if we make certain progress towards delivery of the customized cell line. We estimate the amount of consideration we expect to recognize as revenue that is not probable of having a significant reversal of such recognized revenue, and we place 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, we 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. For additional information, see Note 5 to the consolidated financial statements included in Part II, Item 8 of this report.

License Costs

We recognize certain license costs payable to Factor Limited under the exclusive license agreement we entered into with Factor Limited.

Research and Development Expenses

We expense our research and development costs as incurred. Our research and development expenses consist of costs incurred for company-sponsored research and development activities, as well as support for selected investigator-sponsored research. Upfront payments and milestone payments we make for the in-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, and allocations of various overhead costs related to our product development efforts. Research and development costs for the year ended December 31, 2022 also included expenses related to our former IRX-2 clinical trials as well as insurance coverage for the clinical trials.

We have 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. 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 successful enrollment of patients, the allocation of responsibilities among the parties to the agreement, and the completion of portions of the clinical study or trial 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, 2023 and 2022

	Years ended December 31,		
(in thousands)	2023	2022	Change
Revenue	$ 68	$ -	$ 68
Cost of revenues	236	-	236
Gross loss	(168)	-	(168)
Operating expenses:			
Research and development	5,920	10,392	(4,472)
General and administrative	14,587	16,835	(2,248)
Acquisition of Exacis IPR&D	460	-	460
Impairment of IRX-2 IPR&D	-	5,990	(5,990)
Total operating expenses	20,967	33,217	(12,250)
Loss from operations	(21,135)	(33,217)	12,082
Other expense, net:			
Change in fair value of warrant liabilities	215	10,795	(10,580)
Change in fair value of contingent consideration	118	-	118
Loss on non-controlling investment	(59)	(941)	882
Interest income	138	-	138
Interest expense	(614)	(30)	(584)
Other expense, net	(334)	(1,141)	807
Total other (expense) income, net	(536)	8,683	(9,219)
Loss before income taxes	(21,671)	(24,534)	2,863
Benefit (provision) for income taxes	3	(45)	48
Net loss	$ (21,668)	$ (24,579)	$ 2,911

Revenue

During the year ended December 31, 2023, we recognized revenue related to the cell line customization activities we performed for a third party. We did not perform any such activities, or otherwise recognize any revenue, during the year ended December 31, 2022.

Cost of Revenue

During the year ended December 31, 2023, our cost of revenues includes direct labor and materials to perform the customization cell line activities for a third party, as well as royalty expense owed to Factor Limited in accordance with our exclusive license agreement with Factor Limited. There were no comparable expenses for the year ended December 31, 2022.

Research and Development Expenses

	Years ended December 31,		
	2023	2022	Change
(in thousands)			
License and MSA expense	$ 3,250	$ 4,761	$ (1,511)
Payroll-related	701	2,426	(1,725)
Stock-based compensation	234	1,249	(1,015)
Clinical	74	1,047	(973)
Professional fees	810	312	498
Other expenses, net	851	597	254
Total research and development expenses	$ 5,920	$ 10,392	$ (4,472)

Total research and development expenses decreased by approximately $4.5 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 primarily due to (a) decreased expenses under our master services agreement ("MSA") with Factor Bioscience during 2023 and (b) decreased payroll expense and stock-based compensation expense due to employee terminations and a reduction in clinical trial expense as a result of our clinical trial ending in 2022, partially offset by (i) a full year of fees paid to Factor Bioscience under the MSA during 2023 and (ii) an increase in professional fees in 2023 related to consulting activities.

General and Administrative Expenses

	Years ended December 31,		
	2023	2022	Change
(in thousands)			
Professional fees	$ 6,464	$ 8,499	$ (2,035)
Payroll-related	2,045	2,942	(897)
Insurance	1,140	1,951	(811)
Stock-based compensation	1,008	1,686	(678)
Loss on disposal or sale of fixed assets	1	280	(279)
Occupany expense	3,306	640	2,666
Other expenses, net	623	837	(214)
Total general and administrative expenses	$14,587	$ 16,835	$ (2,248)

Our general and administrative expenses decreased by approximately $2.2 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 primarily due to (a) decreases in professional fees resulting from less legal and consulting fees, (b) decreases in payroll expense and stock-based compensation expense resulting from lower headcount, (c) a reduction in insurance premiums and (d) a reduction in the loss on disposal of fixed assets. These decreases were offset by increased occupancy expenses as a result of the June 2023 rent commencement date for our Somerville lease and the recognition of the related rent expense.

We expect our occupancy expenses to increase substantially in 2024 compared to 2023 due to our payment obligations under our sublease for office and laboratory space in Somerville, Massachusetts. The term of the sublease is approximately 10 years, and our base rent obligations over the term is estimated to be approximately $63.0 million, plus our share of the sublessor's parking spaces and operating expenses.

Acquisition of Exacis In-Process Research and Development

We acquired from Exacis Biotherapeutics Inc. ("Exacis") substantially all of its intellectual property assets, including all of its right, title and interest in and to an exclusive license agreement by and between Exacis and Factor Limited (the "Purchased License"). The Purchased License was determined to be an IPR&D asset that has no alternative future use and no separate economic value from its original intended purpose, which is expensed in the period the cost is incurred. As a result, we expensed the fair value of the Purchased License of approximately $0.5 million during the year ended December 31, 2023. For additional information, see Note 4 to the accompanying consolidated financial statements included in this report.

Impairment of In-Process Research and Development

During the year ended December 31, 2022, we received the results from the INSPIRE phase 2 trial of IRX-2. Despite outcomes that favored IRX-2 in certain predefined subgroups, the trial did not meet its primary endpoint of event-free survival at two years of follow up. Based on the totality of available information, following receipt of the results described above we determined we would not further develop IRX-2 and that the carrying value of the IPR&D asset was impaired. Accordingly, we recognized a non-cash impairment charge of approximately $6.0 million during the year ended December 31, 2022, which reduced the value of this asset to zero.

Change in Fair Value of Warrant Liabilities

For the year ended December 31, 2023 and 2022, we recognized credits to expense related to the change in the fair value of warrant liabilities due to a decrease in the market price of our common stock.

Change in Fair Value of Contingent Consideration

On the closing date of our acquisition of the intellectual property assets of Exacis, we recognized a contingent consideration liability of $0.2 million for future payments that may be payable to Exacis, which was included as part of the $0.5 million fair value of the Purchased License and expensed as IPR&D for the year ended December 31, 2023. We remeasured the fair value of the contingent consideration liability at the end of each quarterly period enduring the year, and for the year ended December 31, 2023, the change in fair value was approximately $0.1 million, which is recognized in the consolidated statement of operations. There were no contingent consideration liabilities during the same period in 2022.

Loss on Non-Controlling Investment

We account for our 25% non-controlling investment in NoveCite, Inc. ("NoveCite") under the equity method. We have not guaranteed any obligations of NoveCite, nor are we otherwise committed to providing further financial support for NoveCite. Therefore, we only record 25% of NoveCite's losses up to our investment carrying amount of $1.0 million. For the years ended December 31, 2023 and 2022, we recognized losses of approximately $0.1 million and $0.9 million, and as of December 31, 2023, the carrying value of our initial investment is zero.

Interest Income

We recognized interest income for the year ended December 31, 2023 due to depositing our cash into interest bearing accounts compared to the same period in 2022.

Interest Expense

We recognized an increase in interest expense for the year ended December 31, 2023 primarily due to interest related to the convertible notes of approximately $0.3 million as well as the amortization of the debt discount and debt issuance costs associated with the convertible note financings. There were no convertible notes for the same period in 2022.

Other (Expense) Income, Net

	Years ended December 31,		
	2023	**2022**	**Change**
(in thousands)			
SEPA fees	$ (280)	$ -	$ (280)
Q1-22 PIPE transaction fees	-	(1,007)	1,007
Liquidated damages	-	(240)	240
Other (expense) income, net	(54)	106	(160)
Total expense, net	$ (334)	$ (1,141)	$ 807

For the year ended December 31, 2023, we recognized (a) commitment fees and other fees related to the SEPA we entered into with Lincoln Park in April 2023 and (b) other miscellaneous expense. During the year ended December 31, 2022, we expensed fees associated with a private placement we completed in the first quarter of 2022, as all of the fees incurred were allocated to the warrants issued in connection with such transaction, and we incurred a loss for liquidated damages under a registration rights agreement we entered into with investors in the private placement resulting from not timely filing our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022.

Provision for Income Taxes

During 2023, we expect to incur state income tax liabilities related to our operations. We have established 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

At December 31, 2023, we had cash and cash equivalents of approximately $11.7 million, of which approximately $4.1 million was restricted cash (see—Material Cash Requirements—Somerville Sublease, below) and an accumulated deficit of approximately $187.0 million. We have to date incurred operating losses, and we expect

these losses to continue in the future. For the year ended December 31, 2023, we incurred a net loss of $21.7 million, and we used $20.4 million in operating activities.

Currently, our sole source of liquidity is through sales of our common stock under the standby equity purchase agreement (the "SEPA") we entered into with Lincoln Park Capital Fund, LLC ("Lincoln Park") in April 2023, pursuant to which Lincoln Park committed to purchase up to $10.0 million of our common stock. Such sales of common stock by us, if any, are subject to certain conditions and limitations set forth in the SEPA, including a condition that we may not direct Lincoln Park to purchase any shares of common stock under the SEPA if such purchase would result in Lincoln Park beneficially owning more than 4.99% of our issued and outstanding shares of common stock. Sales under the SEPA may occur from time to time, at our sole discretion, through April 2025. To date, we have issued and sold approximately 214,000 shares of our common stock to Lincoln Park, including the 74,000 commitment shares, and have received approximately $0.3 million in gross proceeds from such sales.

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 of 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 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.

In addition, while we are not presently pursuing product development, we may do so in the future. Developing product candidates, conducting clinical trials and commercializing products requires substantial capital, and we would need to raise substantial additional funds if we were to pursue the development of one or more product candidates.

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)	For the years ended December 31, 2023	2022	Change
Cash (used in) provided by:			
Operating activities	$ (20,408)	$ (20,976)	$ 568
Investing activities	(19)	(47)	28
Financing activities	16,556	19,579	(3,023)
Net decrease in cash and cash equivalents	$ (3,871)	$ (1,444)	$ (2,427)

Net Cash Used in Operating Activities

There was an increase of approximately $0.6 million in cash used in operating activities for the year ended December, 2023, as compared to year ended December 31, 2022. This change was due to an increase in cash used in operating assets and liabilities of $5.5 million, primarily related to MSA fees, insurance premiums and accrued severance payments, offset by a $6.1 million decrease in net loss, after giving effect to adjustments made for non-cash transactions, for the year ended December 31, 2023 when compared to the year ended December 31, 2022.

Net Cash Used in Investing Activities

Total cash used in investing activities remained relatively flat for the year ended December 31, 2023 compared to 2022. Purchases of property and equipment decreased by $0.3 million for the year ended December 31, 2023 compared to 2022, which was offset by a decrease in proceeds received from the sale of fixed assets of $0.3 million for the year ended December 31, 2022 compared to 2022.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 includes approximately $16.3 million in net proceeds received from convertible note financings and approximately $0.3 million in net proceeds received under the SEPA. Net cash provided by financing activities for the year ended December 31, 2022 includes approximately $19.6 million in net proceeds received from capital raising transactions.

Material Cash Requirements

Somerville Sublease

In October 2022, we entered into a sublease for approximately 45,500 square feet of office and laboratory space in Somerville, Massachusetts. The term of the sublease is approximately 10 years, and our base rent obligations over the term is estimated to be approximately $63.0 million, plus our share of the sublessor's parking spaces and operating expenses. Our base rent obligations under the sublease during 2024 are expected to be $0.5 million per month. As part of the sublease, we delivered a security deposit in the form of a letter of credit in the amount of $4.1 million, which will be reduced on an incremental basis throughout the term of the sublease. The letter of credit was issued by our commercial bank, which required that we cash collateralize the letter of credit with $4.1 million of cash deposited in a restricted account maintained by such bank. The amount of required restricted cash collateral will decline in parallel with the reduction in the amount of the letter of credit over the term of the sublease.

Convertible Notes

As of the date of this report, the aggregate amount outstanding under our convertible notes, including accrued interest, is $18.2 million, of which $9.0 million and $9.2 million relates to the July 2023 convertible notes and the December 2023 convertible notes, respectively. The July 2023 convertible notes mature on July 14, 2028, and the December 2023 convertible notes mature on December 15, 2028 and January 11, 2029, depending on the issuance date of such notes, unless earlier converted or repurchased. We may not redeem any of the convertible notes prior to maturity.

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

Goodwill represents the excess of the purchase price over the fair value of identifiable net assets acquired in the acquisition of IRX Therapeutics, Inc. in November 2018, which was accounted for as a business combination. 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 to the extent the reporting unit's carrying value exceeds its fair value.

Contingent Consideration

Contingent consideration from an asset acquisition that is indexed to or settled in shares of our common stock and that is classified as a liability is initially measured at fair value, with subsequent changes in fair value recognized in earnings. Measuring the fair value requires various inputs, and 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 contingent consideration liability, which could also result in material non-cash gains or losses being reported in the Company's consolidated statement of operations.

Recent Accounting Pronouncements

In June 2022, the Financial Accounting Standard Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions* ("ASU 2022-03"). The FASB issued ASU 2022-03 to (1) clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, (2) to amend a related illustrative example, and (3) to introduce new disclosure requirements for equity related securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820. ASU 2022-03 clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years with early adoption permitted. We do not expect a material impact on our consolidated financial statements as a result of adopting this ASU.

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 2023, the FASB issued ASU No. 2023-07, *Segment Reporting – Improvements to Reportable Segment Disclosures*, which provides updates to qualitative and quantitative reportable segment disclosure requirements, including enhanced disclosures about significant segment expenses and increased interim disclosure requirements, among others. ASU No. 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. Early adoption is permitted, and the amendments should be applied retrospectively. We do not expect the amendments in this ASU to have a material impact on our consolidated financial statements.

In December 2023, the FASB issued 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 is effective for fiscal years beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. 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*

None.

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 not 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 due primarily to the material weakness discussed below.

Management's Plan for Remediation of Material Weakness in Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial

reporting. 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.

We were unable to timely file our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022 with the SEC due to identifying errors in our financial statements reported in our Annual Report on Form 10-K for the years ended December 31, 2021 and 2020 during our preparation of the financial statements for the quarter ended March 31, 2022. Management concluded that the errors were the result of accounting personnel's lack of technical proficiency in complex matters. On June 30, 2022, we filed an amendment to our Annual Report on Form 10-K for the years ended December 31, 2021 and 2020 to correct the errors in our financial statements for the years ended December 31, 2021 and 2020 and for the quarters ended June 30, 2020, September 30, 2020, March 31, 2021, June 30, 2021 and September 30, 2021.

Management has implemented measures designed to ensure that the deficiencies contributing to the ineffectiveness of our internal control over financial reporting are remediated, such that the internal controls are designed, implemented and operating effectively. The remediation actions to date include:

- enhancing the business process controls related to reviews over technical, complex, and non-recurring transactions;
- providing additional training to accounting personnel; and
- using an external accounting advisor to review management's conclusions on technical, complex and non-recurring matters.

The material weakness cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. As of December 31, 2023, we continue to season and enhance such controls to ensure that they will continue to operate effectively for a sufficient period of time before management can make conclusions on the operating effectiveness.

We are committed to developing a strong internal control environment, and we believe the remediation efforts that we have implemented and will implement will result in significant improvements in our control environment. Our management will continue to monitor and evaluate the relevance of our risk-based approach and the effectiveness of our internal controls and procedures over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements, as necessary.

Changes in Internal Control over Financial Reporting

Except for the actions intended to remediate the material weakness as described above, 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 period from October 1, 2023, to December 31, 2023, none of our executive officers or directors adopted or terminated contracts, instructions or written plans for the purchase or sale of our securities.

ITEM 9C. ***Disclosure Regarding Foreign Jurisdictions that Prevent Inspections***

Not Applicable.

PART III

ITEM 10. ***Directors, Executive Officers and Corporate Governance***

DIRECTORS & 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, 2024.

