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, 2022

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 001-39247

IMARA INC.

(Exact name of Registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**81-1523849** **(I.R.S. Employer Identification No.)**
309 Beacon Street, Suite 300, Office 341 **Brookline, Massachusetts** **(Address of principal executive offices)**	**02446** **(Zip Code)**

Registrant's telephone number, including area code: (617) 927-9989

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, par value $0.001 per share	IMRA	The Nasdaq Stock Market LLC

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

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

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

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such 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 Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the Nasdaq Global Select Market on June 30, 2022 was $20,818,052.

The number of shares of Registrant's Common Stock outstanding as of February 6, 2023 was 26,233,901.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders, which the registrant intends to file with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

		Page
PART I		
Item 1.	Business	4
Item 1A.	Risk Factors	9
Item 1B.	Unresolved Staff Comments	52
Item 2.	Properties	52
Item 3.	Legal Proceedings	52
Item 4.	Mine Safety Disclosures	52
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	53
Item 6.	[Reserved]	53
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	54
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	65
Item 8.	Financial Statements and Supplementary Data	65
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	65
Item 9A.	Controls and Procedures	66
Item 9B.	Other Information	66
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	66
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	67
Item 11.	Executive Compensation	68
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	68
Item 13.	Certain Relationships and Related Transactions, and Director Independence	68
Item 14.	Principal Accountant Fees and Services	68
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	69
Item 16	Form 10-K Summary	71

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- statements related to the transactions contemplated by the Agreement and Plan of Merger, dated as of October 13, 2022, or the Merger Agreement, among us, Iguana Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of ours, or Merger Sub, and Enliven Therapeutics, Inc., a Delaware corporation, or Enliven, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Enliven, with Enliven continuing as a wholly owned subsidiary of ours and the surviving corporation of the merger, which we refer to as the Merger;
- anticipated cost savings in connection with our discontinuation of tovinontrine (IMR-687), IMR-261 and our April 2022 workforce reduction;
- the impact of the ongoing COVID-19 pandemic and our response to it;
- our estimates regarding expenses, future revenue, timing of any future revenue, capital requirements and need for additional financing if we decide to pursue any future product development efforts;
- if we decide to pursue any future product development efforts, our plans to develop and, if approved, subsequently commercialize any product candidates;
- the timing of and our ability to submit applications for, obtain and maintain regulatory approvals for any product candidates we may develop if we decide to pursue any future product development efforts;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash, cash equivalents and investments;
- our commercialization, marketing and manufacturing capabilities and strategy if we decide to pursue any future product development and commercialization efforts;
- our expectations regarding our ability to obtain and maintain intellectual property protection for any product candidates we may develop if we decide to pursue any future product development efforts;
- our ability to identify products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives if we decide to pursue any future product development efforts;
- the impact of government laws and regulations;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available if we decide to pursue any future product development efforts;
- our ability to maintain and establish collaborations or obtain additional funding; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act if we decide to pursue any future product development efforts.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

RISK FACTOR SUMMARY

Our business is subject to a number of risks that if realized could materially affect our business, financial condition, results of operations, cash flows and access to liquidity. These risks are discussed more fully in Part I, Item 1A. "Risk Factors" of this Annual Report on Form 10-K. Our principal risks include the following:

- The Merger with Enliven may not be consummated or may not deliver the anticipated benefits we expect;
- Certain provisions of the Merger Agreement may discourage third parties from submitting alternative acquisition proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.
- The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects.
- The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of our common stock, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.
- Lawsuits may be filed against us and the members of our board of directors arising out of the proposed merger, which may delay or prevent the proposed Merger.
- Failure to consummate the Merger may result in us paying a termination fee to Enliven and could harm our common stock price and our future business and operations.
- If we do not successfully consummate the Merger with Enliven, our board of directors may dissolve or liquidate our assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such transaction or liquidation.
- Our decision to discontinue research and development activities and the related reduction in our workforce may not result in the anticipated savings and could disrupt our business
- We have incurred significant losses since our inception, and we expect to incur losses over the next several years.
- If the Merger is not completed, we will reconsider our strategic alternatives, including dissolving and liquidating our assets, pursuing another strategic transaction, or operating our business. Our future capital requirements depend on many factors, and adequate additional financing may not be available to us on acceptable terms, or at all.
- Our limited operating history may make it difficult for you to evaluate the success and operations of our business to date and to assess our future viability or strategy with respect to conducting ongoing operations or liquidations.
- Our business and operations have been and may continue to be adversely affected by the ongoing COVID-19 pandemic, as may the operations of our suppliers and manufacturers and other third-party service providers.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. If we decide to pursue any future product development efforts, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.
- If we decide to pursue any future product development efforts, we expect to face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- If we are unable to obtain, maintain, enforce and protect patent protection for our technology and any product candidates we may seek to develop or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to product candidates we may seek to develop, and our ability to successfully develop and commercialize our technology and any product candidates we may seek to develop may be adversely affected.

PART I

Item 1. Business.

Summary

We are a biopharmaceutical company that has been dedicated to developing and commercializing novel therapeutics to treat patients suffering from serious diseases.

On October 13, 2022, we, Iguana Merger Sub, Inc., a Delaware corporation and our wholly-owned subsidiary, or the Merger Sub, and Enliven Therapeutics, Inc., a Delaware corporation, or Enliven, entered into an Agreement and Plan of Merger, or the Merger Agreement, pursuant to which, among other things, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Enliven, with Enliven continuing as our wholly owned subsidiary and the surviving corporation of the Merger, which transaction is referred to herein as the Merger. If the Merger is completed, the business of Enliven will continue as the business of the combined company.

We expect to devote significant time and resources to the completion of the Merger. However, there can be no assurances that such activities will result in the completion of the Merger. Further, the completion of the Merger may ultimately not deliver the anticipated benefits or enhance shareholder value. If the Merger is not completed, we will reconsider our strategic alternatives. We consider one of the following courses of action to be the most likely alternatives if the Merger is not completed:

- *Dissolve and liquidate our assets*. If, for any reason, the Merger does not close, our board of directors may conclude that it is in the best interest of stockholders to dissolve the company and liquidate our assets. In that event, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims. There would be no assurances as to the amount or timing of available cash remaining to distribute to stockholders after paying our obligations and setting aside funds for reserves.
- *Pursue another strategic transaction*. We may resume the process of evaluating a potential strategic transaction in order to attempt another strategic transaction like the Merger.
- *Operate our business.* Our board of directors may elect to seek new product candidates for development.

Merger Agreement

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, or the Effective Time, (a) each then-outstanding share of Enliven common stock (including shares of Enliven common stock issued upon conversion of Enliven preferred stock, which conversion will occur immediately prior to the Effective Time and shares of Enliven common stock issued in the Financing Transaction (as defined below)) will be converted into the right to receive a number of shares of our common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to the Reverse Stock Split (as defined below)) calculated in accordance with the Merger Agreement (the ratio of such conversion, the Exchange Ratio); and (b) each then-outstanding Enliven stock option to purchase Enliven common stock will be assumed by us, subject to adjustment as set forth in the Merger Agreement.

Subject to the terms and conditions of, and the calculation of the Exchange Ratio pursuant to, the Merger Agreement, it is currently anticipated that upon the closing of the Merger, our pre-Merger stockholders will own approximately 16% of the combined company and pre-Merger Enliven stockholders (including those purchasing Enliven shares in the Financing Transaction) will own approximately 84.1% of the combined company on a pro forma basis, based on the number of shares of our common stock expected to be issued in connection with the Merger.

The provisions for calculating the Exchange Ratio are set forth in the Merger Agreement, and assume a valuation for Enliven equal to $324.6 million, plus the proceeds of the Financing Transaction, and a valuation for us equal to our net cash as of the business day immediately prior to the closing date of the Merger, plus $10 million, in each case as further described in the Merger Agreement. The Exchange Ratio is also based on the relative capitalizations of the companies. For purposes of calculating the Exchange Ratio, shares of our common stock underlying our stock options outstanding immediately prior to the Effective Time with an exercise price per share of less than or equal to $10.00 (as adjusted for the Reverse Stock Split) will be deemed to be outstanding, and all shares of Enliven common stock underlying outstanding Enliven stock options, warrants and other derivative securities will be deemed to be outstanding.

In connection with the Merger, we will seek the approval of our stockholders at a special meeting expected to be held on February 22, 2023 to, among other things, (a) issue the shares of our common stock issuable in connection with the Merger under the rules of The Nasdaq Stock Market LLC, or Nasdaq, pursuant to the terms of the Merger Agreement, or the

Required Voting Proposal, (b) amend our certificate of incorporation to (i) increase the number of authorized shares of our common stock from 200,000,000 shares to 400,000,000 shares and (ii) effect a reverse split of our common stock, at a ratio of not less than 1-for-3 and not more than 1-for-7 and to be determined prior to the Effective Time in accordance with the Merger Agreement, or the Reverse Stock Split, which is intended to ensure that Nasdaq listing requirements are satisfied and (c) amend certain terms of our equity incentive plans as described in the Merger Agreement.