Name	Age	Position[(1)]
Sanjeev Luther	62	President and Chief Executive Officer and Director
Dorothy Clarke	59	General Counsel and Director
Sandra Gurrola	56	Senior Vice President, Finance
James Bristol	77	Chairman of the Board
Peter Cicala	62	Director
William Wexler	64	Director

Sanjeev Luther has served as President, Chief Executive Officer and as a member of our Board of Directors since January 1, 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 include his expertise in the healthcare industry, his business training and education, and his extensive experience managing life science companies.

Dorothy Clarke has served as our General Counsel since January 1, 2024 and as a member of our Board of Directors since August 28, 2023. From April 2002 until November 2022, Ms. Clarke worked at Johnson & Johnson ("J&J"), serving in various roles, including in the law department as a regulatory attorney for pharmaceutical, medical device and consumer businesses, a vice president of law and vice president of regulatory affairs in the medical devices sector, the chief privacy officer of J&J, and a vice president of health care compliance for medical devices and for research and development functions. Since November 2023, Ms. Clarke also serves as a board member of Comera Life Sciences. Ms. Clarke received a B.A. in history from Wesleyan University and a J.D. from the New York University School of Law.

Ms. Clarke's qualifications to serve on our Board include her expertise in the healthcare industry, risk management, regulatory affairs and compliance.

Sandra Gurrola has served as our Senior Vice President of Finance since May 2023 and 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 32 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 Healthcare Partners as a Senior Advisor. Since August 2007, 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. 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 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 include his expertise in pharmaceutical and biotechnology intellectual property law and in strategic management of proprietary technology and products.

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 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 has adopted a Code of 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. The full text of our Code of Conduct and Ethics is available on our website at www.eternatx.com under Investor Relations—Governance and is available in print to any stockholder who requests a copy from our Secretary. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics, or waivers of certain provisions as they relate to our directors and executive officers, at the same location on our website or in our public filings. The information on our website is not intended to form a part of or be incorporated by reference into this Annual Report on Form 10-K.

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.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and persons who beneficially own more than 10% of a registered class of our equity securities to file with the SEC reports of ownership of, and transactions in, our equity securities. To our knowledge, based solely on a review of copies of such reports that we received, our records and written representations received from our directors, executive officers and certain of those persons who own greater than 10% of any class of our equity securities, for the year ended December 31, 2023, all applicable Section 16(a) filing requirements were complied with on a timely basis, with the exception of Dr. Bristol's inadvertent late filing of his Form 3 filed on November 13, 2023, and which was due on November 9, 2023.

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 May 5, 2023.

ITEM 11. *Executive Compensation*

Introduction

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, the Compensation Committee evaluates competitive market benchmark data for a given executive role. Additionally, the Compensation Committee is authorized to engage outside advisors and experts to assist and advise the Compensation Committee on matters relating to executive compensation. In 2023, the Compensation Committee retained the services of Pearl Meyer, an independent compensation consultant, to review the cash and equity compensation package to be offered to Mr. Luther prior to his appointment as our Chief Executive Officer.

Our Chief Executive Officer presents compensation recommendations to the Compensation Committee with respect to the executive officers other than himself. The Compensation Committee considers such recommendations, in conjunction with possible input from the Compensation Committee's independent compensation consultant, in making compensation decisions or recommendations to the full Board. The full Board participates in evaluating the performance of our executive officers, except that our Chief Executive Officer does not participate when the Board evaluates his or her performance and is not present during voting or deliberations regarding his or her 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. The 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, the Compensation Committee considered all components of our compensation program and assessed any associated risks. The 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 the Compensation Committee over performance metrics, if any, established for performance-based bonuses and its administration of our equity incentive plans.

Compensation Recoupment (Clawback) Policy

In 2023, we adopted a clawback policy providing 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 2023, our two most highly compensated executive officers (other than our principal executive officer) who were serving as executive officers at December 31, 2023, 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 2023. Our 2023 named executive officers are identified in the table below:

Name	Title
Matthew Angel[(1)]	Former Chief Executive Officer
Sandra Gurrola	Senior Vice President of Finance
Andrew Jackson [(1)]	Former Chief Financial Officer

(1) Dr. Angel and Mr. Jackson resigned as our Chief Executive Officer and Chief Financial Officer, respectively, effective December 31, 2023 and May 4, 2023, respectively.

Summary Compensation Table

The following table sets out the compensation for our Named Executive Officers for the years ended December 31, 2023 and December 31, 2022:

2023 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$)	Total Compensation (US$)
Matthew Angel, Former Chief Executive Officer and President[2]	2023	$350,000	$—	$—	$461,680	$13,000[3]	$—	$—)	$824,680
	2022	$—	$210,959[4]	$—	$910,453	$—	$—	$29,842[5]	$1,151,254
Sandra Gurrola, Sr. Vice President of Finance[6]	2023	$255,833	$50,050[7]	$—	$—	$—	$—	$—	$305,883
Andrew Jackson, Former Chief Financial Officer[8])	2023	$144,621	$—	$—	$—	$—	$—	$217,487[9]	$362,108
	2022	$243,679	$—	$—	$305,466	$—	$—	$—	$549,145

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 15, Stock-Based Compensation, in the Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K.Dr. Angel was appointed our Interim Chief Executive Officer and President on May 26, 2022 and to our Board effective June 6, 2022. Dr. Angel was appointed our Chief Executive Officer and President on January 1, 2023. Dr. Angel resigned as our Chief Executive Officer and President and from our Board effective August 4, 2023 and was reappointed as our Chief Executive Officer and President on August 9, 2023. Dr. Angel subsequently resigned as our Chief Executive Officer and President effective December 31, 2023.
3. Represents amounts earned pursuant to Dr. Angel's employment offer letter equal to two percent of the gross proceeds that we received from an exclusive option and license agreement entered into with a third party.
4. A cash signing bonus, which represents the salary Dr. Angel would have earned for the period during which he served as interim Chief Executive Officer and President, had Dr. Angel's appointment as Chief Executive Officer and President been in effect beginning May 26, 2022.
5. Represents a reimbursement of legal fees Dr. Angel incurred in connection with entering into his employment offer letter.
6. Ms. Gurrola has served as our Senior Vice President of Finance since May 2023 and was not a named executive officer for the year ended December 31, 2022.
7. Represents a discretionary spot bonus paid to Ms. Gurrola and approved by our Board.
8. Mr. Jackson was appointed Chief Financial Officer effective May 31, 2022 and resigned as our Chief Financial Officer effective May 4, 2023.
9. Includes $207,500 of severance payments, $9,787 in reimbursement payments for COBRA and $200 for cell phone reimbursement.

Narrative to Summary Compensation Table

The following is a discussion of each component of our executive compensation program for 2023.

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 December 2023, upon the recommendation of the Compensation Committee, the Board approved an increase to Ms. Gurrola's annual base salary from $220,000 to $275,000. In addition, the Board approved a lump sum payment of $33,542 to Ms. Gurrola, representing the additional amount of salary Ms. Gurrola would have received had the increase to her annual base salary taken effect as of May 5, 2023.

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, the Compensation Committee or the Board 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. The Board 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, 2023, no performance goals were established for any named executive officer, however, the Compensation Committee approved a discretionary spot bonus to be paid to Ms. Gurrola in the amount of $50,050 to reward her individual performance during the year.

Under the terms of his offer, Dr. Angel was eligible to receive a performance bonus equal to two percent of the gross proceeds that we actually received under licensing, option, collaboration, partnership, joint venture, settlement, and similar agreements that we enter into, or other actions, judgments, or orders, that generate cash proceeds to us, that are originated, negotiated and/or entered into by us during Dr. Angel's employment, subject to certain conditions. During 2023, Dr. Angel received $13,000 in performance bonus payments as a result of an exclusive option and license agreement we entered into with a third party.

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. The Board 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.

In 2023, we granted to Dr. Angel a time-based incentive stock option covering 132,003 shares of common stock, of which 110,043 shares vested immediately on the grant date and the remaining 21,960 shares vest in 35 substantially equal monthly installments on the first day of each month thereafter, subject to his continuous service. In connection with Dr. Angel's resignation effective December 31, 2023, all unvested options were immediately cancelled, and he has 90 days from the date of termination of his employment to exercise any vested options, at which time any unexercised vested options will be cancelled.

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 maintain a retirement savings plan, or 401(k) plan, that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Under the 401(k) Plan, eligible employees may defer up to 90% of their compensation subject to applicable annual contribution limits imposed by the Internal Revenue Code of 1986, as amended (the "Code"), and limits imposed by non-discrimination testing. Our employees' pre-tax contributions are allocated to each participant's individual account and participants are immediately and fully vested

in their contributions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. Beginning on January 1, 2023, we began matching 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 match of 4%.

Pension Benefits

We do not maintain any pension benefit 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.

Matthew Angel

On December 30, 2022, we entered into an offer letter with Dr. Angel effective on January 1, 2023 with respect to terms of his employment as our Chief Executive Officer and President. The compensatory terms of the offer letter, including equity awards, were approved by the Compensation Committee. Dr. Angel's hiring, and his offer letter, were approved by the Board.

From May 24, 2022 until he was appointed as Chief Executive Officer and President, Dr. Angel served as our interim Chief Executive Officer and President. Dr. Angel did not receive any salary or other cash compensation during his tenure as interim Chief Executive Officer and President.

Under the terms of his offer letter, we paid Dr. Angel an annual base salary of $350,000. We also paid Dr. Angel a cash signing bonus of $210,959, which represented the salary Dr. Angel would have earned for the period during which he served as interim Chief Executive Officer and President.

Dr. Angel was eligible to receive a performance bonus equal to two percent of the gross proceeds that we actually received pursuant to all licensing, option, collaboration, partnership, joint venture, settlement, other similar agreements that we entered into, or other actions, judgments, or orders that generate cash proceeds to us, that are originated, negotiated and/or entered into by us during Dr. Angel's employment (commencing on May 26, 2022), subject to certain conditions.

In accordance with the terms of his offer letter, in January 2023, we granted to Dr. Angel a time-based incentive stock option covering 132,003 shares of common stock, of which 110,043 shares vested immediately on the grant date and the remaining 21,960 shares vest in 35 substantially equal monthly installments on the first day of each month thereafter, subject to his continuous service.

Dr. Angel resigned as our Chief Executive Officer and President effective December 31, 2023. Upon termination of Dr. Angel's employment, all unvested options were immediately cancelled, and Dr. Angel has 90 days from the date of termination of his employment to exercise any vested options, at which time any unexercised vested options will be cancelled.

For information on related party transactions with Dr. Angel, see Item 13, *Certain Relationships and Related Transactions, and Director Independence.*

Sandra Gurrola

We entered into an employment agreement, dated as of 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 the Board or the Compensation Committee. 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 the Board or the Compensation Committee and paid annually by March 15 in the year following the performance year on which such bonus is based.

In accordance with the terms of her employment agreement, in June 2021, Ms. Gurrola was granted 1,750 restricted stock units, 25% of which vests on each anniversary of the grant date over four years. Vesting generally requires Ms. Gurrola's continued employment through the relevant vesting date.

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.

Andrew Jackson

We entered into an amended and restated employment agreement, dated as of May 10, 2022, which provided for our at-will employment of Mr. Jackson commencing on May 31, 2022 and continuing until terminated by us or Mr. Jackson. Mr. Jackson resigned as our Chief Financial Officer on May 4, 2023.

Under the terms of his employment agreement, we paid Mr. Jackson an annual base salary of $415,000. Mr. Jackson was also eligible to receive an annual cash bonus award in an amount up to 40% of his base salary upon achievement of agreed upon performance targets. The bonus would be determined by the Board or the Compensation Committee and paid annually by March 15 in the year following the performance year on which such bonus was based.

In accordance with the terms of his employment agreement, Mr. Jackson received a time-based nonqualified stock option covering 33,239 shares of common stock, 25% of which would vest on the first anniversary of the employment agreement's effective date, and the remainder would vest ratably on a monthly basis over the three-year period thereafter. Vesting generally required Mr. Jackson's continued employment through the relevant vesting date. Due to Mr. Jackson's termination prior to the first anniversary of the employment agreement's effective date, none of the shares subject to such option vested and all 33,239 shares were immediately cancelled upon his termination.

We entered into a separation agreement and general release with Mr. Jackson on May 2, 2023, pursuant to which, we paid Mr. Jackson a continuation of his salary for the following six-month period as well as reimbursement of up to six months of his COBRA premiums in exchange for Mr. Jackson entering into and not revoking a general release of claims in favor or our company.

Outstanding Equity Awards at 2023 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, 2023.

	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 ($)
Matthew Angel,	8/1/2022[1]	46,629	—	—	9.80	3/30/2024	—	—	—	—
Former Chief Executive Officer and	1/12/2023[1]	116,753	—	—	4.84	3/30/2024	—	—	—	—
Sandra Gurrola,	6/21/2021[2]	—	—	—	—	—	874	1,573	—	—
Sr. Vice President of Finance[3]	3/11/2022[3]	3,339	2,386	—	38.60	3/11/2032	—	—	—	—
Andrew Jackson,	—	—	—	—	—	—	—	—	—	—
Former Chief Financial Officer										

1. Dr. Angel resigned effective December 31, 2023. Unvested options were immediately cancelled and vested options will expire 90 days from the date of termination.
2. The restricted stock units vest at a rate of 25% of the shares subject to the award in four substantially equal annual installments on the anniversary date of the grant date.
3. The option vests in 36 substantially equal monthly installments.

Employment Agreement with Current Chief Executive Officer

Sanjeev Luther was appointed as our President and Chief Executive Officer effective January 1, 2024. Mr. Luther did not serve as one of our executive officers during 2023, and is therefore not one of our 2023 named executive officers.

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 the Board or the 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 the Board or the Compensation

Committee and paid annually by March 15 in the year following the performance year on which such bonus is based.

In accordance with the terms of his employment agreement, Mr. Luther was granted an equity award on January 1, 2024, consisting of 1,685,218 non-qualified stock options, which will 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. 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.

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 are assessing 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 the 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: a. Board Member: $40,000 b. Board Chair: $70,000
Committee Member Retainers	Paid in cash or stock options, at the 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: c. Audit Committee: $7,500 d. Compensation Committee: $5,000 e. Nominating/Governance Committee: $4,000

Compensation Element	Amount
Leadership Supplemental Retainer	Paid in cash or stock options, at the 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: f. Audit Committee Chair: $15,000 g. Compensation Committee Chair: $10,000 h. Nominating/Governance Committee Chair: $8,000
New Director Equity Award (outside directors)	Option for 8,290 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 the Board, vest in an initial installment of 1/3 of the shares on the first anniversary of the grant date, with the remaining shares to vest in 24 substantially equal installments thereafter.

The Board and the 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.

2023 Director Compensation

During 2023, we did not compensate any of our directors, in either cash or equity, for their service in such capacity. On January 1, 2024, we granted to Dorothy Clarke a stock option to purchase 84,261 shares of our common stock as compensation for her services as a member of our Board from August 28, 2023 until December 31, 2023, for which she had previously not been compensated.

As of December 31, 2023, none of our directors held any outstanding equity awards other than William Wexler, who held a stock option to purchase 15,895 shares of our common stock. As of December 31, 2023, Gregory Fiore, a former director who resigned from our Board effective October 4, 2023, held stock options to purchase 10,742 shares of our common stock, which expired unexercised 90 days following the date of his resignation.