Each of us and Enliven have agreed to customary representations, warranties and covenants in the Merger Agreement, including, among others, covenants relating to (1) using reasonable best efforts to obtain the requisite approvals of our respective stockholders, (2) non-solicitation of alternative acquisition proposals, (3) the conduct of our respective businesses during the period between the date of signing the Merger Agreement and the closing of the Merger, (4) us using reasonable best efforts to maintain the existing listing of our common stock on Nasdaq and causing the shares of our common stock to be issued in connection with the Merger to be approved for listing on Nasdaq prior to the closing of the Merger, (5) us filing with the U.S. Securities and Exchange Commission, or the SEC, and causing to become effective a registration statement to register the shares of our common stock to be issued in connection with the Merger, or the Registration Statement, and (6) each of us and Enliven filing a pre-merger notification requirement under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act.

Consummation of the Merger is subject to certain closing conditions, including, among other things, (1) approval by our stockholders of the Required Voting Proposal, (2) approval by the Enliven stockholders of the adoption of the Merger Agreement, (3) Nasdaq's approval of the listing of the shares of our common stock to be issued in connection with the Merger, (4) the effectiveness of the Registration Statement, (5) our net cash as determined in accordance with the Merger Agreement being between $75 million and $95 million, (6) the waiting period under the HSR Act having expired or been terminated and (7) our closing of the previously announced Asset Sale. The closing condition set forth in clause (2) above was satisfied on January 25, 2023, when the Enliven stockholders approved adoption of the Merger Agreement. The closing condition set forth in clause (4) above was satisfied when the Registration Statement was declared effective by the SEC on January 23, 2023. The closing condition set forth in clause (6) above was satisfied on November 28, 2022, when the waiting period under the HSR Act expired without extension or a request for additional information or documentary material. The closing condition set forth in clause (7) above was satisfied on November 10, 2022, when the Asset Sale was completed.

Each party's obligation to consummate the Merger is also subject to other specified customary conditions, including the representations and warranties of the other party being true and correct as of the date of the Merger Agreement and as of the closing date of the Merger, generally subject to an overall material adverse effect qualification, and the performance in all material respects by the other party of its obligations under the Merger Agreement required to be performed on or prior to the date of the closing of the Merger. Enliven's obligation to consummate the Merger is also subject to the completion of the Financing Transaction such that Enliven receives gross proceeds of at least $131.6 million and our obligation to consummate the Merger is subject to the completion of the Financing Transaction such that Enliven receives gross proceeds of at least $75.0 million.

The Merger Agreement contains certain termination rights of each of us and Enliven, including, subject to compliance with the applicable terms of the Merger Agreement, the right of each party to terminate the Merger Agreement to enter into a definitive agreement for a superior proposal. Upon termination of the Merger Agreement under specified circumstances, we may be required to pay Enliven a termination fee of $3.0 million and Enliven may be required to pay us a termination fee of $9.75 million. In addition, Enliven will be required to pay us a termination fee of $3.0 million if Enliven or we terminate the Merger Agreement at specified times with all conditions to closing of the Merger satisfied other than completion of the Financing Transaction such that Enliven receives gross proceeds of at least $131.6 million or $75 million, respectively.

At the Effective Time, the board of directors of the combined company is expected to consist of nine members, eight of whom will be designated by Enliven and one of whom will be designated by us. Enliven's designees are expected to be the current members of the board of directors of Enliven. Our designee is expected to be Rahul Ballal, our President and Chief Executive Officer.

Concurrently with the execution and delivery of the Merger Agreement, Enliven entered into a common stock purchase agreement, or the Purchase Agreement, with certain new and existing Enliven investors, pursuant to which Enliven agreed to issue and sell to such investors, and such investors agreed to purchase from Enliven, shares of Enliven common stock for an aggregate purchase price of approximately $164.5 million, or the Financing Transaction. The closing of the Financing Transaction is conditioned on the satisfaction or waiver of the closing conditions to the Merger as set forth in the Merger Agreement and other customary closing conditions, and is expected to occur immediately prior to the closing of the Merger, in accordance with the terms of the Purchase Agreement. The shares of Enliven common stock to be issued in connection with the Financing Transaction will be converted into the right to receive a number of shares of our common stock in the Merger in accordance with the Exchange Ratio, or the Converted Financing Stock (subject to the payment of cash in lieu of fractional shares and after giving effect to the Reverse Stock Split).

At or prior to the Effective Time, we will enter into a Contingent Value Rights Agreement, or the CVR Agreement, with a rights agent, or the Rights Agent, pursuant to which our pre-Merger common stockholders will receive one contingent value right (each, a CVR) for each outstanding share of our common stock held by such stockholder on such date. Each CVR will represent the contractual right to receive payments upon the occurrence of certain events related to the Asset Sale, subject to and in accordance with the terms and conditions of, the CVR Agreement.

The contingent payments under the CVR Agreement, if they become payable, will become payable to the Rights Agent for subsequent distribution to the holders of the CVRs. In the event that no such proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that holders of CVRs will receive any amounts with respect thereto. The right to the contingent payments contemplated by the CVR Agreement is a contractual right only and will not be transferable, except in the limited circumstances specified in the CVR Agreement. The CVRs will not be evidenced by a certificate or any other instrument and will not be registered with the SEC. The CVRs will not have any voting or dividend rights and will not represent any equity or ownership interest in us or any of our affiliates. No interest will accrue on any amounts payable in respect of the CVRs.

Asset Purchase Agreement

On September 6, 2022, we entered into an Asset Purchase Agreement, or the Asset Purchase Agreement, with Cardurion Pharmaceuticals, Inc., or Cardurion, providing for the sale of tovinontrine (IMR-687) and all of our other assets related to our PDE9 program, or the Asset Sale. Pursuant to the terms of the Asset Purchase Agreement, we agreed to sell tovinontrine and all of our other assets related to our PDE9 program to Cardurion. As consideration for the Asset Sale, in addition to $250,000 previously paid by Cardurion to us upon execution of a non-binding term sheet, the aggregate purchase price consisted of an upfront cash payment of $34,750,000 upon closing of the transaction and a $10,000,000 potential future payment that may become payable if Cardurion achieves a proof of concept milestone or other specified clinical milestones and a $50,000,000 potential future payment that may become payable if Cardurion achieves specified regulatory and/or commercial milestone events, in each case as described in the Asset Purchase Agreement and subject to the terms of the Asset Purchase Agreement.

The Asset Purchase Agreement contains certain customary representations, warranties and covenants. The Asset Purchase Agreement also contains customary indemnification provisions pursuant to which the parties agree to indemnify each other for certain matters, including, among other things, breaches of certain representations, warranties and covenants in connection with the Asset Sale. At a special meeting of our stockholders held on November 9, 2022, our stockholders voted to approve the Asset Sale. On November 10, 2022, we announced the closing of the Asset Sale.

Business and Programs

Prior to the April 2022 discontinuation of our clinical programs, our business focused on developing and commercializing novel therapeutics to treat patients suffering from rare inherited genetic disorders of hemoglobin, known as hemoglobinopathies, and other serious diseases. Our pipeline was built around tovinontrine, an inhibitor of phosphodiesterase-9, or PDE9. We were evaluating tovinontrine in a Phase 2b clinical trial for the treatment of SCD and ß-thalassemia and had previously announced expectations to evaluate tovinontrine in HFpEF. We had also previously been advancing IMR-261, an activator of nuclear factor erythroid 2–related factor 2, or Nrf2.

Product Candidates

Tovinontrine (IMR-687)

Tovinontrine is a small molecule inhibitor of PDE9 that was sold to Cardurion as part of the Asset Sale.

SCD Program

We conducted the Ardent Phase 2b clinical trial of tovinontrine, a randomized, double-blind, placebo-controlled trial in approximately 115 adult patients with SCD. The Ardent trial followed completion of our Phase 2a clinical trial of tovinontrine in SCD, which demonstrated a well-tolerated safety profile for tovinontrine and potential benefits from tovinontrine with respect to vaso-occlusive crises, or VOCs. In April 2022, we announced the results from interim analyses of the Ardent clinical trial which showed no significant difference in median annualized rate of VOCs in the high-dose tovinontrine group versus placebo in an intent-to-treat population. In addition, no meaningful difference was observed in fetal hemoglobin, or HbF, response in either the high or low dose tovinontrine groups as compared to placebo. Based on the data generated by this interim analysis, we decided to discontinue the Ardent trial as well as the further development of tovinontrine in SCD.

ß-thalassemia Program

We also conducted the Forte Phase 2b clinical trial of tovinontrine, a randomized, double-blind, placebo-controlled trial in approximately 120 patients with ß-thalassemia. In November 2021, we presented data from a pre-specified interim analysis from the Forte trial in patients with transfusion-dependent thalassemia. This initial interim analysis data demonstrated a well-tolerated safety profile for tovinontrine and a trend for reduced transfusion burden in the higher dose cohort. In April 2022, we announced the results from a second interim analysis of the Forte clinical trial that demonstrated no meaningful benefit in transfusion burden or improvement in most disease-related biomarker from treatment with tovinontrine. Based on the data generated by this interim analysis, we decided to discontinue the Forte trial as well as the further development of tovinontrine in ß-thalassemia.

HFpEF Program

We previously announced our expectation to dose the first patient in the SP9IN Phase 2 clinical trial of tovinontrine in HFpEF in the second quarter of 2022. The SP9IN trial was expected to be a randomized, placebo-controlled trial of approximately 170 patients 45 years of age or older with enriched PDE9 expression and persistent symptoms of HFpEF. In April 2022, we decided not to pursue development of tovinontrine in HFpEF and instead to explore strategic options.

IMR-261

We previously commenced research activities for IMR-261 (formerly CXA-10), an activator of Nrf2. In preclinical models of SCD, IMR-261 was observed to activate expression of HbF and reduce VOCs. Furthermore, in a preclinical model of ß-thalassemia, IMR-261 was observed to increase hemoglobin and enhance red blood cell maturation. We had initiated work on drug product manufacturing for IMR-261 as we explored potential clinical development paths in hemoglobinopathies, iron disorders and potentially other areas. In April 2022, we decided to discontinue our development plans with respect to IMR-261 and instead to explore strategic options. As part of our review of strategic options to maximize stockholder value, on November 21, 2022, we provided notice of termination for our two existing license agreements related to IMR-261. The termination of each agreement will be effective on February 16, 2023. We also decided to discontinue prosecution of intellectual property related to IMR-261.

Sales and Marketing

We are not currently conducting sales and marketing efforts with respect to any of our previous programs and our plans for future sales and marketing are dependent on the results of our ongoing strategic evaluation.

Research and Development

We are not currently conducting research and development of any of our previous programs and our plans for future research and development are dependent on the results of our ongoing strategic evaluation.

Intellectual Property

When applicable to our development programs, we strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business, including by seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in our field.

Our future commercial success may depend, in part, on our ability to: obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our intellectual property rights, in particular our patent rights; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating or violating the valid and enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing any products that we develop may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biopharmaceutical companies like ours are generally uncertain and can involve complex legal, scientific and factual issues. We cannot predict whether the patent applications we may pursue will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. We also cannot ensure that patents will issue with respect to any patent applications that we or our licensors may file in the future, nor can we ensure that any of our owned or licensed patents or future patents will be commercially useful in

protecting our product candidates and methods of manufacturing the same. In addition, the coverage claimed in a patent application may be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any products we develop will be protected or remain protectable by enforceable patents. Moreover, any patents that we hold may be challenged, circumvented or invalidated by third parties. See "Risk Factors—Risks Related to Our Intellectual Property" for a more comprehensive description of risks related to our intellectual property.

We generally file patent applications directed to our key programs in an effort to secure our intellectual property positions vis-a-vis these programs. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office may be significantly narrowed before issuance, if issued at all.

In connection with the Asset Sale, our exclusive license agreement, or the Lundbeck Agreement, with H. Lundbeck A/S, or Lundbeck, and all other intellectual property owned by us that related to tovinontrine was assigned to Cardurion. As a result, as of November 10, 2022, we no longer hold a license to the intellectual property that is the subject of the Lundbeck Agreement or own any other intellectual property related to tovinontrine.

As part of our review of strategic options to maximize stockholder value, on November 21, 2022, we provided notice of termination for our two existing license agreements related to IMR-261. The termination of each agreement will be effective on February 16, 2023. We also decided to discontinue prosecution of intellectual property related to IMR-261.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent covering a U.S. Food and Drug Administration, or FDA, approved drug may, in certain cases, be eligible for a patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. If our use of drug candidates or the drug candidate itself receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved use or drug candidate. We also intend to seek patent term extensions in any jurisdictions where available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

In addition to patent protection, we rely upon unpatented trade secrets and confidential know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and confidential know-how are difficult to protect. We seek to protect our proprietary information, in part, using confidentiality agreements with any collaborators, scientific advisors, employees and consultants and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. See "Risk Factors—Risks Related to Our Intellectual Property" for a more comprehensive description of risks related to our intellectual property.

Government Regulation and Product Approvals

Government authorities in the United States at the federal, state and local level, and in other countries and jurisdictions, such as the European Union, or EU, extensively regulate, among other things, the research, development, testing, manufacture, pricing, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of biopharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. While we are not currently developing any product candidates and do not have any products approved for sale, if we decide to pursue any future product development efforts, we would be subject to such government regulation.

Employees and Human Capital Resources

As of December 31, 2022, we had six full-time employees, including one employee with a Ph.D. degree. None of our employees are engaged in research and development or are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate Information

We were incorporated under the laws of the State of Delaware on January 26, 2016. Our principal executive offices are located at 1309 Beacon Street, Suite 300, Office 341, Brookline, MA 02446 and our telephone number is 617-927-9989. Our website address is www.imaratx.com. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission, before deciding to invest in our common stock. The risks described below are not the only risks facing our company. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us, could cause our business, prospects, operating results and financial condition to suffer materially. In such event, the trading price of our common stock could decline, and you might lose all or part of your investment.

Risks Related to the Proposed Merger and Retention of Key Employees

The Merger with Enliven may not be consummated or may not deliver the anticipated benefits we expect.

In April 2022, we announced that we were discontinuing the development of tovinontrine and undertook a strategic review process, which was intended to result in an actionable plan that leverages our assets, capital and capabilities to maximize stockholder value. The strategic review process involved evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction.

On October 13, 2022, we, Iguana Merger Sub, Inc., a Delaware corporation and our wholly-owned subsidiary, or the Merger Sub, and Enliven Therapeutics, Inc., a Delaware corporation, or Enliven, entered into an Agreement and Plan of Merger, or the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Enliven, with Enliven continuing as our wholly owned subsidiary and the surviving corporation of the merger, or Merger. The former Enliven securityholders immediately before the Merger, including those purchasing shares in the Enliven pre-closing financing, are expected to own approximately 84.1% of the aggregate number of shares of the combined company following the Merger, and our securityholders immediately before the Merger are expected to own approximately 15.9% of the aggregate number of shares of the combined company following the Merger, subject to certain assumptions

We are devoting substantially all of our time and resources to consummating the closing of the Merger; however, there can be no assurance that such activities will result in the consummation of the Merger or that such transaction will deliver the anticipated benefits or enhance stockholder value. Any delay in completing the proposed Merger may materially and adversely affect the timing and benefits that are expected to be achieved from the proposed Merger.

Certain provisions of the Merger Agreement may discourage third parties from submitting alternative acquisition proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit each party from soliciting or engaging in discussions with third parties regarding alternative acquisition proposals, except in limited circumstances when such party's board of directors determines in good faith after consultation with outside legal counsel that an unsolicited acquisition proposal constitutes or could reasonably be expected to lead to a superior proposal and that failure to take such action would reasonably be expected to be inconsistent with its fiduciary duties under applicable law. In addition, if the Merger Agreement is terminated by us or Enliven under certain circumstances, including because of a decision of our board of directors to accept a superior proposal, we would be required to pay Enliven a termination fee of $3.0 million. This termination fee may discourage third parties

from submitting alternative takeover proposals to us or our stockholders, and may cause our board of directors to be less inclined to recommend an alternative proposal.

The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects.

The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects. In the event that the Merger is not completed, the announcement of the termination of the Merger Agreement may also adversely affect the trading price of our common stock and our business prospects.

Failure to consummate the Merger may result in us paying a termination fee to Enliven and could harm our common stock price and our future business and operations.

The Merger will not be consummated if the conditions precedent to the consummation of the transaction are not satisfied or waived, or if the Merger Agreement is terminated in accordance with its terms. If the Merger is not consummated, we are subject to the following risks:

- if the Merger Agreement is terminated under certain circumstances, we will be required to pay Enliven a termination fee of $3.0 million; and
- the price of our common stock may decline and remain volatile.

If the Merger does not close for any reason, our board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of our various assets, dissolve or liquidate our assets or seek to continue to operate our business. If we seek another strategic transaction or attempt to sell or otherwise dispose of our remaining assets, there is no assurance that we will be able to do so, that the terms would be equal to or superior to the terms of the Merger or as to the timing of such transaction. If we decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

If we were to seek to continue our business, we would need to determine whether to acquire one or more other product candidates. We would also need to raise funds to support continued operations and re-assess our workforce requirements in consideration of our reduced workforce.