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, 2024 (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 5,410,331 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 Eterna 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	Series A Convertible Preferred Stock Beneficially Owned	Percentage of Series A Convertible Preferred Stock Beneficially Owned	Percentage of Total Voting Power
Greater than 5% Stockholders:					
Charles Cherington[(1)]	1,212,707	19.99%	71,306	45.7%	19.99%
George Denny[(2)]	1,237,448	19.99%	71,306	45.7%	19.99%
Freebird Partners LP[(3)]	1,283,634	19.99%	—	—	19.99%
Nicholas J. Singer[(4)]	600,480	9.99%	—	—	9.99%
IAF, LLC[(5)]	576,899	9.99%	—	—	9.99%
John Halpern[(6)]	550,282	9.99%	—	—	9.99%
Named Executive Officers and Directors:					
Matthew Angel[(7)]	337,864	6.06%	—	—	6.06%
Sandra Gurrola[(8)]	4,903	*	—	—	*
Andrew Jackson	—	—	—	—	—
James Bristol	—	—	—	—	—
Dorothy Clarke	—	—	—	—	—
Sanjeev Luther	—	—	—	—	—
William Wexler[(9)]	15,204	*	—	—	*
All current directors and executive officers as a group (5 persons)[(10)]	20,107	6.43%	—	—	6.43%

* Less than 1%

(1) The number of common shares beneficially owned consists of (i) 556,465 shares of common stock, (ii) 8,460 shares of common stock issuable upon the conversion of shares of Series A convertible preferred stock (assuming a conversion rate of 8.4282 per share) and (iii) 656,242 shares of common stock issuable upon exercise of note warrants and/or the conversion of convertible notes (assuming a conversion price of $1.9194 per share). As further described below, such warrants and convertible notes are subject to a 19.99% 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 note warrants and convertible notes, the number of shares of common stock that may be acquired by the holder thereof upon exercise of the note warrants and/or conversion of the convertible notes is limited, to the extent

necessary, to ensure that following such exercise and/or conversion, 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 19.99% 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%. Mr. Cherington's address is c/o Ara Partners, LLC, 200 Berkeley Street, 26th Floor, Boston, MA, 02116.

(2) Denny Family Partners II, LLC owns 50,453 shares of common stock and the George Denny III Trust dated 6/11/1981 owns 406,785 shares of common stock. Mr. Denny disclaims beneficial ownership of the shares held by Denny Family Partners II, LLC except to the extent of his pecuniary interest therein. Mr. Denny has sole voting and dispositive power over 204 shares of common stock and has shared voting and dispositive power over 460,209 shares of common stock. Mr. Denny's address is PO Box 423, Poland, ME 04274. The foregoing information has been included solely in reliance upon, and without independent investigation of, the disclosures contained in the Schedule 13G/A filed by Mr. Denny with the SEC on March 6, 2023.

The number of common shares beneficially owned consists of (i) 457,442 shares of common stock, (ii) 8,460 shares of common stock issuable upon the conversion of shares of Series A convertible preferred stock (assuming a conversion rate of 8.4282 per share) and (iii) 780,006 shares of common stock issuable upon exercise of note warrants and/or the conversion of convertible notes (assuming a conversion price of $1.9194 per share). As further described below, such warrants and convertible notes are subject to a 19.99% 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 note warrants and convertible notes, the number of shares of common stock that may be acquired by the holder thereof upon exercise of the note warrants and/or conversion of the convertible notes is limited, to the extent necessary, to ensure that following such exercise and/or conversion, 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 19.99% 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%.

(3) The number of common shares beneficially owned consists of (i) 272,583 shares of common stock and (ii) 1,011,055 shares of common stock issuable upon exercise of note warrants and/or the conversion of convertible notes (assuming a conversion price of $1.9194 per share). As further described below, such warrants and convertible notes are subject to a 19.99% 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 note warrants and convertible notes, the number of shares of common stock that may be acquired by the holder thereof upon exercise of the note warrants and/or conversion of the convertible notes is limited, to the extent necessary, to ensure that following such exercise and/or conversion, 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 19.99% 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%. Curtis Huff is the sole member of Freebird Partners, LP. Freebird Partners, LP's address is 2800 Post Oak Blvd, Suite 2000, Houston, TX 77056.

(4) The number of common shares beneficially owned consists of shares of common stock issuable upon exercise of note warrants and/or the conversion of convertible notes held by Purchase Capital LLC, of which Mr. Singer is the controlling person, or by Pacific Premier Trust as custodian for the benefit of Mr. Singer . The foregoing information has been included in reliance upon, and without independent investigation of, the disclosures contained in the Schedule 13G/A filed by Mr. Singer with the SEC on January 19, 2024. As further described below, such warrants and convertible notes are subject to 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 note warrants and convertible notes, the number of shares of common stock that may be acquired by the holder thereof upon exercise of the note warrants and/or conversion of the convertible notes is limited, to the extent necessary, to ensure that following such exercise and/or conversion, 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%. Mr. Singer's address is 1395 Brickell Avenue, Suite 800, Miami, FL 33131.

(5) The number of common shares beneficially owned consists of (i) 212,464 shares of common stock and (ii) 364,435 shares of common stock issuable upon exercise of note warrants and/or the conversion of convertible notes (assuming a conversion price of $1.9194 per share). As further described below, such warrants and convertible notes are subject to 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 note warrants and convertible notes, the number of shares of common stock that may be acquired by the holder thereof upon exercise of the note warrants and/or conversion of the convertible notes is limited, to the extent necessary, to ensure that following such exercise and/or conversion, 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%. IAF, LLC has sole voting and dispositive powers. IAF LLC's address is 115 Church Street, Charleston, SC 29401.

(6) The number of common shares beneficially owned consists of (i) 452,284 shares of common stock held by the John D. Halpern Revocable Trust, of which, Mr. Halpern and Katherine H. Halpern are trustees and (ii) 97,998 shares of common stock issuable upon exercise of note warrants and/or the conversion of convertible notes (assuming a conversion price of $1.9194 per share). As further described below, such warrants and convertible notes are subject to 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 note warrants and convertible notes, the number of shares of common stock that may be acquired by the holder thereof upon exercise of the note warrants and/or conversion of the convertible notes is limited, to the extent necessary, to ensure that following such exercise and/or

conversion, 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%. Mr. Halpern and Ms. Halpern share voting and dispositive powers. Mr. Halpern's address is PO Box 540 Portsmouth, New Hampshire 03802.

(7) Includes 163,382 shares of common stock issuable upon exercise of options.

(8) Includes 3,975 shares of common stock issuable upon exercise of options.

(9) Represents shares of common stock issuable upon exercise of options.

(10) Includes 19,179 shares of common stock issuable upon exercise of options.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table contains information as of December 31, 2023 with respect to compensation plans under which our equity securities are authorized for issuance.

	Equity Compensation Plan Information		
Plan Category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
	(a)	**(b)**	**(c)**
Equity compensation plans approved by securityholders[1]	296,116	$9.79	684,023
Equity compensation plans not approved by securityholders[2]	93,545	$158.80	67,863
Total	389,661	$45.00	751,886

(1) At our 2021 annual meeting of stockholders, our stockholders approved a restatement of the Eterna Therapeutics Inc. Restated 2020 Stock Incentive Plan (the "Restated 2020 Plan"). The Restated 2020 Plan is a broad-based incentive plan, which allows for the grant of stock options, restricted stock, restricted stock units, performance awards, unrestricted stock awards and similar kinds of equity-based compensation to employees, directors, consultants and prospective employees.

(2) In May 2021, our Board adopted our 2021 Inducement Stock Incentive Plan (the "2021 Inducement Plan"). The 2021 Inducement Plan was adopted without stockholder approval pursuant to Section 711 of the Company Guide of the NYSE American LLC, the stock exchange on which our common stock was listed at the time the 2021 Inducement Plan was adopted by our Board. The 2021 Inducement Plan provides for the grant of equity-based awards, including non-qualified stock options, performance shares, performance units, restricted stock, restricted stock units, and stock appreciation rights. The awards available for grant under the 2021 Inducement Plan are available only to new employees and incentive stock options may not be issued under the 2021 Inducement Plan.

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

Except as described in Note 11 (Related Party Transactions) to the consolidated financial statements included in Part II, Item 8 of this report, which is incorporated by reference into this Item 13, since January 1, 2022, 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.

Director Independence

Our Board undertook a review of the independence of each individual serving on our Board. Based on information provided by each such individual concerning his or her background, employment, and affiliations, our Board determined that the Board meets the independence requirements under Nasdaq's listing rules and the SEC's applicable rules and regulations. Our Board affirmatively determined that each of our non-employee directors—James Bristol, Peter Cicala and William Wexler—are "independent" as defined in Nasdaq's listing rules. In making these determinations, our Board considered the current and prior relationships that each individual director has with us and other facts and circumstances our Board deemed relevant in assessing their independence. Under Nasdaq's listing rules, a director who is, or at any time during the past three years was, employed by us cannot be considered "independent." Accordingly, our Board determined that neither of the other two members of our Board (Sanjeev Luther, our President and Chief Executive Officer, and Dorothy Clarke, our General Counsel) are "independent" as defined in Nasdaq's listing rules.

ITEM 14. *Principal Accounting Fees and Services*

Fees and Services of Independent Registered Public Accounting Firm

The table below summarizes the fees and expenses billed to us by Grant Thornton for the years ended December 31, 2023 and 2022.

Year	Audit Fees	Audit-Related Fees	Tax Fees	All Other Fees	Total
2023	$516,224	$—	$—	$—	$516,224
2022	$435,750	$—	$—	$—	$435,750

Audit Fees. Audit fees consist of services rendered by an independent registered public accounting firm for the audit of our consolidated financial statements (including tax services performed to fulfill the auditor's responsibility under generally accepted auditing standards) and our internal control over financial reporting, reviews of the interim financial statements included in Forms 10-Q and includes services that generally only an external auditor can reasonably provide, such as comfort letters, statutory audits, attest services, consents and assistance with and review of documents filed with the SEC.

Audit-Related Fees. Audit-related fees consist of assurance and related services (e.g., due diligence) by an external auditor that are reasonably related to the audit or review of financial statements, including 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 services rendered by an external auditor for tax compliance, tax consulting and tax planning.

All Other Fees. All other fees are for any other permissible work that is not an Audit, Audit-Related or Tax Fee.

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
Plans of Acquisition		
2.1	Asset Purchase Agreement, dated April 26, 2023, by and among Eterna Therapeutics Inc., Exacis Biotherapeutics Inc., the stockholders party hereto and, with respect to certain provisions, Factor Bioscience Limited.	Exhibit 10.1 to Form 8-K filed on May 2, 2023
Articles of Incorporation and Bylaws		
3.1	Composite Restated Certificate of Incorporation of the Company	Filed herewith.
3.2	Second Amended and Restated Bylaws of the Company	Exhibit 3.2 to Form 8-K filed on October 11, 2022
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	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	Exhibit 4.1 to Form 10-K filed on April 15, 2022
Material Contracts		
10.1(a)	Securities Purchase Agreement, dated as of March 6, 2022, between Eterna Therapeutics Inc. and the purchaser party thereto	Exhibit 10.1 to Form 8-K filed on March 9, 2022
10.1(b)	Registration Rights Agreement, dated as of March 6, 2022, between Eterna Therapeutics Inc. and the purchaser party thereto	Exhibit 10.4 to Form 8-K filed on March 9, 2022
10.1(c)	Form of Pre-Funded Warrant (March 2022)	Exhibit 10.2 to Form 8-K filed on March 9, 2022
10.1(d)	Form of Common Stock Warrant (March 2022)	Exhibit 10.3 to Form 8-K filed on March 9, 2022
10.2(a)	Securities Purchase Agreement, dated as of November 23, 2022, by and among Eterna Therapeutics Inc. and the purchasers party thereto	Exhibit 10.1 to Form 8-K filed on November 25, 2022
10.2(b)	Form of Warrant (November 2022)	Exhibit 10.1 to Form 8-K filed on December 5, 2022
10.2(c)	Registration Rights Agreement, dated as of December 2, 2022, by and among Eterna Therapeutics Inc. and the purchasers party thereto	Exhibit 10.2 to Form 8-K filed on December 5, 2022
10.3(a)	Registration Rights Agreement, dated as of April 5, 2023, by and between Eterna Therapeutics Inc. and Lincoln Park Capital Fund, LLC	Exhibit 10.2 to Form 8-K filed on April 11, 2023
10.3(b)	Purchase Agreement, dated as of April 5, 2023, by and between Eterna Therapeutics Inc. and Lincoln Park Capital Fund, LLC	Exhibit 10.1 to Form 8-K filed on April 11, 2023
10.4(a)	Securities Purchase Agreement, dated as of July 13, 2023, by and among Eterna Therapeutics Inc. and the purchasers party thereto.	Exhibit 10.1 to Form 8-K filed on July 18, 2023
10.4(b)	Registration Rights Agreement, dated as of July 13, 2023, by and among Eterna Therapeutics Inc. and the purchasers party thereto.	Exhibit 10.4 to Form 8-K filed on July 18, 2023
10.4(c)	Form of 6% Senior Convertible Note (July 2023)	Exhibit 10.2 to Form 8-K filed on July 18, 2023

Exhibit	Description	Incorporated By Reference
10.4(d)	Form of Common Stock Purchase Warrant (July 2023)	Exhibit 10.3 to Form 8-K filed on July 18, 2023
10.5(a)#	Securities Purchase Agreement, dated as of December 14, 2023, by and among Eterna Therapeutics Inc. and the purchasers party thereto.	Exhibit 10.1 to Form 8-K filed on December 20, 2023
10.5(b)	Registration Rights Agreement, dated as of December 14, 2023, by and among Eterna Therapeutics Inc. and the parties thereto.	Exhibit 10.2 to Form 8-K filed on December 20, 2023
10.5(c)	Form of 12.0% Senior Convertible Note (December 2023 and January 2024)	Exhibit 4.1 to Form 8-K filed on December 20, 2023
10.5(d)	Form of Warrant (December 2023 and January 2024)	Exhibit 4.2 to Form 8-K filed on December 20, 2023
10.6**^	Amended and Restated Exclusive License Agreement, dated November 14, 2023, by and between Factor Bioscience Limited and Eterna Therapeutics Inc.	Exhibit 10.1 to Form 8-K filed on November 16, 2023
10.7	Master Services Agreement, dated September 9, 2022, by and between Factor Bioscience Inc. and Eterna Therapeutics Inc.	Exhibit 10.1 to Form 8-K filed on September 15, 2022
10.8*	Offer Letter, dated December 30, 2022, by and among Eterna Therapeutics Inc. and Dr. Matthew Angel	Exhibit 10.1 to Form 8-K filed on January 4, 2023
10.9(a)	Agreement to Assign Space Lease dated March 5, 2022 between Eterna Therapeutics LLC and Regen Lab USA LLC.	Exhibit 10.5 to Form 10-Q filed on July 1, 2022
10.9(b)	Assignment and Assumption of Lease dated March 25, 2022 between Eterna Therapeutics LLC and Regen Lab USA LLC	Exhibit 10.6 to Form 10-Q filed on July 1, 2022
10.10	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
10.11(a)*	Amended and Restated Executive Employment Agreement, dated as of May 10, 2022, by and between Eterna Therapeutics Inc. and Andrew Jackson	Exhibit 10.1 to Form 8-K filed on May 31, 2022
10.11(b)*	Separation Agreement and General Release, dated May 2, 2023, by and between Eterna Therapeutics Inc. and Andrew Jackson.	Exhibit 10.1 to Form 8-K filed on May 5, 2023
10.12*	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
10.13(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
10.13(b)*	Form of Stock Option Inducement Award for issuances under the 2021 Inducement Plan	Filed herewith
10.13(c)*	Form of Restricted Stock Unit Inducement Award for issuances under the 2021 Inducement Plan	Filed herewith
10.14(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
10.14(b)*	Form of Stock Option Inducement Award for issuances under the Restated 2020 Plan	Filed herewith
10.14(c)*	Form of Restricted Stock Unit Inducement Award for issuances under the Restated 2020 Plan	Filed herewith
10.15*	Inducement Stock Option Award Agreement entered into with Sanjeev Luther	Exhibit 99.1 to Form S-8 filed on January 16, 2024
10.16*	Employment Agreement, effective January 1, 2023, by and among Eterna Therapeutics Inc. and Dorothy Clarke.	Filed herewith
10.17*	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
10.18	Form of indemnification agreement for directors and officers	Exhibit 10.1 to Form 8-K filed on April 16, 2021
21.1	Subsidiaries of the Company	Filed herewith
23.1	Consent of the Independent Registered Accounting Firm, Grant Thornton LLP	Filed herewith

Exhibit	Description	Incorporated By Reference
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	Filed herewith
101.INS	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
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

ETERNA THERAPEUTICS INC.