The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of our common stock, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed.

The Merger Agreement has set the exchange ratio for Enliven capital stock being converted into our common stock, and the exchange ratio is based on the outstanding capital stock of Enliven and our outstanding common stock, in each case immediately prior to the closing of the Merger. Applying the exchange ratio formula in the Merger Agreement, our pre-Merger stockholders will own approximately 15.9% of the combined company and pre-Merger Enliven stockholders (including those purchasing Enliven shares in the Financing Transaction) will own approximately 84.1% of the combined company on a pro forma basis, based on the number of shares of our common stock expected to be issued in connection with the Merger. Under certain circumstances further described in the Merger Agreement, however, these ownership percentages may be adjusted upward or downward based on our cash level at the closing of the Merger, and as a result, either our stockholders or the Enliven stockholders could own less of the combined company than expected.

Any changes in the market price of our common stock before the completion of the Merger will not affect the number of shares of our common stock issuable to Enliven's stockholders pursuant to the Merger Agreement. Therefore, if before the completion of the Merger the market price of our common stock declines from the market price on the date of the Merger Agreement, then Enliven's stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date of the Merger Agreement. Similarly, if before the completion of the Merger the market price of our common stock increases from the market price of our common stock on the date of the Merger Agreement, then Enliven's stockholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the Merger Agreement. The Merger Agreement does not include a price-based termination right.

If the Merger is not consummated, we may be unable to retain the services of key remaining members of our management team and, as a result, may be unable to seek or consummate another strategic transaction, properly dissolve and liquidate our assets or continue our business.

If we do not successfully consummate the transaction with Enliven, our board of directors may dissolve or liquidate our assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such transaction or liquidation.

If the Merger does not close for any reason, our board of directors may elect to, among other things, dissolve or liquidate our assets, which may include seeking protection from creditors in a bankruptcy proceeding. If we decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

In the event of a dissolution and liquidation, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations in preparation for the consummation of the Merger. Further, the Merger Agreement contains certain termination rights for each party, and provides that, upon termination under specified circumstances, we may be required to pay Enliven a termination fee of $3.0 million, which would further decrease our available cash resources. If our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under our clinical trials; (ii) obligations under our employment, separation and retention agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of us; and (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of us. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of our liquidation, dissolution or winding up.

Lawsuits may be filed against us and the members of our board of directors arising out of the proposed Merger, which may delay or prevent the proposed Merger.

Putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against us, our board of directors, Enliven, Enliven’s board of directors and others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, and we may not be successful in defending against any such future claims. Lawsuits that may be filed against us, our board of directors, Enliven, or Enliven’s board of directors could delay or prevent the Merger, divert the attention of our management and employees from our day-to-day business and otherwise adversely affect our financial condition.

Certain of our officers and directors may have interests in the proposed Merger that are different from, or in conflict with or in addition to, those of our stockholders generally.

Certain officers and directors of ours may have interests in the proposed Merger that are different from the interests of our stockholders generally, including potentially, among others, the continued service as a director of the combined company, the acceleration of stock option vesting, and continued indemnification.

The closing of the Merger may also result in the acceleration of vesting of options to purchase shares of our common stock held by our executive officers and directors, whether or not there is a covered termination of such officer's employment. In addition, certain of our current directors and executive officers are expected to become directors of the surviving company upon the closing of the Merger, and all of our directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. These interests, among others, may influence our officers and directors and cause them to view the Merger differently from how our stockholders generally may view it.

As a result of our decision to discontinue further investment in tovinontrine and the reductions in our workforce, we have only six full-time employees remaining as of the date of this filing. If we are unable to retain certain of our remaining employees, our ability to consummate the planned Merger may be delayed or seriously jeopardized.

In April 2022, we announced workforce reductions, and current headcount has been reduced to six full-time employees as of the date of this filing. Our cash conservation activities may yield unintended consequences, such as attrition beyond the planned workforce reductions and reduced employee morale, which may cause the remaining employees to seek alternate employment. Competition among biotechnology companies for qualified employees is intense, and the ability to retain the remaining employees is critical to our ability to effectively manage our business and to consummate the planned Merger. Additional attrition could have a material adverse effect on our business and ability to consummate the Merger. In addition, as a result of the reduction in our workforce, we face an increased risk of employment litigation.

Our stockholders potentially may not receive any payment on the contingent value rights and the contingent value rights may otherwise expire valueless.

The Merger Agreement contemplates that, at or prior to the effective time of the Merger, we will enter into a Contingent Value Rights Agreement, or the CVR Agreement, with a rights agent pursuant to which each of our stockholders of record immediately prior to the Merger will receive one contingent value right, or a CVR, for each outstanding share of our common stock held by such stockholder on such date. Each CVR will represent the contractual right to receive payments upon the occurrence of certain events related to the Asset Sale, subject to and in accordance with the terms and conditions of, the CVR Agreement. The right of our stockholders to derive any value from the CVRs will be contingent solely upon the disposition of such assets within the time periods specified in the CVR Agreement.

We may not be able to achieve successful results from the disposition of such assets as described above. If this is not achieved for any reason within the time periods specified in the CVR Agreement, no payments will be made under the CVRs, and the CVRs will expire valueless.

Risks Related to Our Business

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur operating losses for the foreseeable future and may never achieve or maintain profitability.

Our net income was $1.5 million for the year ended December 31, 2022 and our net loss was $51.4 million for the year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of $146.0 million. To date, we have financed our operations primarily through the sale of common stock and the sale of convertible preferred stock. We have historically devoted substantially all of our financial resources and efforts to research and development, including clinical trials and preclinical studies of tovinontrine.

In April 2022, we made the decision to discontinue development of tovinontrine and are not currently developing product candidates. We may never generate revenues that are significant enough to achieve profitability. We are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

If the Merger is not completed, we will reconsider our strategic alternatives, including dissolving and liquidating our assets, pursuing another strategic transaction, or operating our business. Our future capital requirements depend on many factors, and adequate additional financing may not be available to us on acceptable terms, or at all.

We expect to devote significant time and resources to the completion of the Merger. However, there can be no assurances that such activities will result in the completion of the Merger. If the Merger is not completed, we will reconsider our strategic alternatives. We consider one of the following courses of action to be the most likely alternatives if the Merger is not completed:

- Dissolve and liquidate our assets. If, for any reason, the Merger does not close, our board of directors may conclude that it is in the best interest of stockholders to dissolve the company and liquidate our assets. In that event, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims. There would be no assurances as to the amount or timing of available cash remaining to distribute to stockholders after paying our obligations and setting aside funds for reserves.

- Pursue another strategic transaction. We may resume the process of evaluating a potential strategic transaction in order to attempt another strategic transaction like the Merger.

- Operate our business. Our board of directors may elect to seek new product candidates for development.

If our board of directors elects to seek new product candidates for development, we expect that we would incur significant research and development expenses. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate any such future research and development programs or commercialization efforts and/or we could be forced to revise or abandon our current business strategy.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, any product candidates, if approved, may not achieve commercial success. Commercial revenues, if any, will not be derived unless and until we can achieve sales of products, which we do not anticipate for several years, if at all. Accordingly, if we decide to pursue any future product development efforts, we will need to obtain substantial additional funding in connection with our continuing operations.

In April 2021, we entered into a sales agreement, or the Sales Agreement, with Cantor Fitzgerald & Co, LLC, as sales agent, providing for the offering, issuance and sale by us of up to an aggregate $75.0 million of our common stock from time to time in “at-the-market” offerings under a shelf registration statement on Form S-3. As of December 31, 2022, we have issued and sold 231,291 shares of common stock under the Sales Agreement, resulting in net proceeds of $1.4 million after deducting commissions and offering expenses. The extent to which we utilize the Sales Agreement as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, general market conditions and the extent to which we are able to secure funds from other sources. Accordingly, we may not be able to sell shares under the Sales Agreement at prices or amounts that we deem acceptable, and there can be no assurance that we will sell any further common stock pursuant to the Sales Agreement.

As of December 31, 2022, we had cash and cash equivalents of $88.2 million. Our future capital requirements will depend on many factors, including:

- whether we complete the Merger with Enliven and, if the Merger is completed, the capital requirements of the combined company;
- whether we realize the anticipated cost savings in connection with our April 2022 workforce reduction;
- if we decide to pursue any future product development efforts, our ability to bring any such product candidate through preclinical and clinical development, and the timing and scope of these research and development activities;
- the costs of obtaining clinical and commercial supplies of any product candidates we may develop;
- our ability to successfully commercialize any product candidates we may develop;
- the manufacturing, selling and marketing costs associated with any product candidates we may develop, including the cost and timing of establishing our sales and marketing capabilities;
- the amount and timing of sales and other revenues from any product candidates we may develop, including the sales price and the availability of coverage and adequate third-party reimbursement;
- the time and cost necessary to respond to technological and market developments;
- the extent to which we may acquire or in-license product candidates and technologies;
- the impact of the COVID-19 pandemic and our response to it;

- the costs of maintaining, expanding and protecting our intellectual property portfolio; and
- the costs associated with operating as a public company and maintaining compliance with exchange listing and SEC requirements.