Date: March 14, 2024

By: *_/s/ Sandra Gurrola_*

Sandra Gurrola
Senior Vice President of Finance
(Principal Financial Officer and
Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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 14, 2024
/s/ Sandra Gurrola **Sandra Gurrola**	Senior Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)	March 14, 2024
/s/ James Bristol **James Bristol**	Chairman of the Board	March 14, 2024
/s/ Peter Cicala **Peter Cicala**	Director	March 14, 2024
/s/ Dorothy Clarke **Dorothy Clarke**	Director	March 14, 2024
/s/ William Wexler **William Wexler**	Director	March 14, 2024

ETERNA THERAPEUTICS INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Eterna Therapeutics Inc.

Opinion on the financial statements
We have audited the accompanying consolidated balance sheets of Eterna Therapeutics Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going concern
The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company incurred a net loss of $21,668,000 during the year ended December 31, 2023, and had an accumulated deficit of approximately $187,000,000 as of December 31, 2023. These conditions, along with other matters as set forth in Note 2, 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. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. 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 audits 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 audits, 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

Critical audit matters
Critical audit matters are matters arising from the current period audit of the 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 financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2022.

New York, New York
March 14, 2024

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash	$ 7,575	$ 11,446
Other receivables	425	951
Prepaid expenses and other current assets	1,599	1,284
Total current assets	9,599	13,681
Restricted cash	4,095	4,095
Property and equipment, net	493	236
Right-of-use assets - operating leases	32,781	1,030
Goodwill	2,044	2,044
Investment in non-controlling interest	-	59
Other assets	120	1,134
Total assets	$ 49,132	$ 22,279
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,067	$ 1,620
Accrued expenses	1,893	3,626
Income taxes payable	2	-
Operating lease liabilities, current	2,216	295
Due to related party, current	1,205	1,750
Deferred revenue, current	190	-
Other current liabilities	-	363
Total current liabilities	6,573	7,654
Convertible notes, net	6,773	-
Warrant liabilities	116	331
Operating lease liabilities, non-current	32,854	887
Due to related party, non-current	-	1,206
Deferred revenue, non-current	392	-
Contingent consideration liability	107	-
Other liabilities	84	94
Total liabilities	46,899	10,172
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, 2023 and 2022, $156 liquidation preference	1	1
Common stock, $0.005 par value, 100,000 shares authorized at December 31, 2023 and 2022; 5,410 and 5,127 issued and outstanding at December 31, 2023 and 2022, respectively	27	26
Additional paid-in capital	189,186	177,377
Accumulated deficit	(186,981)	(165,297)
Total stockholders' equity	2,233	12,107
Total liabilities and stockholders' equity	$ 49,132	$ 22,279

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

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

	Years ended December 31,	
	2023	**2022**
Revenue	$ 68	$ -
Cost of revenues	236	-
Gross loss	(168)	-
Operating expenses:		
Research and development	5,920	10,392
General and administrative	14,587	16,835
Acquisition of Exacis in-process research and development	460	-
Impairment of in-process research and development	-	5,990
Total operating expenses	20,967	33,217
Loss from operations	(21,135)	(33,217)
Other expense, net:		
Change in fair value of warrant liabilities	215	10,795
Change in fair value of contingent consideration	118	-
Loss on non-controlling investment	(59)	(941)
Interest income	138	-
Interest expense	(614)	(30)
Other expense, net	(334)	(1,141)
Total other (expense) income, net	(536)	8,683
Loss before income taxes	(21,671)	(24,534)
Benefit (provision) for income taxes	3	(45)
Net loss	(21,668)	(24,579)
Series A convertible preferred stock dividend	(16)	(16)
Net loss attributable to common stockholders	$ (21,684)	$ (24,595)
Net loss per common share - basic and diluted	$ (4.08)	$ (8.06)
Weighted average shares outstanding - basic and diluted	5,314	3,051

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

ETERNA THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the years December 31, 2023 and 2022
(In thousands)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balances at January 1, 2022	156	$ 1	2,601	$ 13	$ 166,191	$ (140,702)	$ 25,503
Issuance of common stock in connection with private offering	-	-	275	1	(1)	-	-
Issuance of common stock from vested restricted stock units	-	-	2	-	(5)	-	(5)
Issuance of common stock and warrants in connection with November 2022 private offering, net.	-	-	2,185	12	7,383	-	7,395
Forfeiture of unvested restricted stock	-	-	(4)	-	-	-	-
Cash dividends to Series A convertible preferred stockholders	-	-	-	-	-	(16)	(16)
Stock-based compensation	-	-	-	-	2,935	-	2,935
Net loss	-	-	-	-	-	(24,579)	(24,579)
Balances at January 1, 2023	156	$ 1	5,127	$ 26	$ 177,377	$ (165,297)	$ 12,107
Issuance of common stock in connection with Exacis asset acquisition	-	-	69	-	208	-	208
Issuance of common stock related to stock purchase agreement with Lincoln Park Capital Fund, LLC, net	-	-	214	1	579	-	580
Issuance of note warrants	-	-	-	-	9,014	-	9,014
Repricing of warrants in connection with December 2023 financing	-	-	-	-	766	-	766
Cash dividends to Series A convertible preferred stockholders	-	-	-	-	-	(16)	(16)
Stock-based compensation	-	-	-	-	1,242	-	1,242
Net loss	-	-	-	-	-	(21,668)	(21,668)
Balances at December 31, 2023	156	$ 1	5,410	$ 27	$ 189,186	$ (186,981)	$ 2,233

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

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

	For years ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (21,668)	$ (24,579)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	84	161
Stock-based compensation	1,242	2,935
Commitment shares issued to Lincoln Park Capital, LLC	249	-
Loss on shares sold to Lincoln Park Capital, LLC	11	-
Amortization of right-of-use asset	1,039	336
Impairment of right-of-use asset	-	772
Non-cash component of acquisition of Exacis in-process research and development	433	-
Gain on remeasurement of operating lease liability and right-of-use-asset	-	(642)
Impairment of in-process research and development	-	5,990
Loss on disposal of fixed assets	1	280
Gain on lease termination	-	(85)
Accrued interest expense	176	-
Paid-in-kind interest expense	113	-
Amortization of debt discount and debt issuance costs	303	-
Change in fair value of warrant liabilities	(215)	(10,795)
Change in fair value of contingent consideration liability	(118)	-
Loss on non-controlling investment	59	941
Changes in operating assets and liabilities:		
Other receivables	527	(262)
Prepaid expenses and other current assets	(556)	(187)
Other non-current assets	1,014	(646)
Accounts payable and accrued expenses	(2,898)	2,034
Operating lease liability	1,338	(340)
Due to related party	(1,750)	2,956
Deferred revenue	582	-
Other liabilities	(374)	155
Net cash used in operating activities	(20,408)	(20,976)
Cash flows from investing activities:		
Purchase of property and equipment	(19)	(297)
Proceeds from the sale of fixed assets	-	250
Net cash used in investing activities	(19)	(47)
Cash flows from financing activities:		
Proceeds received from the convertible notes financings	16,503	-
Fees paid related to the Convertible Notes Financings	(251)	-
Proceeds received under promissory note	1,500	
Principal payment made on promissory note	(1,500)	
Proceeds from sale of common stock pursuant to stock purchase agreement with Lincoln Park Capital Fund, LLC	320	-
Proceeds from issuance of common stock and warrants in connection with private offering	-	19,706
Fees paid in connection with private offering	-	(110)
Issuance of common stock from exercise of pre-funded warrants	-	7
Payroll tax remitted on net share settlement of equity awards	-	(5)
Dividends paid to Series A convertible preferred stockholders	(16)	(16)
Cash paid for fractional shares in connection with reverse stock split	-	(1)
Principal payments on finance leases	-	(2)
Net cash provided by financing activities	16,556	19,579
Net decrease in cash and cash equivalents	(3,871)	(1,444)
Cash, cash equivalents and restricted cash at beginning of period	15,541	16,985
Cash, cash equivalents and restrictd cash at end of period	$ 11,670	$ 15,541
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ 20	$ 30
Income taxes	$ 4	$ 15
Supplemental disclosure of non-cash investing and financing activities:		
Contingent consideration for Exacis asset acquisition	$ 225	$ -
Issuance of common stock for Exacis asset acquisition	$ 208	$ -
Note warrants issued	$ 9,219	$ -
Repricing of warrants in connection with December 2023 financing	$ 766	$ -
Unpaid fees incurred in connection with the December 2023 financing	$ 116	$ -
Paid-in-kind interest added to convertible notes principal	$ 113	$ -
Initial measurement of ROU assets	$ 34,410	$ 1,706
Initial measurement of lease liabilities	$ 34,170	$ 1,706
Adjustment to lease liability and ROU asset due to remeasurement	$ (1,620)	$ -
Accrual for purchases of property and equipment	$ 323	$ -
Conversion of warrant liability to equity	$ -	$ 867
Unpaid fees incurred in connction with November 2022 private offering	$ -	$ 208
Initial measurement of finance lease liabilities	$ -	$ 10
Reconciliation of cash, cash equivalents and restricted cash at end of period:		
Cash and cash equivalents	$ 7,575	$ 11,446
Restricted cash	4,095	4,095
Total cash, cash equivalents and restriced cash at end of period	$ 11,670	$ 15,541

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

1) Organization and Description of Business Operations

Eterna Therapeutics Inc. is a life science company committed to realizing the potential of mRNA cell engineering to provide patients with transformational new medicines. Eterna has in-licensed a portfolio of over 100 patents covering key mRNA cell engineering technologies, including technologies for mRNA cell reprogramming, mRNA gene editing, the NoveSlice™ and UltraSlice™ gene-editing proteins, and the ToRNAdo™ mRNA delivery system, which Eterna collectively refers to as our "mRNA technology platform." Eterna refers to aspects of its mRNA technology platform as "mRNA delivery," "mRNA gene editing" and "mRNA cell reprogramming." Eterna licenses its mRNA technology platform from Factor Bioscience Limited ("Factor Limited") under an exclusive license agreement. As used herein, the "Company" or "Eterna" refers collectively to Eterna and its consolidated subsidiaries (Eterna LLC, Novellus, Inc. and Novellus Therapeutics Limited) unless otherwise stated or the context otherwise requires.

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, including conducting clinical trials and providing general and administrative support for operations. As of December 31, 2023, the Company had an unrestricted cash balance of approximately $7.6 million and an accumulated deficit of approximately $187.0 million. For the year ended December 31, 2023, the Company incurred a net loss of $21.7 million, and the Company used cash of $20.4 million in operating activities.

In October 2022, the Company entered into a sublease for approximately 45,500 square feet of office and laboratory space in Somerville, Massachusetts. Pursuant to the sublease, the Company delivered to the sublessor a security deposit in the form of a letter of credit in the amount of $4.1 million, which will be reduced on an incremental basis throughout the term of the sublease. The letter of credit was issued by the Company's commercial bank, which required that the Company cash collateralize the letter of credit by depositing $4.1 million in a restricted cash account with such bank. The amount of required restricted cash collateral will decline in parallel with the reduction in the amount of the letter of credit over the term of the sublease.

In April 2023, the Company entered into a standby equity purchase agreement (the "SEPA") and a registration rights agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park committed to purchase up to $10.0 million of the Company's common stock in an "equity line" financing arrangement. During the year ended December 31, 2023, the Company issued and sold approximately 214,000 shares of common stock under the SEPA for gross proceeds of $0.3 million.

In July and December 2023, the Company received $16.5 million in gross proceeds from the issuance of convertible notes and in January 2024 received an additional $1.4 million in gross proceeds from the issuance of additional convertible notes. See Notes 6 and 18 for additional information regarding these financings.

In connection with preparing the accompanying consolidated financial statements as of and for the year ended December 31, 2023, 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 the sales of shares of its common stock under the SEPA, public or private equity offerings, debt financings, out-licensing the Company's intellectual property, strategic partnerships or other means. Other than the SEPA, 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

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.

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; 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, Cash Equivalents and Restricted Cash

The Company classifies highly liquid investments with a remaining contractual maturity at date of purchase of three months or less as cash equivalents. The Company had no cash equivalents as of December 31, 2023 or 2022.

Restricted cash consists of a cash collateralization of $4.1 million for a security deposit in the form of a letter of credit issued by the Company's commercial bank and delivered to the sublessor of office and laboratory space the Company subleases in Somerville, Massachusetts. The amount of required restricted cash collateral will decline in parallel with the reduction in the amount of the letter of credit over the term of the sublease.

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 net assets acquired in the acquisition of IRX Therapeutics, Inc. ("IRX") in November 2018, which was accounted for as a business combination. 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 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 to the extent the reporting unit's carrying value exceeds its fair value.

In-Process Research & Development

In-process research and development ("IPR&D") assets represent the fair value assigned to technologies that were acquired in connection with the acquisition of IRX in November 2018, which have not reached technological feasibility and have no alternative future use. IPR&D assets are considered to be indefinite lived until the completion or abandonment of the associated research and development projects. During the period that the IPR&D assets are considered indefinite-lived, they are tested for impairment on an annual basis or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval, and the Company is able to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives beginning at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

Revenue Recognition

The Company recognizes the related revenue under ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, the Company recognizes revenue 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 has one revenue generating contract. Such contract relates to an option and license agreement as well as certain development activities. See Note 5.

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, 2023 or 2022.

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 any related revenue at a later date, upon satisfaction of the contract obligations. As of December 31, 2023, contract liabilities were $0.6 million and are recognized as deferred revenue in the accompanying consolidated balance sheet. The Company recognized $0.1 million of revenue during the year ended December 31, 2023 from contract liabilities that arose in 2023. There were no contract liabilities as of December 31, 2022.

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, as well as support for selected investigator-sponsored research. 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, and 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 successful enrollment of patients, the allocation of responsibilities among the parties to the agreement, and the completion of portions of the clinical study or trial 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 entitle the holders of such notes to participate in dividends but does 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, without consideration for potentially dilutive securities. 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 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's convertible notes are also considered potential shares of common stock and are included in the calculation of diluted net loss per share using the "if-converted" method, and the more dilutive of either the two-class method or the if-converted method is reported. 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's chief operating decision maker, who is the chief executive officer, reviews operating results on a consolidated basis to make decisions about allocating resources and assessing performance of the Company. As a result, in accordance with ASC No. 280, *Segment Reporting*, the Company has determined that it operates as one operating segment.

Concentration of Credit Risk

The Company maintains its cash balances in financial institutions located in the United States. 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, 2023 and 2022, 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 balance sheet for cash and cash equivalents, 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 Company 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 No.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 long-term 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

In June 2022, the Financial Accounting Standard Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions* ("ASU 2022-03"). The FASB issued ASU 2022-03 to (1) clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, (2) to amend a related illustrative example, and (3) to introduce new disclosure requirements for equity related securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820. ASU 2022-03 clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years with early adoption permitted. The Company does not expect a material impact to its consolidated financial statements as a result of adopting this ASU.

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 2023, the FASB issued ASU No. 2023-07, *Segment Reporting – Improvements to Reportable Segment Disclosures*, which provides updates to qualitative and quantitative reportable segment disclosure requirements, including enhanced disclosures about significant segment expenses and increased interim disclosure requirements, among others. ASU No. 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. Early adoption is permitted, and the amendments should be applied retrospectively. The Company does not expect the amendments in this ASU to have a material impact on its consolidated financial statements.

In December 2023, the FASB issued 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 is effective for fiscal years beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The Company does not expect the amendments in this ASU to have a material impact on its consolidated financial statements.

4) Asset Acquisition

In April 2023, the Company entered into an asset purchase agreement (the "Exacis Purchase Agreement"), with Exacis Biotherapeutics Inc. ("Exacis"), the stockholders party thereto and, with respect to specified provisions therein, Factor Limited (the "Exacis Acquisition"). Pursuant to the Exacis Purchase Agreement, the Company acquired from Exacis substantially all of Exacis' intellectual property assets (the "Exacis Assets"), including all of Exacis' right, title and interest in and to an exclusive license agreement by and between Exacis and Factor Limited (the "Purchased License"). The Company assumed none of Exacis' liabilities, other than liabilities under the Purchased License that accrue subsequent to the closing date.