We may seek additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital when market conditions are favorable, or for strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis or on terms acceptable to us, we may be required to delay, limit, reduce or terminate any preclinical studies, clinical trials or other activities for any product candidates under development at such time, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize any product candidates.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of the sale of one or more of our product candidates or other assets, equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures or declaring dividends.

If we raise additional funds through the sale of one or more of our product candidates or other assets, collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed or on terms acceptable to us, we may be required to delay, limit, reduce or terminate any product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

We commenced activities in 2016 and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, and undertaking preclinical studies and clinical trials of our product candidates. We have not yet demonstrated our ability to successfully develop any product candidate, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

We expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Each of our announcements regarding the termination of development of tovinontrine and the related workforce reduction, the Asset Sale, and the signing of the Merger Agreement are likely to further increase the variability of our operating results in the coming quarters as compared to prior quarters. Accordingly, our stockholders should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Our ability to use our net operating losses, or NOLs, and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.

We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future; thus, we do not know whether or when we will generate taxable income necessary to utilize our NOLs or research and development tax credit carryforwards. As of December 31, 2022, we had federal NOLs of $123.5 million and state NOLs of $113.8 million.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three year period, is subject to limitations on its ability to utilize its pre-change NOLs and research and development tax credit carryforwards to offset future taxable income. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the past, including as a result of our public offering of shares of common stock in July 2021, and the Merger, if completed, will result in such an ownership change. We may experience additional ownership changes in the future as a result of subsequent changes in our stock ownership (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations.

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 become unavailable to offset future income tax liabilities. As described below in "Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition," the Tax Cuts and Jobs Act, or the TCJA, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. Additionally, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Our business and operations have been and may continue to be adversely affected by the COVID-19 pandemic, as may the operations of our third-party service providers.

The COVID-19 pandemic and government measures taken in response to it have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen. The future progression of the pandemic and its effects on our business and operations are uncertain.

The COVID-19 pandemic has affected our operations to date, including by causing delays in the conduct of clinical trials. While we have not experienced any significant disruptions with the third parties on which we rely, the COVID-19 pandemic, or the spread of another infectious disease, could also negatively affect the operations of our third-party manufacturers, which could result in disruptions in the supply of any product candidates we may develop. In addition, many of our employees are currently working remotely. The COVID-19 pandemic continues to rapidly evolve and could more significantly impact our operations in the future.

Although we are not currently developing any product candidates, if we decide to pursue any future product development efforts, the COVID-19 pandemic may adversely affect our development activities, including our ability to recruit and retain patients in clinical trials, as a result of many factors, including:

- diversion of healthcare resources away from the conduct of our clinical trials in order to focus on pandemic concerns, including the availability of necessary materials, the attention of physicians serving as clinical trial investigators, access to hospitals serving as clinical trial sites, availability of hospital staff supporting the conduct of clinical trials and the reluctance of patients enrolled in clinical trials to visit clinical trial sites;
- potential interruptions in global shipping affecting the transport of clinical trial materials, such as investigational drug product, patient samples and other supplies used in clinical trials;
- the impact of further limitations on travel that could interrupt key clinical trial activities, such as clinical trial site initiations and monitoring activities, travel by our employees, contractors or patients to clinical trial sites, or the ability of employees at any of our contract manufacturers or contract research organizations, or CROs, to report to work, any of which could delay or adversely impact the conduct or progress of clinical trials, and limit the amount of clinical data we will be able to report;
- any future interruption of, or delays in receiving, supplies of clinical trial material from our contract manufacturing organizations, or CMOs, due to staffing shortages, production slowdowns or stoppages or disruptions in delivery systems; and
- availability of future capacity at contract manufacturers to produce sufficient drug substance and drug product to meet forecasted clinical trial demand if any of these manufacturers elect or are required to divert attention or resources to the manufacture of other pharmaceutical products.

Additionally, while the potential economic impact and the duration of the COVID-19 pandemic is difficult to assess or predict, any impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity.

While we expect the impacts of COVID-19 will continue to have some adverse effect on our business, the extent to which COVID-19 impacts our operations will depend on future developments, which remain uncertain and cannot be predicted with confidence, including the duration of the pandemic, new information which may emerge concerning the severity of COVID-19 and variants of COVID-19, the actions to contain COVID-19 or treat its impact and changes in government spending or priorities, among others. The COVID-19 pandemic is a widespread health crisis that continues to adversely affect the global economy and financial markets of many countries, and any economic downturn could also affect our operations, our ability to raise additional funds through public offerings and the volatility of our stock price and trading in our stock. Even after the COVID-19 pandemic has subsided, we may continue to experience adverse impacts to our business as a result of any economic recession or depression that has occurred or may occur in the future.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We do not currently have any product candidates in active development. Future clinical trials of our product candidates, if any, may not be successful. If we are unable to successfully develop or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

As discussed above, if the Merger is not completed, we will reconsider our strategic alternatives, including dissolving and liquidating our assets, pursuing another strategic transaction, or operating our business. If our board of directors elects to seek new product candidates for development, we will face the risks related to discovery, development and commercialization of our product candidates set forth in this section, in addition to other risks described in this Risk Factors section.

Although we have invested a significant portion of our efforts and financial resources in the development of our product candidates, we are not currently actively developing any of our product candidates. If we decide to pursue any future product development efforts, our ability to generate meaningful product revenues will depend heavily on the successful development of our product candidates. To the extent that we pursue any development efforts in the future, our success will depend on several factors, including the following:

- successfully completing clinical trials;
- acceptance by the FDA or other regulatory agencies of regulatory filings;
- expanding and maintaining a workforce of experienced clinical-stage drug development professionals and others to continue to develop our product candidates;
- obtaining and maintaining intellectual property protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other existing therapies, if any;
- obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- patients' willingness to pay out-of-pocket for our product candidates in the absence of coverage and/or adequate reimbursement from third-party payors; and
- maintaining a continued acceptable safety profile following receipt of any regulatory approvals.

Many of these factors are beyond our control, including clinical outcomes, the regulatory review process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive marketing approval for and successfully commercialize any product candidates we seek to develop, or if we experience delays as a result of any of these factors or otherwise, we may need to spend significant additional time and resources to identify additional product candidates, advance them through preclinical and clinical

development and apply for regulatory approvals, which would adversely affect our business, prospects, financial condition and results of operations.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.

The risk of failure for any product candidates we may develop is high. It is impossible to predict when or if any product candidates we may develop will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidate in humans. Clinical trials may fail to demonstrate that any product candidates we may develop are safe for humans and effective for indicated uses. For example, in April 2022 we discontinued development of tovinontrine in SCD and β-thalassemia based on the results of interim analyses of our Ardent and Forte Phase 2b clinical trial of tovinontrine in patients with SCD and β-thalassemia. Even if clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned investigational new drug applications, or INDs, and other regulatory filings in the United States and abroad. We cannot be certain of the timely completion or outcome of our preclinical testing and studies, and cannot predict if the FDA or other regulatory agencies will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of any product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrent with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates we may develop, including:

- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators may decide the design of our clinical trials is flawed, for example if our trial protocol does not evaluate treatment effects in trial subjects for a sufficient length of time;
- clinical trials of any product candidates we may develop may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities would consider likely to predict clinical benefit;
- the number of patients required for clinical trials of any product candidates we may develop may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we may decide, or regulators or IRBs may require us, to suspend or terminate clinical trials of any product candidates we may develop for various reasons, including non-compliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or IRBs may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving any product candidates we may develop, or such requirements may not be as we anticipate;
- the cost of clinical trials of any product candidates we may develop may be greater than we anticipate;
- the supply or quality of any product candidates we may develop or other materials necessary to conduct clinical trials of such product candidates may be insufficient or inadequate;
- any product candidates we may develop may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the trials; and
- regulators may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a risk evaluation and mitigation strategy, or REMS.

If we are required to conduct additional clinical trials or other testing beyond those that we contemplate, if we are unable to successfully complete clinical trials or other testing of any product candidates we may develop, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for any product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling or a REMS that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also change the design or protocol of one or more of our clinical trials, including to add additional patients or arms, which could result in increased costs and expenses and/or delays. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize any product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize any product candidates and may harm our business and results of operations.

The outcome of preclinical studies and earlier-stage clinical trials may not be predictive of the success of later-stage clinical trials.

The outcome of preclinical testing and earlier-stage clinical trials may not be predictive of the success of later-stage clinical trials. Any product candidates we may develop may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. For example, data from the interim analysis in our Ardent Phase 2b clinical trial of tovinontrine in SCD did not replicate our previously observed positive vaso-occlusive crisis data from our Phase 2a and OLE clinical trials of tovinontrine in SCD. Similarly, data from the interim analysis in our Forte Phase 2b clinical trial of tovinontrine in β-thalassemia showed no meaningful benefit from treatment with tovinontrine as compared to placebo, despite previous positive preclinical data for tovinontrine in β-thalassemia. In April 2022, we discontinued the Ardent and Forte trials as well as the further development of tovinontrine in SCD and β-thalassemia.

Several companies in the pharmaceutical and biotechnology industries have suffered similar setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks in any future product development we may pursue. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain

marketing approval of their products. Furthermore, the failure of any product candidate to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of any other product candidates then under development and/or cause the FDA or other regulatory authorities to require additional testing before approving any other such product candidates.

If we decide to pursue any future product development efforts and experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Although we are not currently developing our product candidates, if we decide to pursue any future product development efforts, identifying and qualifying patients to participate in clinical trials for any product candidates we may develop will be critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the trial until its conclusion. We may not be able to initiate or continue clinical trials for any product candidates we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States. We may not be able to identify, recruit, and enroll a sufficient number of patients to complete clinical trials of any product candidate we may develop because of the perceived risks and benefits of such product candidate, the availability of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective subjects and the subject referral practices of physicians, among other factors.

Patient enrollment is affected by a variety of other factors, including:

- the prevalence and severity of the disease under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate under trial;
- the requirements of the trial protocols;
- the availability of existing commercially-available treatments for the indications for which we are conducting clinical trials;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- the conduct of clinical trials by competitors for product candidates that treat the same indications as any product candidates we may develop;
- the ability to identify specific patient populations for biomarker-defined trial cohort(s); and
- the cost to, or lack of adequate compensation for, prospective patients.

Our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for any product candidates we may develop, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause any product candidates we may develop to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more

clinical trials, increase clinical trial costs, delay approval of the affected product candidate and jeopardize our ability to commence sales and generate revenue.

If serious adverse events or unacceptable side effects are identified during the development of any product candidates we may develop, we may need to abandon or limit our development of those product candidates.

Clinical trials by their nature utilize a sample of the potential patient population. Many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented their further development. If we decide to pursue any future product development efforts and any product candidates we develop are associated with undesirable side effects in clinical trials or have characteristics that are unexpected in clinical trials or preclinical testing, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In pharmaceutical development, many compounds that initially show promise in early-stage or clinical testing are later found to cause side effects that delay or prevent further development of the compound.

Additionally, if results of clinical trials reveal unacceptable side effects, we, the FDA or similar regulatory authorities outside of the United States, or the IRBs or Ethics Committees at the institutions in which our studies are conducted could suspend or terminate clinical trials or the FDA or similar foreign regulatory authorities could order us to cease clinical trials or deny approval of any product candidates we may develop for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any clinical trials. If we elect or are forced to suspend or terminate any clinical trial of any product candidates we may develop, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue from such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business.

If any product candidate receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

If we decide to pursue any future product development efforts, the conduct of any clinical trials of product candidates is likely to be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If any product candidate receives regulatory approval, and we, or others, later discover that it is less effective than previously believed, or causes undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a “black box” warning or contraindication;
- decrease or elimination of third-party reimbursement;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

If we decide to pursue any future product development efforts, we may not be successful in our efforts to identify or discover product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

If we decide to pursue any future product development efforts, there can be no assurance that we will be successful in our efforts to identify or acquire potential product candidates. Even if we identify or acquire additional product candidates, there can be no assurance that our development efforts will be successful.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through a sale, strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

Even if any product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any product candidate receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Sales of medical products depend in part on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that any product we may develop is safe, therapeutically effective and cost effective as compared with competing treatments. Efforts to educate the medical community and third-party payors on the benefits of any product candidates we may develop may require significant resources and may not be successful. If any product candidates we may develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and to continue treatment over time and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out of pocket for required co-payments or in the absence of third-party coverage or adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products, if approved, together with other medications.

If we decide to pursue any future product development efforts and we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing any product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties should we pursue developing and commercializing novel therapeutics.

In the future, we expect that we would begin to build a sales and marketing infrastructure to market any product candidates we may develop, if and when approved by the applicable regulatory authority. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts would be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to educate adequate numbers of physicians on the benefits of any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the inability to price products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and we enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we would develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute any product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. If we decide to pursue any future product development efforts, we will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. If any product candidates achieve marketing approval, we expect that they would be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third

parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. There can be no assurance that any product candidates, even if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and process apart from Medicare determinations. As a result, obtaining and maintaining coverage and adequate reimbursement is often time-consuming and costly. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

If we decide to pursue any future product development efforts, our success may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that, if they materialize, could harm our business.

If we decide to pursue any future product development efforts, our future profitability may depend, in part, on our ability to commercialize any product candidates we may develop in markets outside of the United States and the European

Union. If we commercialize any product candidates we may develop in foreign markets, we will be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- tariffs and trade barriers, as well as other governmental controls and trade restrictions;
- other trade protection measures, import or export licensing requirements, economic sanctions or other restrictive actions by U.S. or foreign governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing foreign reimbursement landscapes;
- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

If risks related to any of these uncertainties materializes, it could have a material adverse effect on our business.

Clinical trial and product liability lawsuits against us could divert our resources, could cause us to incur substantial liabilities and could limit commercialization of any products that we may develop.

We face an inherent risk of clinical trial and product liability exposure related to the testing of any product candidates we may develop in clinical trials, and we will face an even greater risk if we commercially sell any products that we may develop. While we currently are not developing any product candidates and have no products that have been approved for commercial sale, the future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. If we cannot successfully defend ourselves against claims that any product candidates or products we may develop caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we currently hold clinical trial liability insurance coverage in amounts we believe to be adequate with respect to completed and discontinued clinical trials, we may need to increase our insurance coverage if we decide to pursue any future product development efforts and or if we commence commercialization of any product candidates. Insurance coverage

is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Risks Related to Our Dependence on Third Parties

We may enter into collaborations with third parties for the development or commercialization of product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates and our business could be adversely affected.

We are not currently party to any sales, marketing, distribution, development, licensing or broader collaboration arrangements with ongoing activities. However, if we do enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may develop. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue commercialization of any product candidates we may develop that achieve regulatory approval or may elect not to continue or renew commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that may divert resources or create competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with any product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of any product candidates;
- a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under

these agreements, our development of any product candidates could be delayed and we may need additional resources to develop any product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

If we are not able to establish or maintain collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

In connection with any future product development efforts, we may decide to collaborate with pharmaceutical or biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical and biotechnology companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop any product candidates or bring them to market.

If we decide to pursue any future product development efforts, we expect to rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may harm our business.

We historically have relied on third-party clinical research organizations to conduct our clinical trials, including our discontinued Ardent and Forte Phase 2b clinical trials in SCD and in β-thalassemia. If we decide to pursue any future product development efforts, we do not expect to independently conduct clinical trials of any such product candidates. We expect we would rely on third parties, such as clinical research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct any such clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities, should we pursue them, might be delayed.

Our reliance on these third parties for research and development activities would reduce our control over these activities but will not relieve us of our responsibilities. For example, we would remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register clinical trials and

post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize any product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors.

We also expect to rely on other third parties to store and distribute drug supplies for any clinical trials we may conduct. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may successfully develop and commercialization of our products, producing additional losses and depriving us of potential product revenue.

If we decide to pursue any future product development efforts, we expect to contract with third parties for the manufacture of any product candidates we may develop for preclinical and clinical testing and would expect to continue to do so for commercialization. This reliance on third parties entails risks, including that such third parties may not be able to comply with applicable regulatory requirements. Any performance failure on the part of our manufacturers could delay clinical development or marketing approval.

We do not have any manufacturing facilities and if we decide to pursue any future product development efforts, we expect to rely on third parties for the manufacture of any product candidates for preclinical and clinical testing. Reliance on third-party manufacturers entails additional risks, including:

- reliance on the third-party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third-party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Any product candidates or products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. Historically, we relied on a single manufacturer of active pharmaceutical ingredient and a different single manufacturer for finished drug product in the development of our product candidates. If we decide to pursue any future product development efforts, we expect we may similarly rely on a single or limited number of manufacturers at each stage of the manufacturing process. If any of our future contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture any product candidates we may develop, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of any product candidates or products we may develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Risks Related to our Intellectual Property

If we are unable to obtain, maintain, enforce and protect patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

If we decide to pursue any future product development efforts, our success will depend in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others or may license from others, particularly patents, in the United States and other countries with respect to any proprietary technology and product candidates we develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to any product candidates we may develop that are important to our business and by in-licensing intellectual property related to our technologies and product candidates. If we are unable to obtain or maintain patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. Therefore, these in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the scope of patent protection outside of the United States is uncertain and laws of non-U.S. countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Further, we may not be aware of all third-party intellectual property rights potentially relating to any product candidates we may develop. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing of the priority application, or in some cases not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and in-licensed patent rights are highly uncertain. Moreover, our owned and in-licensed pending and future patent applications may not result in patents being issued that protect our technology and product candidates, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value of, or narrow the scope of, our patent rights.

Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. 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 product candidates.

Patents may never issue from our patent applications, or the scope of any patent may not be sufficient to provide a competitive advantage. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue

as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in 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 product candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. 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 commercialized. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and product candidates.

Patent terms may be inadequate to protect our competitive position on any product candidates for an adequate amount of time.

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 any product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. 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 commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Given the expected expiration date of these patents, and the fact that safe harbor protections in many jurisdictions permit third parties to engage in development, including clinical trials, these patents may not provide us with a meaningful competitive advantage.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

If we decide to pursue any future product development efforts, it may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in non-U.S. countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug 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. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when any product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any non-U.S. country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering any product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering any product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If a product candidate is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art,

provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings 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 patent rights and our ability to protect, defend and enforce our patent rights in the future.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our current and future licensors' issued patents or other intellectual property. As a result, we or any current or future licensor may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are 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, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such 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, interference proceedings, derivation proceedings, and equivalent proceedings in non-U.S. jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable.

An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third-party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and prospects.

Interference or derivation proceedings provoked by third parties, or brought by us or by our licensors, or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring any product candidates to market.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

If we decide to pursue any future product development efforts, our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell any product candidates we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in non-U.S. jurisdictions such as oppositions before the European Patent Office. Numerous U.S. and non-U.S. issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as any product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third-party's intellectual property.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods, such as methods of manufacture or methods for treatment, related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, be forced to indemnify our customers or collaborators or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, we could also be required to obtain a license from such third-party to continue developing, manufacturing and marketing our technology and product candidates. 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 and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. A finding of infringement could prevent us from commercializing any product candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign any product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, 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 may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

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, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and non-U.S. patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various non-U.S. governmental patent agencies also require compliance with a number of procedural, documentary and other similar provisions during the patent application process. In certain circumstances, we may rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service, outside firms and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our current or future licensors fail to maintain the patents and patent applications covering any product candidates, it may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of non-U.S. countries may not protect our rights to the same extent as the laws of the United States. In addition, the laws of some non-U.S. countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, 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 obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in non-U.S. jurisdictions. The legal systems of certain countries do not favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment.

Proceedings to enforce our intellectual property and proprietary rights in non-U.S. 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, could put 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. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our current or future licensors is 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.

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 owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing any product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed 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 any product 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 be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, or we have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Certain of our employees, consultants and contractors were previously employed at universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require that 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. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. 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, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to seeking patents for any product candidates we may seek to develop, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate

collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, but we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. 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 any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position may be materially and adversely harmed.

Intellectual property rights do not necessarily address all potential threats.

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 or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own;
- 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 applications 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 make the inventions covered by the issued patent or pending patent applications 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 our owned or in-licensed intellectual property rights;
- it is possible that our owned and in-licensed pending patent applications or those we may own or in-license 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;
- our competitors 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 in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect any product candidates;
- we cannot ensure that any patents issued to us or our current or future licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize any product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and

- we may choose not to file a patent in order to maintain certain technology as a trade secrets or know-how, and a third-party may subsequently file a patent application covering such technology.

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

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

If we decide to pursue any future product development efforts, even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of any product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize any product candidates, and our ability to generate revenue will be materially impaired.

If we decide to pursue any future product development efforts, any product candidates we may develop and the activities associated with their development and commercialization, including design, testing, manufacture, packaging, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export, import and adverse event reporting, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside of the United States. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of any such product candidates.

Marketing approval of drugs in the United States requires the submission of a new drug application, or NDA, to the FDA and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the NDA for that product. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, toxicology, and chemistry, manufacturing and controls. We have not submitted an application for or received marketing approval for any product candidates we may develop in the United States or in any other jurisdiction.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations or other third-party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing processes to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of any product candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate in various countries. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for any product candidates may be harmed and our ability to generate revenues will be materially impaired.

We may not be able to obtain or maintain orphan drug designation or exclusivity for any product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

If we decide to pursue any future product development efforts, we may seek orphan drug designation in indications or for any product candidates we develop. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act,

the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because competing drugs containing a different active ingredient can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

On August 3, 2017, the U.S. Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority.

The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process.

If we decide to pursue any future product development efforts, we may seek Fast Track designation for product candidates we may develop. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot be certain that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

Accelerated approval by the FDA, even if granted for any product candidates does not increase the likelihood that any product candidates will ultimately receive full approval.

If we decide to pursue any future product development efforts, we may seek approval of any other product candidates we may develop using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. The FDA makes the determination regarding whether to accept a biomarker as a proposed surrogate endpoint.

Prior to seeking such accelerated approval, we will request feedback from the FDA regarding the eligibility of the drug product candidate for accelerated approval and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of accelerated approval, the FDA will require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be

completed with due diligence and we may be required to evaluate different or additional endpoints in these post-marketing confirmatory trials. In addition, the FDA currently requires as a condition for accelerated approval pre-clearance of promotional materials prior to use, which could adversely impact the timing of the commercial launch of the product.

There can be no assurance that the FDA will agree with our surrogate endpoints or intermediate clinical endpoints, or that we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all.

Moreover, as noted above, for drugs granted accelerated approval, the FDA requires post-marketing trials to confirm the benefit of the drug. These confirmatory trials must be completed with due diligence. We may be required to evaluate additional or different clinical endpoints in these post-marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for any product candidates we may develop, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Even if we do receive accelerated approval, we may not ultimately be able to obtain full FDA approval.

If we decide to pursue any future product development efforts, a failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates from being marketed abroad.

If we decide to pursue any future product development efforts, in order to market and sell our products in the European Union and many other foreign jurisdictions, we or our potential third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the product be approved for reimbursement before the product can be made available for sale in that country. We or our potential third-party collaborators may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and European Union Customs Union. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to European Union rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law of the United Kingdom the body of European Union law governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. 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. 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 FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our 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.

Separately, in response to the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. As of May 26, 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

Accordingly, if a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets

If we decide to pursue any future product development efforts, any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

If we decide to pursue any future product development efforts, any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS. If any product candidate receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, including the adoption and implementation of REMS. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure, among other things, that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies impose and enforce stringent restrictions on manufacturers' communications regarding off-label use, and if we promote our products beyond their approved indications, we may be subject to enforcement action or prosecution arising from off-label promotion. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product. Violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, and other statutes and regulations relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, including the False Claims Act, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have various consequences, including:

- suspension of or restrictions on such products, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension of any ongoing clinical trials;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure or detention;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our products.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a REMS.

Similar restrictions apply to the approval of our products in the European Union. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the European Union's stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory; and the marketing and promotion of authorized drugs, which are strictly regulated in the European Union and are also subject to European Union Member State laws. The failure to comply with these and other European Union requirements can also lead to significant penalties and sanctions.

We may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings.

Healthcare providers, third-party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with healthcare providers and third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Potentially applicable U.S. federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare programs such as Medicare and Medicaid;
- The federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or *qui tam* actions against individuals or entities for knowingly presenting, or causing to be presented to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with specific exceptions) to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value made by that entity to physicians, other healthcare providers and teaching hospitals and ownership and investment interests held by physicians, other healthcare providers and their family members; and
- analogous state laws and regulations, such as state anti- kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant lawsuits or fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding data subjects in the European Union, including personal health data, is subject to the European Union General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that such rules should apply to transfers of personal data from clinical trial sites located in the EEA to the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Given the breadth and depth of changes in data protection obligations, complying with the GDPR's requirements is rigorous and time intensive and requires significant resources and an ongoing review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Similar privacy and data security requirements are either in place or underway in the United States. There are a broad variety of data protection laws that may be applicable to our activities, and a range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act, or CCPA, which became effective on January 1, 2020, is creating similar risks and obligations as those created by GDPR, although the CCPA does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). Many other states have passed similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with current and any future federal and state laws regarding privacy and security of personal information could expose us to fines and penalties. We also face a threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain reimbursement for any of our candidate products that do receive marketing approval and our ability to generate revenue will be materially impaired.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the CARES Act. These Medicare sequester reductions were suspended through the end of March 2022. From April 2022 through June 2022 a 1% sequester cut will be in effect, with the full 2% cut resuming thereafter. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the ACA, there have been and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the TCJA in 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court heard this case on November 10, 2020 and on June 17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing

conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

Current and future legislative efforts may limit the costs for our products, if and when they are licensed for marketing, and that could materially impact our ability to generate revenues.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule to rescind it. With the issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, the Department of Health and Human Services, or HHS, and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule was implemented on January 1, 2023. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, which was implemented on January 1, 2023.