In consideration for the Exacis Assets, on the closing date of the transaction, the Company issued to Exacis an aggregate of approximately 69,000 shares of the Company's common stock, which shares are subject to a 12-month lockup, pursuant to which Exacis may not sell or otherwise transfer such shares. The shares were issued to Exacis at a price based on the Company having an assumed equity valuation of $75.0 million, divided by the number of issued and outstanding shares of common stock as of the close of business two trading days prior to the closing date. For accounting purposes, the shares issued were valued at $3.00 per share, which was the closing price of the Company's common stock on the date of issuance. The Company additionally agreed to make the following contingent payments:

(i) if, at any time during the three-year period commencing on the closing date and ending on the three-year anniversary of the closing date, the Company's market capitalization equals or exceeds $100.0 million for at least ten consecutive trading days, then the Company will issue to Exacis a number of shares of common stock equal to (x) $2.0 million divided by (y) the quotient of $100.00 million divided by the number of the Company's then issued and outstanding shares of common stock;

(ii) if, at any time during the three-year period commencing on the closing date and ending on the three-year anniversary of the closing date, the Company's market capitalization equals or exceeds $200.0 million for at least ten consecutive trading days, then the Company will issue to Exacis a number of additional shares of common stock equal to (x) $2.0 million divided by (y) the quotient of $200.00 million divided by the number of the Company's then issued and outstanding shares of common stock (collectively with (i) above, the "Market Cap Contingent Consideration"); and

(iii) during the five-year period commencing on the closing date and ending on the five-year anniversary of the closing date, the Company will pay or deliver to Exacis 20% of all cash or other consideration (collectively, "License Contingent Consideration") actually received by the Company during such five-year period from (i) third-party licensees or sublicensees of the intellectual property rights acquired by the Company from Exacis pursuant to the Exacis Purchase Agreement, or (ii) subject to certain exceptions, the sale of such intellectual property rights; provided, that the License Contingent Consideration shall not in any event exceed $45.0 million.

The Company accounted for the Exacis Acquisition as an asset acquisition because it determined that substantially all of the fair value of the assets acquired was concentrated in the Purchased License. Assets acquired in an asset acquisition are recognized based on their cost to the acquirer and generally allocated to the assets on a relative fair value basis. The Company's cost for acquiring the Exacis Assets includes the issuance of the shares of the Company's common stock, direct acquisition-related costs and contingent consideration.

The Market Cap Contingent Consideration is indexed to or settled in the Company's own shares. As a result, the Company classified the Market Cap Contingent Consideration as a liability measured at fair value because the financial instrument embodies a conditional obligation (the Company would only issue the shares on the condition that the market capitalization thresholds are met), and at inception, the monetary value of the obligation is based solely on a fixed monetary amount ($2.0 million of shares for each target), which will be settleable with a variable number of the Company's shares. The Company used a Monte Carlo simulation model to estimate the fair value of the Market Cap Contingent Consideration as of the acquisition date using the following assumptions:

Stock price	$3.00
Risk-free rate	3.58%
Volatility	100%
Dividend yield	0%
Expected term	3.0 years

The License Contingent Consideration is to be settled in cash and is generally recognized when the liability is probable and estimable. As of the acquisition date and as of December 31, 2023, the Company concluded that paying the License Contingent Consideration was not probable or estimable. Therefore, there was no applicable contingent consideration liability recognized.

The table below shows the total fair value of the consideration paid for the Exacis Assets (in thousands).

	Fair Value of Consideration
Shares issued	$ 208
Contingent consideration	225
Direct costs	27
Total fair value	$ 460

The Company allocated 100% of the fair value of the consideration to the Purchased License, which the Company determined is an IPR&D asset. IPR&D assets acquired through an asset purchase that have no alternative future uses and no separate economic values from their original intended purpose are expensed in the period the cost is incurred. As a result, the Company expensed the fair value of the Purchased License during the year ended December 31, 2023.

5) Contract with Customer

On February 21, 2023, the Company and Lineage Cell Therapeutics, Inc. ("Lineage") entered into an exclusive option and license agreement (the "Lineage Agreement"), which provided Lineage with the option (the "Option Right") to obtain an exclusive sublicense of intellectual property from the Company and to request the Company to develop a customized cell line. The Lineage Agreement was amended in August 2023 to provide for changes specifically related to the cell line customization activities such as (i) payment terms, (ii) certain definitions, (iii) certain courses of action if the customized cell line selected by Lineage is not successful and (iv) documentation requirements. Lineage 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, per the amended payment terms. If Lineage obtains the sublicense, the Company would be entitled to receive additional license fees, including milestone payments and royalties.

Pursuant to ASC 606, the Company determined that the Option Right was an unexercised right held by Lineage under the Lineage Agreement at contract inception, as the cell line customization activities and the sublicense were optional purchases at contract inception. These optional purchases of goods and services would be treated as separate contracts if and when Lineage determines that it will make such purchases. Therefore, 100% of the Option Fee was allocated to the Option Right. The Option Fee will remain in deferred revenue until such time that Lineage enters into the sublicense or when the Option Right expires.

The Option Right and the cell line customization activities are accounted for as separate contracts, and the Company has determined that the amended terms discussed above represent a modification to the cell line customization contract. Because there were no goods or services transferred to Lineage before entering into the amendment, and therefore, no previously recognized revenue, there was no catch-up adjustment to revenue required at the time of the amendment.

Lineage will make payments to the Company for the cell line customization activities over the development period. The Company will only earn the remaining full amount of the cell line customization fee if it makes certain progress towards delivery of the customized cell line. The Company has determined that $0.4 million of consideration received could be recognized without the probability of being reversed, and it has placed a constraint on the remaining contractual customization fee. The $0.4 million is being recognized equally over the development period, which is expected to be approximately 20 to 25 months, as the level of effort to perform the services is happening at the same rate over time. If the development period is expected to be longer or shorter than originally planned, the Company will recognize a cumulative catch-up adjustment in the period that such determination is made. For the year ended December 31, 2023, the Company recognized approximately $0.1 million of revenue for the customization activities.

The granting of the license that the Company may provide to Lineage if Lineage exercises the Option Right is not considered a performance obligation at this time, as it is an optional request that the customer may make in the future and will be accounted for as a separate contract when the customer exercises the Option Right.

The Company recognizes direct labor and supplies used in the customization activities as incurred and are recorded as a cost of revenue. As provided for in the A&R Factor License Agreement discussed in Note 11, the Company is obligated to pay Factor Limited 20% of any amounts the Company receives from a customer that is related to the licensed technology under the A&R Factor License Agreement, which is also recorded as a cost of revenue.

6) Promissory Note and Convertible Note Financings

On July 14, 2023, the Company received $8.7 million from a private placement in which the Company issued $8.7 million in aggregate principal amount of convertible notes (the "July 2023 convertible notes") and warrants to purchase an aggregate of approximately 6.1 million shares of its common stock (the "July 2023 warrants"). The Company recognized approximately $0.2 million in fees associated with the transaction.

On December 8, 2023, the Company received $1.5 million in exchange for the issuance of 6% promissory note with an aggregate principal amount of $1.5 million to Charles Cherington. The promissory note was to mature on January 8, 2024, and interest accrued at a rate of 6.0% per annum, payable at maturity. On December 14, 2023, the Company repaid the $1.5 million of principal and $1,500 of accrued interest due under the promissory note. There are no further obligations under the promissory note.

On December 14, 2023, the Company entered into a purchase agreement with certain purchasers for the private placement of $9.2 million of convertible notes (the "December 2023 convertible notes" and together with the July 2023 convertible notes, the "convertible notes") and warrants to purchase an aggregate of approximately 9.6 million shares of the Company's common stock (the "December 2023 warrants" and together with the July 2023 warrants, the "note warrants"). There were two closings under this purchase agreement. The first closing occurred on December 15, 2023, and the Company received $7.8 million and issued $7.8 million of December 2023 convertible notes and December 2023 warrants to purchase approximately 8.1 million shares of our common stock. The second closing, in which the Company received the reaming $1.4 million under the purchase agreement, occurred in January 2024. See Note 18 for additional information regarding the second closing.

See Note 16 for more information on the note warrants.

The July 2023 convertible notes bear interest at 6% per annum, and the December 2023 convertible notes bear interest at 12% per annum, both of which are 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 convertible notes. The July 2023 convertible notes mature on July 14, 2028, and the December 2023 convertible notes issued on December 15, 2023 mature on December 15, 2028, unless earlier converted or repurchased. The Company does not have the option to redeem any of the convertible notes prior to maturity.

At the option of the holders, the convertible notes may be converted from time-to-time in whole or in part into shares of the Company's common stock at an initial conversion rate of, with respect to the July 2023 convertible notes, $2.86 per share and, with respect to the December 2023 convertible notes, $1.9194 per share, subject to customary adjustments for stock splits, stock dividends, recapitalization and the like. As of December 31, 2023, none of the convertible notes were converted into shares of common stock.

The convertible notes do not contain any ratchet or other financial antidilution provisions. The convertible notes contain conversion limitations such that no conversion may be made if the aggregate number of shares of common stock beneficially owned by the holder thereof would exceed 4.99%, 9.99% or 19.99% immediately after conversion thereof, subject to certain increases not in excess of either 9.99% or 19.99% at the option of such holder.

The convertible notes provide for customary events of default which include (subject in certain cases to customary grace and cure periods), among others: nonpayment of principal or interest, breach of covenants or other agreements in the convertible notes; the occurrence of a material adverse effect event (as defined in the related securities purchase agreement) and certain events of bankruptcy. Generally, if an event of default occurs and is continuing under the convertible notes, the holder thereof may require the Company to repurchase some or all of their convertible notes at a repurchase price equal to 100% of the principal amount of the convertible notes being repurchased, plus accrued and unpaid interest thereon.

In connection with the issuance of the December 2023 convertible notes, the Company agreed to reduce the exercise price of the warrants the Company issued in a private placement in December 2022 (see Note 16) to purchase an aggregate of approximately 4.4 million shares of the Company's common stock from $3.28 to $1.43 per share and of the July 2023 warrants from $2.61 to $1.43 per share. The effect of the reduction of the exercise price of these warrants was approximately $1.6 million and measured as the excess of the fair value of the modified instruments over the fair value of the instruments immediately before they were modified. The change in the fair value of the repriced warrants is considered an issuance cost to the December 2023 convertible notes and December 2023 warrants. As such, the $1.6 million was allocated to each of those respective instruments based on their relative fair values, or approximately $0.8 million to each of the December 2023 convertible notes and December 2023 warrants.

The Company determined that there were no embedded derivatives within the convertible notes that required bifurcation from the host agreement. The Company allocated the gross proceeds received, the fees incurred, and as applicable, the impact of repricing the warrants discussed above, over the July 2023 convertible notes and July 2023 warrants and over the December 2023 convertible notes and December 2023 warrants, as applicable, based on their relative fair values as follows (in thousands):

			Allocation of Proceeds and Costs:		Allocation of
	Relative Fair Value	Allocation Percentage	Proceeds	Costs	Proceeds, Net
July 2023 convertible notes	$ 8,715	39.94%	$ 3,481	$ (80)	$ 3,401
July 2023 warrants	13,103	60.06%	5,234	(121)	5,113
	$ 21,818	100.00%	$ 8,715	$ (201)	$ 8,514

			Allocation of Proceeds and Costs:			Allocation of
	Relative Fair Value	Allocation Percentage	Proceeds	Costs	Warrant Repricing	Proceeds, Net
December 2023 convertible notes	$ 9,059	48.83%	$ 3,803	$ (81)	$ (766)	$ 2,956
December 2023 warrants	9,495	51.17%	3,985	(85)	(802)	3,098
	$ 18,554	100.00%	$ 7,788	$ (166)	$ (1,568)	$ 6,054

The Company estimated the fair values of the convertible notes as of July 14, 2023 and December 15, 2023 based off a valuation performed by a third-party specialist using a binomial tree model and the following assumptions:

	Stock Price	Credit Spread	Volatility	Risk-Free Rate
July 2023 convertible notes	$ 2.81	2,500	108%	4.60%
December 2023 convertible notes	$ 1.51	2,000	109%	3.90%

The fair value of the note warrants, all of which qualified for equity classification, was determined using the Black-Scholes pricing model as of each of July 14, 2023 and December 15, 2023 using the following assumptions:

	Stock Price	Exercise Price	Expected Life	Volatility	Dividend	Risk-Free Rate
July 2023 warrants	$ 2.81	$ 2.61	5 years	98%	0.00%	4.04%
December 2023 warrants	$ 1.51	$ 1.43	5 years	101%	0.00%	3.91%

The amount of proceeds allocated to the note warrants resulted in a corresponding reduction in the carrying value of the respective convertible notes as a debt discount, which is amortized with the debt issuance costs as a component of interest expense based on the effective interest rate method over the contractual terms of the convertible notes.

The following table shows the activity that occurred during the year ended December 31, 2023 for the convertible notes on the accompanying consolidated balance sheet:

Gross convertible notes at issuance	$ 16,503
Debt discount and debt issuance costs	(10,146)
Amortization of debt discount and debt issuance costs	303
Paid-in-kind interest added to principal	113
Convertible notes, net, at December 31, 2023	$ 6,773

The future minimum principal payments under the convertible notes as of December 31, 2023 are as follows:

Years ending December 31,	Principal Payments
2024	$ -
2025	-
2026	-
2027	-
2028	16,616
Total	$ 16,616

The Company has recognized approximately $0.6 million in interest expense for the year ended December 31, 2023 for the convertible notes, which includes $0.3 million for the amortization of the debt discount and debt issuance costs. Of the remaining $0.3 million in interest expense, $0.1 million was paid in-kind and added to the principal of the respective notes and $0.2 million of interest is in accrued expenses in the accompanying consolidated balance sheet.

7) Property and Equipment

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

	As of December 31, 2023	2022
Laboratory and manufacturing equipment	$ 40	$ 28
Furniture and fixtures	19	-
Leasehold improvements	274	-
Computer equipment and programs	274	240
	607	268
Less accumulated depreciation and amortization	(114)	(32)
Property and equipment, net	$ 493	$ 236

During the year ended December 31, 2023, the Company recognized a de minimis loss on disposal of fixed assets. During the year ended December 31, 2022, the Company consolidated its research and development activities in Cambridge, Massachusetts and entered into lease termination agreements for its Brooklyn, New York and San Diego, California facilities. As a result, the Company disposed of certain assets it would no longer use and recognized a loss on disposal of fixed assets of approximately $0.3 million, which was composed of $0.6 million in remaining net book value of such assets, offset by proceeds received from selling certain fixed assets for approximately $0.3 million.

Depreciation expense totaled $0.1 million and $0.2 million for the years ended December 31, 2023 and 2022, respectively. No depreciation expense is recorded on fixed assets in process until such time as the assets are completed and are placed into service.

8) Leases

Operating Leases

The Company currently has operating leases for office and laboratory space in (a) the borough of Manhattan in New York, New York, (b) Cambridge, Massachusetts, and (c) Somerville, Massachusetts, which expire in 2026, 2028, and 2033, respectively.

Until March 2022, the Company also leased a facility in Brooklyn, New York. In March 2022, the Company entered into an agreement to assign that lease to an unaffiliated third party, who also agreed to purchase certain equipment from the Company for $50,000, which partially reimbursed the Company for certain existing unamortized leasehold improvements, and to reimburse the Company for the approximately $63,000 security deposit under the lease. Under the assignment agreement, the unaffiliated third party assumed all of the obligations, liabilities, covenants and conditions of the Company as tenant under the lease. As a result of the lease assignment, the Company wrote off the remaining ROU asset balance of approximately $1.4 million and the corresponding lease liability of approximately $1.5 million.

The Company had also leased a facility in San Diego, California. During the second quarter of 2022, the Company determined to consolidate its research and development efforts in Cambridge, Massachusetts and sublease its San Diego lab and office space. As a result, the Company recognized an impairment charge of approximately $0.8 million on the San Diego lease ROU asset during the year ended December 31, 2022. In November 2022, the Company entered into a lease termination agreement, effective January 31, 2023; and as of December 31, 2023, there was no lease liability or ROU asset balances remaining for the San Diego lease.

In October 2022, the Company entered into a sublease with a subsidiary of Bristol-Myers Squibb Company, as sublessor ("Sublessor"), for office, laboratory and research and development space of approximately 45,500 square feet in Somerville, Massachusetts. The lease expires in November 2033 and is subject to a five-year extension. Rent payments under the sublease began on November 29, 2023. The Company pays base rent of approximately $0.5 million per month during the first year of the term, which will increase 3% per year thereafter. The Company also makes monthly payments for parking, which are based on market rates that can change from time to time, and pay its share of traditional lease expenses, including certain taxes, operating expenses and utilities.

The Company paid the Sublessor a security deposit in the form of a letter of credit in the amount of approximately $4.1 million. Provided there are no events of default by the Company under the sublease, the letter of credit will be reduced on an incremental basis throughout the term.

The Sublessor agreed to provide the Company with a tenant improvement allowance ("TIA") of $190 per rentable square foot, or $8.6 million. Tenant improvements in excess of this amount will be at the Company's own cost. Construction was substantially complete in January 2024 and the total out-of-pocket costs for the improvements is estimated to be approximately $2.1 million. As of December 31, 2023, the Company received the entire $8.6 million TIA.

The Company obtained access and control of the premises on June 21, 2023, and as such, the Company determined that the commencement date for accounting purposes was June 21, 2023. The Company also performed an analysis on the accounting ownership of the tenant improvement assets and determined that such assets were sublessor/lessor owned. As a result, TIA payments made by the Sublessor to the Company for the tenant improvement assets are considered a reimbursement rather than a lease incentive and not included as part of the consideration of the contract. Amounts paid by the Company for sublessor/lessor owned assets in excess of the TIA are considered non-cash lease payments and are added to the consideration in the contract.

The Company measured the lease liability and corresponding ROU asset for the sublease as of June 21, 2023, which includes lease payments the Company must make over the ten-year lease term. The Company did not include the option to extend the lease for an additional five years in the initial measurement because the Company was not reasonably certain as of June 21, 2023 that it would exercise its right to extend the lease term. As a result, the Company recorded a lease liability of $34.4 million, which included $0.6 million for the incremental amount above the TIA that the Company expected to pay for sublessor/lessor owned assets as of the initial measurement date, and a corresponding ROU asset of $34.7 million as of June 30, 2023.

In December 2023, the Company incurred additional out-of-pocket expenses of approximately $0.4 million for sublessor/lessor owned assets as a result of out-of-scope changes. These cost changes were accounted for as a lease modification of the existing lease. The Company determined that the lease continued to be classified as an operating lease after modification and remeasured the liability for the remaining unpaid lease payments, including the aggregate $1.0 million of unpaid out-of-pocket costs above the TIA that the Company will pay for sublessor/lessor

owned assets, as well as remeasuring any variable lease payment that is based on an index or rate. The Company also requested a third-party specialist to reassess the incremental borrowing rate, which is the rate of interest that a lessee would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. This reassessment resulted in an increased incremental borrowing rate from 12.7% as of the initial measurement date to 14.4% as of the modification date. The remeasurement resulted in a decrease to the lease liability of approximately $1.6 million with a corresponding adjustment to the ROU asset.

For the years ended December 31, 2023 and 2022, the net operating lease expenses were as follows (in thousands):

	Years ended December 31,	
	2023	2022
Operating lease expense	$ 3,399	$ 595
Sublease income	(84)	(84)
Variable lease expense	136	150
Total lease expense	$ 3,451	$ 661

The tables below show the beginning balances of the operating ROU assets and lease liabilities as of January 1, 2023 and the ending balances as of December 31 2023, including the changes during the period (in thousands).

	Operating Lease ROU Assets
Operating lease ROU assets at January 1, 2023	$ 1,030
Recognition of ROU asset for Somerville Sublease	34,410
Adjustment to ROU asset for remeasurement of Somvervile Sublease liability	(1,620)
Amortization of operating lease ROU assets	(1,039)
Operating lease ROU assets at December 31, 2023	$ 32,781

	Operating Lease Liabilities
Operating lease liabilities at January 1, 2023	$ 1,182
Recognition of lease liability for Somerville Sublease	34,169
Accretion of interest for Somerville Sublease	1,858
Adjustment to lease liablity due to remeasurement of Somerville Sublease	(1,620)
Principal payments on operating lease liabilities	(519)
Operating lease liabilities at December 31, 2023	35,070
Less non-current portion	32,854
Current portion at December 31, 2023	$ 2,216

As of December 31, 2023, the Company's operating leases had a weighted-average remaining life of 9.8 years with a weighted-average discount rate of 14.24%. The maturities of the operating lease liabilities are as follows (in thousands):

	As of December 31, 2023
2024	$ 6,972
2025	6,075
2026	6,238
2027	6,308
2028	6,406
Thereafter	33,879
Total payments	65,878
Less imputed interest	(30,808)
Total operating lease liabilities	$ 35,070

Manhattan Sublease

In April 2019, the Company entered into a sublease with an unaffiliated third party (the "Subtenant"), whereby the Subtenant agreed to sublease approximately 999 square feet of space rented by the Company in the borough of Manhattan in New York, New York commencing on May 15, 2019. 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, 2023 and 2022, respectively. In accordance with ASC Topic 842, 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.

The following tables shows the future payments the Company expects to receive from the Subtenant over the remaining term of the sublease (in thousands):

	As of December 31, 2023
2024	$ 86
2025	88
2026	75
Total payments	$ 249

9) Fair Value of Financial Instruments

The following tables summarize the liabilities that are measured at fair value as of December 31, 2023 and, 2022 (in thousands):

		As of December 31,	
Description	**Level**	**2023**	**2022**
Liabilities:			
Warrant liabilities - Common Warrants	3	$ 116	$ 331
Market Cap Contingent Consideration	3	$ 107	$ -

The Company uses a Black-Scholes option pricing model to estimate the fair value of its warrant liabilities and a Monte Carlo simulation model to estimate the fair value of the Market Cap Contingent Consideration, both of which are considered a Level 3 fair value measurement. The Company remeasures the fair value of the warrant liabilities and the Market Cap Contingent Consideration at each reporting period and changes in the fair values are recognized in the statement of operations.

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 statement of operations.

The following table presents the changes in the liabilities measured at fair value from January 1, 2023, or from the initial measurement date if later than January 1, 2023, through December 31, 2023 (in thousands):

	Warrant Liabilities	Contingent Consideration
Fair value at January 1, 2023	$ 331	$ -
Initial measurement	-	225
Change in fair value	(215)	(118)
Fair value at December 31, 2023	$ 116	$ 107

The Black-Scholes valuation assumptions used at December 31, 2023 for the warrant liabilities were 3.69 years expected term, 3.93% risk-free rate, 103% volatility and 0% dividend yield.

With the assistance of a third-party specialist, the Company assesses the fair value of the Market Cap Contingent Consideration at each quarterly reporting period using the Monte Carlo model, and as of June 30, 2023, determined that the fair value of the contingent consideration had been reduced by approximately $0.1 million from the initial measurement. The Company assessed the fair value of the Market Cap Contingent Consideration as of September 30, 2023 and as of December 31, 2023, and determined that there was no material change to the Market Cap Contingent Consideration for either period, and therefore, did not recognize a change in the fair value of the Market Cap Contingent Consideration since the June 30, 2023 remeasurement. The Company assessed the fair value as of December 31, 2023, and the inputs used for that assessment was risk-free rate of 4.07%, expected term of 2.3 years, stock price of $1.80, volatility of 108% and dividend yield of 0%.

The table below is provided for comparative purposes only and presents information about the fair value of the convertible notes relative to the carrying values recognized in the consolidated balance sheet as of December 31, 2023 (in thousands). The Company did not have any of the convertible notes or similar instruments outstanding as of December 31, 2022.

		December 31, 2023	
	Level	Carrying Value	Fair Value
Convertible Notes	3	$ 16,616	$ 17,594

The carrying value in the table above is shown before the allocation of the proceeds to the note warrants. The Company assesses the fair value of the convertible notes using the binomial model, which is considered a Level 3 measurement. The weighted average inputs used in the binomial model as of December 31, 2023 was stock price of $1.80, credit spread of 1,891, volatility of 109% and risk-free rate of 3.87%.

10) Goodwill and In-Process Research & Development

Goodwill

In November 2018, the Company acquired IRX, which was accounted for as a business combination. The Company recorded goodwill in the amount of $2.0 million related to the acquisition. The Company performed its annual qualitative assessment as of December 31, 2023 and 2022, and based on the assessments, the Company determined that it was more likely than not that the fair value of the entity exceeded its carrying value for such years and that the performance of the quantitative impairment test was not required. Therefore, no impairment was required for any of the periods presented.

In-Process Research & Development

In 2018, Company recorded IPR&D in the amount of $6.0 million, which represented the fair value assigned to technologies that were acquired in connection with the acquisition of IRX in November 2018 and which had not reached technological feasibility and had no alternative future use.

In June 2022, the Company received results from the INSPIRE phase 2 trial of IRX-2, a multi-cytokine biologic immunotherapy, in patients with newly diagnosed stage II, III or IVA squamous cell carcinoma of the oral cavity. The IRX-2 multi-cytokine biologic immunotherapy represents substantially all the fair value assigned to the technologies of IRX that the Company acquired. Despite outcomes that favored IRX-2 in certain predefined subgroups, the INSPIRE trial did not meet its primary endpoint of event-free survival. Significant additional clinical development work would be required to advance IRX-2 in the form of additional Phase 2 and 3 studies to further evaluate the treatment effect of IRX-2 in patient subgroups and in combination with checkpoint inhibitor therapies. The INSPIRE trial was the only Company-sponsored study of IRX-2. Based on the totality of available information, the Company decided not to further develop IRX-2. As such, the Company determined that the carrying value of the IPR&D asset was impaired and recognized a non-cash impairment charge of approximately $6.0 million on the consolidated statement of operations during 2022, which reduced the value of the asset to zero.

11) Related Party Transactions

Agreements with Factor Bioscience Inc. and Affiliates

As of December 31, 2023, the Company had the agreements described below with Factor Bioscience Inc. and/or Dr. Matthew Angel. These agreements have been deemed related party transactions because the Company's former chief executive officer, Dr. Angel, is the chairman and chief executive officer of Factor Bioscience Inc. and a director of its subsidiary, Factor Bioscience Limited ("Factor Limited" and together with Factor Bioscience Inc. and its other affiliates, "Factor Bioscience"). Dr. Angel resigned as the Company's chief executive officer effective December 31, 2023.

In September 2022, the Company entered into a Master Services Agreement (the "MSA") with Factor Bioscience, pursuant to which Factor Bioscience agreed to provide services to the Company as agreed between the Company and Factor Bioscience and as set forth in one or more work orders under the MSA, including the first work order included in the MSA ("WO1"). The MSA contains customary confidentiality provisions and representations and warranties of the parties, and the MSA may be terminated by either party upon 30 days' prior notice, subject to any superseding termination provisions contained in a particular work order.

Under WO1, Factor Bioscience agreed to provide the Company with mRNA cell engineering research support services, including access to certain facilities, equipment, materials and training, and the Company agreed to pay Factor Bioscience an initial fee of $5.0 million, payable in 12 equal monthly installments of approximately $0.4 million. Of the $5.0 million, the Company allocated $3.5 million to the License Fee Obligation (as defined below). Following the initial 12-month period, the Company agreed to continue paying Factor Bioscience the monthly fee of $0.4 million until such time as WO1 is terminated. Upon entering into the MSA, the Company paid a deposit of $0.4 million, which will be applied to the last month of WO1. The Company may terminate WO1 on or after the second anniversary of the date of the MSA, subject to providing Factor Bioscience with 120 days' prior notice. Factor Bioscience may terminate WO1 only on and after the fourth anniversary of the date of the MSA, subject to providing the Company with 120 days' prior notice.

In connection with entering into the MSA, Factor Limited entered into a waiver agreement with Eterna LLC, pursuant to which Factor Limited agreed to waive payment of $3.5 million otherwise payable to it (the "License Fee Obligation") in October 2022 by Eterna LLC under the exclusive license agreement entered into in April 2021 by and among Eterna LLC, Novellus Limited and Factor Limited (the "Original Factor License Agreement"). Under the terms of the waiver agreement, the License Fee Obligation is waived conditionally on the Company paying Factor Bioscience a minimum of $3.5 million due under the MSA.

Because the License Fee Obligation was conditionally waived until the Company paid Factor Bioscience a minimum of $3.5 million under the MSA, the Company recorded a liability of $3.5 million. As of December 31, 2023, there was approximately $1.2 million of the unamortized License Fee Obligation remaining, which is recorded on the accompanying consolidated balance sheet in the "due to related party, current" line item.

In September 2022, Novellus Inc. ("Novellus") and the Company entered into a Second Amendment to the Limited Waiver and Assignment Agreement (the "Waiver and Assignment Agreement") with Drs. Matthew Angel and Christopher Rohde (the "Founders") whereby the Company agreed to be responsible for all future, reasonable and substantiated legal fees, costs, settlements and judgments incurred by the Founders, the Company or Novellus. for certain claims and actions and any pending or future litigation brought against the Founders, Novellus and/or the Company by or on behalf of the Westman and Sowyrda legal matters described in Note 13 (the "Covered Claims"). The Founders will continue to be solely responsible for any payments made to satisfy a judgement or settlement of any pending or future wage act claims. Under the Waiver and Assignment Agreement, the Founders agreed that they are not entitled to, and waived any right to, indemnification or advancement of past, present or future legal fees, costs, judgments, settlement or other liabilities they may have been entitled to receive from the Company or Novellus in

respect of the Covered Claims. The Company and the Founders will share in any recoveries up to the point at which the parties have been fully compensated for legal fees, costs and expenses incurred, with the Company retaining any excess recoveries. The Company has the sole authority to direct and control the prosecution, defense and settlement of the Covered Claims.

In November 2022, following the expiration of one of the milestone deadlines for certain regulatory filings required under the Third Amended and Restated Exclusive License Agreement between Novellus Limited and Factor Limited entered into in November 2020 (the "Novellus-Factor License Agreement"), which permitted Factor Limited to terminate the license granted to Novellus Limited thereunder, the Company entered into the first amendment to the Original Factor License Agreement (as amended, the "2021 Factor License Agreement"), pursuant to which, among other things, Factor Limited granted to Eterna LLC an exclusive, sublicensable license under certain patents owned by Factor Limited (the "Factor Patents") for the purpose of identifying and pursuing certain opportunities to grant to third parties sublicenses to the Factor Patents. The Original Factor License Agreement also (i) terminated the Novellus-Factor License Agreement, (ii) confirmed Factor Limited's grant to Eterna LLC of the rights and licenses Novellus Limited previously granted to Eterna LLC under the Novellus-Factor License Agreement on the same terms and conditions as granted by Novellus Limited to Eterna LLC under such agreement, (iii) confirmed that the sublicense granted by Novellus Limited in accordance with the Novellus-Factor License Agreement to NoveCite, Inc., a company which the Company has a 25% non-controlling interest ("NoveCite"), survived termination of the Novellus-Factor License Agreement; and (iv) removed Novellus Limited from the Original Factor License Agreement and the license agreement entered into on October 6, 2020 between Novellus Limited and NoveCite, Inc, as amended, and replaced Novellus Limited with Factor Limited as the direct licensor to Eterna LLC and NoveCite under such agreements, respectively.

On February 20, 2023, the Company, entered into an exclusive license agreement (the "Feb 2023 Factor Exclusive License Agreement") with Factor Limited, pursuant to which Factor Limited granted to the Company an exclusive, sublicensable, worldwide license under certain patents owned by Factor Limited for the purpose of, among other things, identifying and pursuing certain opportunities to develop products in respect of such patents and to otherwise grant to third parties sublicenses to such patents. The Feb 2023 Factor Exclusive License Agreement, which terminated and superseded the Amended Factor License Agreement, was subsequently terminated and superseded by the A&R Factor License Agreement (as defined below).

On November 14, 2023, the Company entered into an amended and restated exclusive license agreement (the "A&R Factor License Agreement") with Factor Limited to replace in its entirety the exclusive license agreement between the parties dated February 20, 2023 and the amendment thereto. Under the terms of the A&R Factor License Agreement, Factor Limited granted to the Company an exclusive, sublicensable license under certain patents owned by Factor Limited (the "Factor Patents"). The A&R Factor License Agreement also provides for, among other things, the expansion of the Company's license rights to include (i) the field of use of the Factor Patents to include veterinary uses (ii) know-how that is necessary or reasonably useful to practice to the licensed patents, (iii) the ability to sublicense through multiple tiers (as opposed to only permitting a direct sublicense) and (iv) the transfer of technology to the Company, subject to the use restrictions in the A&R Factor License Agreement. The term of the A&R Factor License Agreement expires on November 22, 2027, but will be automatically extended for an additional five years (such period, the "Renewal Term") if the Company pays at least $6.0 million to Factor Limited from fees from sublicenses to the Factor Patents ("Sublicense Fees"), other cash on hand or a combination of both sources of funds. The Company will pay to Factor Limited 20% of any Sublicense Fee received by the Company during the term of the A&R Factor License Agreement. Beginning in September 2024, the Company will also begin paying Factor Limited a monthly maintenance fee of approximately $0.4 million until the expiration of the A&R Factor License Agreement, including any Renewal Term. The Company may terminate the A&R Factor License Agreement upon 120 days' written notice to Factor Limited, and both parties have additional customary termination rights. Under the A&R Factor License Agreement, the Company is obligated to pay the expenses incurred by Factor Limited in preparing, filing, prosecuting and maintaining the Factor Patents and the Company agreed to bear all costs and expenses associated with enforcing and defending the Factor Patents in any action or proceeding arising from pursuit of sublicensing opportunities under the license granted under the A&R Factor License Agreement.

Exacis Asset Acquisition

On April 26, 2023, the Company entered into the Exacis Purchase Agreement to acquire the Exacis Assets, including all of Exacis' right, title and interest in the Purchased License. The Company assumed none of Exacis' liabilities, other than liabilities under the Purchased License that accrue subsequent to the closing date. See Note 4.

The Exacis Acquisition was deemed a related party transaction because Dr. Gregory Fiore, who was the chief executive officer of Exacis at the time of the Exacis Acquisition, was also a member of the Company's board of directors at the time of the Exacis Acquisition. Additionally, Dr. Angel, who was the Company's chief executive

officer at the time of the Exacis Acquisition, was chairman of Exacis' scientific advisory board, and an affiliate of Factor Bioscience was the majority stockholder of Exacis at the time of the Exacis Acquisition.

In October 2022, the Company entered into an Option Agreement on October 8, 2022 with Exacis (the "Exacis Option Agreement"), pursuant to which Exacis granted the Company the option to negotiate and enter into an exclusive worldwide license to certain of the technology licensed by Exacis for the treatment of cancer in humans. The Exacis Option Agreement provided for the Company paying Exacis a fee of $250,000 for the option, which would be creditable against the fees or purchase price payable under any such license if entered into by the Company in accordance with Exacis Option Agreement. The Company did not exercise the option, and the Exacis Option Agreement terminated on December 31, 2022.

Consulting Agreement with Former Director

In May 2023, the Company entered into a consulting agreement with Dr. Fiore, whereby Dr. Fiore agreed to provide business development consulting services to the Company for a monthly retainer of $20,000. The consulting agreement was terminable for any reason by either party upon 15 days' written notice. The Company terminated the consulting agreement, effective July 31, 2023. Dr. Fiore served on the Company's board of directors from June 2022 to October 4, 2023.

July 2023 and December 2023 Financings

Investors in the July 2023 convertible note financing included Brant Binder, Richard Wagner, Charles Cherington and Nicholas Singer, and investors in the December 2023 convertible note financing included Messrs. Cherington and Singer. Each of them participated in the applicable financing under the same terms and subject to the same conditions as all the other investors. See Note 6 for additional information regarding the financings. Mr. Binder served on the Company's board of directors from July 6, 2023 to August 8, 2023, Mr. Wagner served on the Company's board of directors from July 6, 2023 to August 8, 2023, Mr. Cherington served on the Company's board of directors from March 2021 to July 6, 2023, and Mr. Singer served on the Company's board of directors from June 2022 to July 6, 2023.

Q4-22 PIPE

In November 2022, the Company entered into a securities purchase agreement with certain investors providing for the issuance of approximately of 2,185,000 units, each unit consisting of (i) one share of the Company's common stock and (ii) two warrants to purchase shares of the Company's common stock, at a purchase price of $3.53 per unit. The financing closed in December 2022. Messrs. Cherington and Singer invested in the financing on the same terms and subject to the same conditions as all other investors in the financing. Mr. Cherington served on the Company's board of directors from March 2021 to July 6, 2023, and Mr. Singer served on the Company's board of directors from June 2022 to July 6, 2023.

12) Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2023	2022
Legal fees and related	$ 643	$ 1,139
Professional fees	239	124
Somerville facility	218	138
Convertible Notes interest	176	-
Accrued compensation	109	1,065
Clinical	18	570
Other	490	590
Total accrued expenses	$ 1,893	$ 3,626

13) Commitments and Contingencies

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.

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 the Company's 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 Messrs. Sowyrda and Westman. On July 1, 2022, Mr. Westman filed a motion to compel arbitration or in the alternative, to stay the litigation pending the disposition of certain litigation in the Court of Chancery for the State of Delaware filed by Mr. Sowyrda against Novellus LLC, Dr. Christopher Rohde, Dr. Matthew Angel, Leonard Mazur and Factor Bioscience, Inc. captioned *Zelickson et al., v. Angel et al.,* C.A. 2021-1014-JRS and by Mr. Westman against Novellus LLC captioned *Westman v. Novellus LLC*, C.A. No. 2021-0882-NAC (together, the "Delaware Actions"). On July 1, 2022, Mr. Sowyrda answered the complaint and asserted counterclaims against Novellus, Inc, and third-party defendants Dr. Angel and Dr. Rohde alleging violations of the Massachusetts Wage Act, Massachusetts Minimum Fair Wage Law, the Fair Labor Standards Act, breach of contract, unjust enrichment and quantum meruit. Mr. Sowyrda also joined in Mr. Westman's motion to stay the case pending the Delaware Actions. Novellus, Inc.'s claims and Mr. Sowyrda's counterclaims relate to alleged conduct that took place before the Company acquired Novellus, Inc.

On November 15, 2022, prior to a decision on Messrs. Westman's and Sowyrda's motion to compel or stay, the parties agreed to voluntarily dismiss and consolidate the Delaware Actions with this action. On December 15, 2022, Mr. Sowyrda filed an Amended Answer to the Amended Complaint, asserted affirmative defenses and filed Amended Counterclaims against Dr. Angel, Dr. Rohde, Novellus LLC, Novellus Inc., Factor Bioscience Inc., and the Company (collectively, the "Counterclaim Defendants") alleging against various Counterclaim Defendants breach of contract, breaches of the implied duty of good faith and fair dealing, breaches of fiduciary duty, breaches of the operating agreement, aiding and abetting breaches of fiduciary duty, tortious interference with contract, equitable accounting, violations of the Massachusetts Wage Act, Massachusetts Minimum Fair Wage Law, the Fair Labor Standards Act, unjust enrichment, and quantum meruit. Also on December 15, 2022, Mr. Westman filed an answer to the Amended Complaint and asserted similar counterclaims against the same Counterclaim Defendants. Messrs. Westman and Sowyrda each asserted claims for indemnification and/or advancement against Novellus, Inc. On January 11, 2023, Messrs. Westman and Sowyrda served a joint motion to enforce their advancement and/or indemnification rights against Novellus Inc. Novellus Inc. vigorously opposes this motion and served its opposition on January 27, 2023. On February 8, 2023, Messrs. Westman and Sowyrda served a reply in support of their motion to enforce indemnification/advancement rights, and submitted the motion to the Court. Novellus Inc. answered Messrs. Westman and Sowyrda's counterclaims on January 27, 2023, denying liability. The remaining Counterclaim Defendants served a motion to dismiss most of the remaining counterclaims on January 27, 2023. The Court entered an order granting the Counterclaim Defendants' motion to dismiss and denying Messrs. Sowyrda and Westman's motion to enforce on June 15, 2023. The Court's order dismissed all of Mr. Westman's claims against Counterclaim Defendants except his claim for indemnification, and all of Mr. Sowyrda's claims except his claim for indemnification and his employment-related claims, which Counterclaim Defendants did not move to dismiss. On July 6, 2023, Messrs. Westman and Sowyrda filed a petition for interlocutory review with a single justice of the Massachusetts Appeals Court, seeking to overturn the judge's decision granting the Counterclaim Defendants' motion to dismiss most of the remaining counterclaims, but not the decision denying Messrs. Westman and Sowyrda's motion to enforce advancement rights. On July 25, 2023, the parties to the appeal filed a joint motion to the single justice in the appellate court to stay the appeal to allow for amended counterclaims to be filed by Counterclaim Plaintiffs and a motion to dismiss to be filed by Counterclaim Defendants. Counterclaim Plaintiffs filed an initial set of amended counterclaims on August 15, 2023. Counterclaim Plaintiffs amended and refiled their amended counterclaims on September 29, 2023. Counterclaim Defendants served their motion to dismiss all of the amended counterclaims, except for Mr. Sowyrda's employment-related claims, on October 13, 2023.

Under applicable Delaware law and Novellus Inc.'s organizational documents, the Company may be required to advance or reimburse certain legal expenses incurred by former officers and directors of Novellus, Inc. in connection with the foregoing matters. However, a future advance or reimbursement is not currently probable nor can it be reasonably estimated.

eTheRNA Immunotherapies NV and eTheRNA Inc. v. Eterna Therapeutics Inc. C.A. No. 123CV11732

On July 31, 2023, eTheRNA Immunotherapies NV and eTheRNA Inc. filed a complaint in court against the Company alleging: (1) federal trademark infringement; (2) federal unfair competition; (3) Massachusetts state common law trademark infringement; (4) Massachusetts state unfair competition. Service of process for the

complaint was completed on August 1, 2023. The Company's answer was filed on October 10, 2023. At this stage in the litigation, the Company is not able to predict the probability of a favorable or unfavorable outcome.

Dhesh Govender v. Eterna Therapeutics LLC, et al., Index No. 650847/2021 (N.Y. Sup. Ct. N.Y. Cty. 2021)

On or about February 5, 2021, Dhesh Govender, a former short-term consultant of Eterna LLC, filed a complaint against Eterna LLC and certain individuals that plaintiff alleged were directors of Eterna LLC. Plaintiff alleged that Eterna LLC and certain of its officers and directors engaged in unlawful and discriminatory conduct based on race, national origin and hostile work environment. Plaintiff also asserted various breach of contract, fraud and quantum meruit claims based on an alleged oral agreement pursuant to which he alleged Eterna LLC agreed to hire him as an executive once the merger involving the Company and NTN Buzztime, Inc. was completed. On December 15, 2022, the parties executed a Confidential Settlement Agreement and Release of All Claims. On January 11, 2023, the parties filed a Stipulation to Discontinue in the Court action. Also on January 11, 2023, plaintiff voluntarily dismissed the arbitration.

John Westman v. Novellus, Inc., Christopher Rohde, and Matthew Angel, Civil Action No. 2181CV01949 (Middlesex County (Massachusetts) Superior Court)

On or about September 7, 2021, John Westman, a former employee of Novellus, Inc. filed a complaint in Middlesex County (Massachusetts) Superior Court against Novellus, Inc. and Novellus, Inc.'s founders and former executives, Dr. Rohde and Dr. Angel. The case includes allegations that Novellus, Inc. violated the Massachusetts Wage Act. The Company acquired Novellus, Inc. on July 16, 2021. Mr. Westman's claims relate to alleged conduct that took place before the Company acquired Novellus, Inc. Mr. Westman agreed to dismiss the lawsuit and proceed with his claims in arbitration. Following mediation, the parties settled this dispute in December 2022.

The aggregate settlement amount payable by the Company for the Westman and Govender matters discussed above was approximately $0.5 million, both of which were recognized as expense in the consolidated statement of operations for the year ended December 31, 2022 and were fully paid during the year ended December 31, 2023.

Emerald Private Equity Fund, LLC Matter

By a letter dated July 7, 2021, Emerald Private Equity Fund, LLC ("Emerald"), a stockholder of the Company, made a demand pursuant to 8 Del. C. 220 to inspect certain books and records of the Company. The stated purpose of the demand was to investigate possible wrongdoing by persons responsible for the implementation of the merger involving the Company and NTN Buzztime, Inc. and the issuance of paper stock certificates, including investigating whether: (i) the Company's stock certificates were issued in accordance with the merger agreement; (ii) certain restrictions on the sale of the Company's common stock following the merger were proper and applied without favor; (iii) anyone received priority in post-merger issuances of the Company's stock certificates that allowed them to benefit from an increase in the trading price of the Company's common stock; and (iv) it should pursue remedial measures and/or report alleged misconduct to the SEC. The Company responded to the demand letter and produced certain information to Emerald in connection with the demand, which is subject to the terms of a confidentiality agreement entered into among the parties, including certain additional stockholders who subsequently joined as parties to such agreement. Following discussions, with no admission of wrongdoing, the Company and Emerald entered into a confidential settlement agreement, pursuant to which the Company paid $1.2 million in 2022 in full settlement of all of the Emerald's purported claims, including a release by the Emerald in favor of the Company in respect of any and all such claims.

Licensing Agreements

Factor Limited

On November 14, 2023, the Company and Factor Limited entered into the A&R Factor License Agreement, which terminated and superseded the exclusive license agreement between the parties dated February 20, 2023 and the amendment thereto. See Note 11 for additional information regarding the A&R Factor License Agreement.

The Company has other license, collaboration and royalty agreements with third parties related to IRX-2, including an agreement entered into with University of South Florida Research Association, Inc. ("USFRF") in February 2024 to revoke certain license agreements with USFRF related to IRX-2. The Company does not intend to further develop IRX-2 and has provided USFRF with notice that the Company intends to abandon the IRX-2 patents. USFRF has 30 days to provide the Company with its notice to assume control of such patents. As a result of abandoning the IRX-2 patents, the Company will no longer have any obligations under the existing related agreements. existing related agreements.

Retirement Savings Plan

The Company established a defined contribution plan, organized under Section 401(k) of the Internal Revenue Code, which allows employees to defer up to 90% of their pay on a pre-tax basis. Beginning on January 1, 2023, the Company began matching 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%. For the year ended December 31, 2023, the Company matched less than $0.1 million towards employees' 401k contributions.

14) 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,	
	2023	2022
Numerator:		
Net loss attributable to common stockholders	$ (21,684)	$ (24,595)
Denominator:		
Weighted average shares outstanding - basic and diluted	5,314	3,051
Net loss per common share - basic and diluted	$ (4.08)	$ (8.06)

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 warrants, stock options, 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, 2023 and 2022, as their effect was anti-dilutive (in thousands):

	Years ended December 31,	
	2023	2022
Warrants	18,922	4,713
Convertible Notes converted into common stock	7,877	-
Stock options	389	359
Preferred stock converted into common stock	18	7
RSUs	1	4
Total potential common shares excluded from computation	27,207	5,083

15) 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 724,000 shares of common stock that can be issued under the Restated 2020 Plan, which includes an increase to the Restated 2020 Plan of 300,000 that was approved by the Company's stockholders at the 2023 annual meeting of stockholders on June 16, 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"). As of January 1, 2023, pursuant to the evergreen provision, the number of shares issuable under the Restated 2020 Plan was increased by approximately 256,000. Based on the number of shares of common stock outstanding on December 31, 2023, as of

January 1, 2024, pursuant to the evergreen provision, the number of shares issuable under the Restated 2020 Plan was increased by approximately 271,000.

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, 2023, there was approximately 684,000 shares of common stock remaining to be issued under the Restated 2020 Plan. As of December 31, 2023, there were approximately 296,000 stock options outstanding under the Restated 2020 Plan and no RSUs granted under the Restated 2020 Plan were outstanding.

The 2021 Inducement Plan provides for the grant of up to 75,000 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, 2023, there was approximately 68,000 shares of common stock remaining to be issued under the 2021 Inducement Plan. As of December 31, 2022, there were approximately 4,000 stock options outstanding and approximately 1,000 RSUs outstanding that were granted under the 2021 Inducement Plan.

Equity Awards

Stock Options

The Company records stock-based compensation in accordance with ASC Topic 718, Compensation – *Stock Compensation*. 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-lined basis.

The risk-free rate is based on the observed interest rates appropriate for the expected life. The expected life (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 life of the stock option granted, and the Company assumes no dividends. Forfeitures are recognized as incurred.

The following weighted-average assumptions were used for stock options granted during the years ended December 31, 2023 and 2022:

	Year ended December 31,	
	2023	**2022**
Weighted average risk-free rate	3.82%	2.52%
Weighted average volatility	95.15%	90.49%
Dividend yield	0%	0%
Expected term	5.44 years	5.79 years

The following table summarizes stock option activity for the years ended December 31, 2023 and 2022 (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, 2022	199	$ 168	9.38	$ -
Granted	287	17		
Cancelled	(127)	141		
Outstanding December 31, 2022	359	57	7.57	-
Granted	237	4		
Cancelled	(207)	19		
Outstanding December 31, 2023	389	$ 45	7.04	$ -
Options vested and exercisable at December 31, 2023	331	$ 50	6.69	$ -

The per-share weighted average grant-date fair value of stock options granted during the year ended December 31, 2022 and 2021 was $2.99 and $12.91, respectively.

As of December 31, 2023, the unamortized stock-based compensation expense related to outstanding unvested options was approximately $0.6 million with a weighted average remaining requisite service period of 1.91 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.

During the year ended December 31, 2022, the Company accelerated the vesting of approximately 40,000 stock options under certain time-based vesting stock option grants previously awarded to Dr. Howard Federoff, the Company's former chief executive officer, pursuant to a separation agreement entered into with Dr. Federoff. The Company also waived a performance condition under a performance-based stock option grant and accelerated the vesting of approximately 21,000 stock options under such grant. Lastly, the Company extended the post-termination exercise period from 90 days to 36 months immediately following his separation date for any options that were vested, including the options that accelerating in vesting, as described above.

The above modifications to Dr. Federoff's stock options grants resulted in modification accounting under ASC 718, *Compensation – Stock Compensation.* As a result, the Company immediately recognized approximately $0.1 million during 2022 for the incremental fair value of stock options that were vested prior to the modification by calculating the difference between the fair value of the modified award and the fair value of the original award immediately before it was modified. For stock options that were not vested prior to the modification but then vested as a result of the acceleration, the Company reversed any stock compensation expense previously recognized, remeasured the fair value of the modified award and immediately recognized approximately $0.1 million during 2022 of stock compensation expense in full since there was no future service period required to be provided.

Restricted Stock Units

The following table summarizes RSU activity for the years ended December 31, 2023 and 2022 (in thousands except for per-share data):

	Outstanding Restricted Stock Units	Weighted Average Fair Value per Share
January 1, 2022	12	$ 276
Granted	55	39
Released	(3)	271
Cancelled	(60)	61
December 31, 2022	4	236
Cancelled	(3)	199
December 31, 2023	1	$ 322
Balance expected to vest at December 31, 2023	1	$ 322

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 year ended December 31, 2023, less than 1,000 RSUs vested. During the year ended December 31, 2022, approximately 3,000 RSUs vested. The Company withheld approximately 1,000 RSUs to cover withholding taxes, and the net 2,000 shares were issued upon settlement.

Stock-Based Compensation Expense

For the years ended December 31, 2023 and 2022, the Company recognized stock-based compensation expense as follows (in thousands):

	Years ended December 31, 2023	2022
Research and development	$ 234	$ 1,249
General and administrative	1,008	1,686
Total	$ 1,242	$ 2,935

16) Equity and Warrants

Private Placements

Q4-22 PIPE Transaction

On November 23, 2022, the Company entered into a purchase agreement with certain investors pursuant to which the Company issued an aggregate of approximately 2.2 million units, with each unit consisting of (i) one share of common stock and (ii) two warrants, each exercisable to purchase one share of common stock at an exercise price of $3.28 per, at a purchase price of $3.53 per unit (inclusive of $0.125 per warrant). The transaction closed on December 2, 2022. The Company received aggregate gross proceeds of approximately $7.7 million. The Company incurred fees of approximately $0.3 million through December 31, 2022 related to the transaction.

Each warrant had an exercise price of $3.28 per share (subject to customary adjustments), became exercisable six months from the date of issuance, and expires five-and-one-half years from the date of issuance. The warrants meet the criteria for equity classification.

As discussed in Note 6, in connection with the December 2023 convertible note financing, the exercise price of the warrants was reduced from $3.28 per share to $1.43 per share.

Q1-22 Private Placement

On March 6, 2022, the Company entered into a purchase agreement with an investor pursuant to which the Company issued approximately 343,000 units, each unit consisting of (i) one share of the Company's common stock (or, in lieu thereof, one pre-funded warrant to purchase one share of common stock) and (ii) one warrant to purchase one share of common stock, for an aggregate gross purchase price of approximately $12.0 million. The transaction closed on March 9, 2022. The Company issued 275,000 shares of common stock, approximately 68,000 pre-funded warrants and warrants to purchase approximately 343,000 shares of common stock. The Company incurred fees of approximately $1.0 million through December 31, 2022 related to this transaction, which were allocated to the fair value of the pre-funded warrants and warrants and Each pre-funded warrant had an exercise price of $0.10 per share (subject to customary adjustments), was immediately exercisable, could be exercised at any time, and had no expiration date.

Each warrant has an exercise price of $38.20 per share (subject to customary adjustments), became exercisable six months following the date of issuance, and expires five-and-one-half years from the date of issuance.

The pre-funded warrants and warrants were accounted for as liabilities under ASC 815-40, as these warrants provide for a cashless settlement provision that does not meet the requirements of the indexation guidance under ASC 815-40. These warrant liabilities are measured at fair value at inception and on a recurring basis, with changes in fair value presented within the statement of operations. (See Note 9 for more information related to changes in fair value.) Upon exercise, the fair value of the pre-funded warrants and/or warrants on the exercise date is reclassified from warrant liabilities to equity.

The fair values of the pre-funded warrants and warrants at the issuance date totaled $12.6 million in the aggregate, or $0.6 million more than the aggregate gross purchase price of the units sold in the offering. The $0.6 million represents an inducement to the investor to enter into the purchase agreement and was recorded in warrant liabilities expense in the accompanying consolidated statement of operations.

On July 12, 2022, all the pre-funded warrants were exercised. The Company issued approximately 68,000 shares of common stock upon exercise and received approximately $7,000 of proceeds. The fair value of the pre-funded warrants as of the exercise date (approximately $0.7 million) was reclassified from warrant liabilities to equity.

In connection with the transaction, the Company and the investor also entered into a registration rights agreement pursuant to which the Company agreed to prepare and file a registration statement with the SEC to register the resale of the shares of common stock issued in the offering and issuable upon exercise of the pre-funded warrants and warrants. The resale registration statement became effective on May 11, 2022.

Pursuant to the registration rights agreement, the Company is obligated to pay the investor liquidated damages equal to 2% of the purchase price for the units per month, with a maximum aggregate payment of 12 of the purchase price for the units, in the event the investor is not permitted to use the registration statement to resell the securities registered for resale thereunder for more than a specified period of time.

On May 24, 2022, the Company notified the investor that the investor was not able to use the registration agreement because the Company had not timely filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 with the SEC, and that the investor could not use the registration statement until the Company filed that quarterly report, which was filed on June 30, 2022. The Company accrued $0.2 million during 2022 for the contingent loss the Company incurred as liquidated damages as a result of the late filing, which is recorded in other expense, net for the year ended December 31, 2022 in the accompanying consolidated statements of operations. The Company paid the $0.2 million liquidated damages to the investor in June 2022.

Note Warrants

As discussed in Note 6, in connection with the July 2023 and December 2023 convertible note financings, the Company issued note warrants to purchase an aggregate of approximately 14.2 million shares of common stock. The exercise price of all such warrants is currently $1.43 per share (subject to customary adjustments), are expire five years following the date of issuance. All such warrants qualified for equity classification.

The following table shows the Company's warrant activity for the year ended December 31, 2023 (in thousands except for per-share data):

	Q1-22 Common Warrants	Q4-22 Warrants	July 2023 Warrants	December 2023 Warrants	Total Warrants
Balance as of January 1, 2023	343	4,370	-	-	4,713
Granted	-	-	6,094	8,115	14,209
Balance as of December 31, 2023	343	4,370	6,094	8,115	18,922

As of December 31, 2023, the weighted average remaining contractual life of the warrants outstanding was 4.68 years and the weighted average exercise price was $2.10 per share.

SEPA

On April 5, 2023, the Company entered into the SEPA with Lincoln Park, pursuant to which Lincoln Park committed to purchase up to $10.0 million of the Company's common stock. Such sales of common stock by the Company, if any, are subject to certain conditions and limitations set forth in the SEPA, including a condition that the Company may not direct Lincoln Park to purchase any shares of common stock under the SEPA if such purchase would result in Lincoln Park beneficially owning more than 4.99% of the Company's issued and outstanding shares of common stock. Sales under the SEPA may occur from time to time, at the Company's sole discretion, through April 2025.

In consideration of Lincoln Park's entry into the SEPA, the Company issued to Lincoln Park approximately 74,000 shares of common stock (the "Commitment Shares"). The value of the Commitment Shares was recorded as a period expense and included in other expense, net, in the accompanying consolidated statements of operations for year ended December 31, 2023.

The Company evaluated the contract that includes the right to require Lincoln Park to purchase shares of common stock in the future ("put right") considering the guidance in ASC 815-40, *Derivatives and Hedging — Contracts on an Entity's Own Equity* and concluded that it is an equity-linked contract that does not qualify for equity classification, and therefore requires fair value accounting. The Company analyzed the terms of the freestanding put right and concluded that it has an immaterial value as of December 31, 2023.

During the year ended December 31, 2023, the Company issued and sold approximately 214,000 shares of common stock under the SEPA, including the 74,000 Commitment Shares, for gross proceeds of approximately $0.3 million. As of December 31, 2023, there were approximately 2,860,000 shares remaining to be sold under the SEPA.

In connection with entry into the SEPA, the Company terminated its prior purchase agreements with Lincoln Park entered into during 2021.

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, 2023.

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 paid approximately $16,000 in cash for payment of dividends during the years ended December 31, 2023 and 2022.

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 that are surrendered for conversion divided by the conversion rate. At December 31, 2023, the conversion rate was 8.8016 and, based on that conversion rate, one share of Series A Preferred Stock would have converted into approximately 0.11 shares of common stock, and all the outstanding shares of the Series A Preferred Stock would have converted into approximately 18,000 shares of common stock in the aggregate. There were no conversions during the years ended December 31, 2023 and 2022. 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:

1. 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.

2. 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.

3. 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.

17) Income Taxes

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

	Years ended December 31,	
	2023	2022
(in thousands)		
Domestic	$ (21,654)	$ (24,513)
Foreign	(17)	(21)
Total loss before income taxes	$ (21,671)	$ (24,534)

For each of the years ended December 31, 2023 and 2022, current tax provisions and current deferred tax provisions were recorded as follows (in thousands):

	Years ended December 31,	
	2023	2022
Current Tax Provision		
Federal	$ -	$ -
State	1	4
Foreign	-	-
	1	4
Deferred Tax Provision		
Federal	(2,155)	(6,851)
State	8	(1,602)
Foreign	(2)	(187)
	(2,149)	(8,640)
Change in valuation allowance	2,145	8,681
Total tax (benefit) provision for income taxes	$ (3)	$ 45

Deferred tax assets and liabilities consist of the effects of temporary differences as shown in the table below (in thousands). Deferred tax assets have been fully reserved by a valuation allowance since it is more likely than not that such tax benefits will not be realized.

	As of December 31, 2023	As of December 31, 2022
Deferred Tax Assets:		
Net operating losses	$ 12,740	$ 9,382
Foreign net operating losses	784	782
Stock compensation	2,141	2,173
In-process research and development	1,009	1,233
Capitalized rearch and development expenses	3,105	1,502
R&D credit carryforwards	437	517
Compensation accrual	3	81
ROU Liabilities	8,932	334
Other	132	549
Total gross deferred tax assets	29,283	16,553
Valuation allowance	(18,302)	(16,157)
Net deferred tax assets	10,981	396
Deferred Tax Liabilities:		
Fixed assets	(6)	(10)
ROU Assets	(8,349)	(291)
Convertible debt	(2,507)	-
Intangibles - goodwill	(179)	(160)
Total deferred tax liabilities	(11,041)	(461)
Net deferred taxes	$ (60)	$ (65)

The reconciliation of computed expected income taxes to effective income taxes by applying the federal statutory rate of 21% is as follows:

	As of December 31, 2023	As of December 31, 2022
Tax at federal income tax rate	21.00%	21.00%
State income tax, net of federal tax	4.92%	6.52%
Foreign tax differential	(0.01%)	(0.01%)
Non-deductible expenses/excludable items	(0.74%)	6.09%
Change in valuation allowance	(9.90%)	(35.38%)
Convertible debt	(11.92%)	0.00%
Credits	0.00%	0.98%
Uncertain tax positions	0.00%	(0.49%)
Other	(3.34%)	1.11%
Benefit (provision) for income taxes	0.01%	(0.18%)

The net increase in the total valuation allowance for the year ended December 31, 2023 was an increase of approximately $2.1 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 difference 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, 2023 and 2022, the Company has available net operating loss ("NOL") carryforwards of approximately $48.4 million and $35.6 million for federal income tax purposes, respectively, of which approximately $48.4 million can be carried forward indefinitely. The Company has available $39.6 million and $28.8 million state NOLs for the years ended December 31, 2023 and 2022, 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, 2023 and 2022, 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.

At December 31, 2023 and 2022 the Company has federal and state income tax credit carryforwards of approximately $0.4 million and $0.5 million, respectively. 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, 2023 and 2022 (in thousands):

	As of December 31,	
	2023	2022
Beginning balance of uncertain tax positions	$ 121	$ -
Additions based on current year's tax positions	-	45
Net changes based on prior year's tax positions	272	76
Ending balance of uncertain tax positions	$ 393	$ 121

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, 2023 or December 31, 2022.

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, 2023, the 2020 – 2023 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.

On August 16, 2022, the Inflation Reduction Act of 2022 (the "IRA") was enacted into law. Among other changes to the tax code, the IRA imposes a 1% excise tax on certain repurchases of corporate stock by certain publicly traded corporations. The 1% stock buyback tax applies to redemptions by domestic corporations occurring in taxable years beginning after December 31, 2022. A number of exceptions to the stock buyback tax are available including exceptions to certain reorganizations. However, while these exceptions may be helpful in limiting the application of the stock buyback tax in situations in which it was not intended to apply, more guidance will be necessary for taxpayers to analyze the potential application of these exceptions and whether they will be able to rely upon them.

18) Subsequent Event

CEO Inducement Grant

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 1,685,000 shares of the Company's common stock. The stock option has an exercise price of $1.80 per share, which was equal to the fair market value 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).

Remaining Funding Received from December 2023 Financing

On January 11, 2024, the second and final closing of the December 2023 convertible note financing occurred. At this closing, the Company received approximately $1.4 million and issued an aggregate of $1.4 million of December 2023 convertible notes and note warrants to purchase approximately 1.5 million shares of common stock.

The December 2023 convertible notes issued on January 11, 2024 have the same terms as those issued on December 15, 2023, except that the one issued on January 11, 2024 expire on January 11, 2029. The note warrants issued on January 11, 2024 have the same terms as the note warrants issued on December 15, 2023, except that the one issued on January 11, 2024 expire on January 11, 2029. See Note 6 for more information regarding the December 2023 convertible note financing, the December 2023 convertible notes and the note warrants.