At the state level, legislatures are increasingly passing legislation and implementing 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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for any product candidates or additional pricing pressures.

Finally, outside the United States, in some nations, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

If we or any third-party manufacturers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could harm our business.

If we decide to pursue any future product development efforts, we and any third-party manufacturers we may engage will be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. If we decide to pursue any future product development efforts, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We expect we would contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Liability under certain environmental laws governing the release and cleanup of hazardous materials is joint and several and could be imposed without regard to fault. We also could incur significant costs associated with civil or criminal fines and penalties or become subject to injunctions limiting or prohibiting our activities for failure to comply with such laws and regulations.

Although we currently maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We currently do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of any third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of any product candidates or products. In addition, our supply chain could be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws

or Trade Control laws by United Kingdom, U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Our employees, independent contractors, consultants and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants and vendors. Misconduct by these partners could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or similar foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union Data Protection Directive. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of any collaborators, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyberattacks by malicious third parties. Cyber incidents are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. For example, we have experienced attempts at phishing and e-mail fraud with the goal of causing payments to be transmitted to an unintended recipient. Cyber incidents could also include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The risk of cyber incidents could also be increased by cyberwarfare in connection with the ongoing conflict between Russia and Ukraine, including potential proliferation of malware from the conflict into systems unrelated to the conflict.

While we have not experienced any material system failure, accident, cyber incidents or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position and reputation could be harmed and the further development and commercialization of any product candidates we may develop could be delayed.

Risks Related to Our Common Stock and Our Status as a Public Company

An active trading market for our common stock may not continue to develop or be sustained.

Our shares began trading on the Nasdaq Global Select Market on March 12, 2020. Prior to March 12, 2020, there was no public market for our common stock, and we cannot be certain that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or at all.

If securities analysts do not publish or cease publishing research or reports or publish misleading, inaccurate or unfavorable research about our business or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not have control over these analysts. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analyst will provide favorable coverage. If one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price paid for their shares. The market price for our common stock may be influenced by many factors, including:

- results of or developments in preclinical studies and clinical trials of any product candidates we may develop or those of our competitors or potential collaborators;
- timing of the results of our preclinical studies and clinical trials or those of our competitors;
- our success in commercializing any product candidates, if and when approved;
- the success of competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any product candidates we may develop;
- the results of our efforts to discover, develop, acquire or in-license products, product candidates, technologies or data referencing rights, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, including, without limitation, the current adverse impact of the COVID-19 pandemic and political and economic instability caused by the current conflict between Russia and Ukraine and economic sanctions adopted in response to the conflict; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Such litigation may also cause us to incur other substantial costs to defend such claims and divert management’s attention and resources.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control all matters submitted to stockholders for approval.

As of December 31, 2022, our executive officers and directors and our stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially owned shares representing approximately 39% of our common stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would have significant influence over the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and board of directors; or
- delay or prevent a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

This concentration of ownership may also adversely affect the market price of our common stock.

We have broad discretion in the use of our cash, cash equivalents and investments and may not use them effectively.

Our management has broad discretion in the application of our cash, cash equivalents and investments and could use such funds in ways that do not, despite the exercise of reasonable judgement, improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of any product candidates we may develop. Pending their use, we may invest our cash, cash equivalents and investments in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.

We have never declared or paid cash dividends on our capital stock and we have no current plans to pay cash dividends on our common stock. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock, impair our ability to raise capital through the sale of additional equity securities, and make it more difficult for our stockholders to sell their common stock at a time and price that they deem appropriate. Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such persons sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline.

We currently have on file with the SEC a universal shelf registration statement which allows us to offer and sell registered common stock, preferred stock, debt securities, warrants and/or units from time to time pursuant to one or more offerings up to an aggregate of $200 million, at prices and terms to be determined at the time of sale. In July 2021, we issued and sold 8,333,333 shares of common stock with aggregate gross proceeds of approximately $50 million under this universal shelf registration statement.

Moreover, holders of an aggregate of 11,005,600 shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all 4,654,296 shares of common stock that we may issue under our equity compensation plans and such shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates, vesting arrangements and exercise of options.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until December 31, 2025, although if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $1.0 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some or all of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to take advantage of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an EGC.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that either (i) our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations, such as an exemption from providing selected financial data and an ability to provide simplified executive compensation information and only two years of audited financial statements.

We have incurred and will continue to incur costs as a result of operating as a public company, and our management has devoted and will continued to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an EGC, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements, and will make some activities more time-consuming and costly.

We continuously evaluate these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting with our Annual Reports on Form 10-K. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To comply with Section 404, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public company, we are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted the TCJA, which significantly reformed the Code. The TCJA, as amended by the CARES Act, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for NOLs to 80% of current year taxable income and the elimination of NOL carrybacks, in each case, for NOLs arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely and such NOLs arising in taxable years beginning before January 1, 2021 are generally eligible to be carried back up to five years), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits.

In addition to the CARES Act, as part of Congress' response to the COVID-19 pandemic, economic relief legislation has been enacted in 2020 and 2021 containing tax provisions. In addition, the Inflation Reduction Act, or the IRA, was signed into law in August 2022. The IRA introduced new tax provisions, including a 1% excise tax imposed on certain stock repurchases by publicly traded companies. In the absence of regulatory guidance, the 1% excise tax generally applies to certain acquisitions of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. Regulatory guidance under the TCJA and such additional legislation, is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to the TCJA and additional tax legislation.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our restated certificate of incorporation or for stockholders to amend or repeal our amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which generally prohibits a person who, together with their affiliates and associates,

owns 15% or more of a company's outstanding voting stock from, among other things, merging or combining with the company for a period of three years after the date of the transaction in which the person acquired ownership of 15% or more of the company's outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors, officers and employees.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our restated certificate of incorporation or amended and restated bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which federal courts have exclusive jurisdiction.

These exclusive forum provisions may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We do not currently own or lease any office space. Our headquarters previously consisted of approximately 9,236 square feet of office space in Boston, Massachusetts. In July 2022, we entered into a termination of the office lease agreement covering that space and the termination became effective on August 7, 2022.

Our employees are currently working remotely and we do not anticipate the need for office space for the foreseeable future and we believe that suitable space will be available as and when needed.

Item 3. Legal Proceedings.

We are not party to any material legal proceedings.

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 publicly traded on The Nasdaq Global Market under the symbol "IMRA."

Holders

As of February 3, 2023, there were approximately 15 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our results of operations, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant

Use of Proceeds from Initial Public Offering

On March 16, 2020, we received aggregate net proceeds from our initial public offering of our common stock, or IPO, inclusive of the underwriters' option to purchase additional shares, of approximately $76.5 million, after deducting $6.1 million of underwriting discounts and commissions and $3.9 million of other offering expenses payable by us. The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-236465), which was declared effective by the Securities and Exchange Commission on March 11, 2020. We have used substantially all of the net proceeds from the IPO as of December 31, 2022.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Form Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

We are a biopharmaceutical company that has been dedicated to developing and commercializing novel therapeutics to treat patients suffering from serious diseases.

In April 2022, we announced the results from interim analyses of our Ardent Phase 2b clinical trial of tovinontrine (IMR-687) in patients with sickle cell disease, or SCD, and Forte Phase 2b clinical trial of tovinontrine in patients with ß-thalassemia. Based on the data generated by these interim analyses, we decided to discontinue the Ardent and Forte trials as well as the further development of tovinontrine in SCD and ß-thalassemia. We also decided to discontinue development of tovinontrine in heart failure with preserved ejection fraction, as well as our development plans with respect to IMR-261. In connection with these events, our board of directors approved a reduction in workforce designed to substantially reduce our operating expenses while we undertake a comprehensive assessment of our strategic options to maximize stockholder value.

Following an extensive process of evaluating strategic alternatives, including identifying and reviewing potential candidates for a strategic acquisition or other transaction, on September 6, 2022, we entered into an Asset Purchase Agreement, or the Asset Purchase Agreement, with Cardurion Pharmaceuticals, Inc., or Cardurion, providing for the sale of tovinontrine (IMR-687) and all of our other assets related to our PDE9 program, or the Asset Sale. On November 10, 2022, we announced the closing of the Asset Sale.

On October 13, 2022, we, Iguana Merger Sub, Inc., a Delaware corporation and our wholly-owned subsidiary, or the Merger Sub, and Enliven Therapeutics, Inc., a Delaware corporation, or Enliven, entered into an Agreement and Plan of Merger, or the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Enliven, with Enliven continuing as our wholly owned subsidiary and the surviving corporation of the merger, or Merger. If the Merger is completed, the business of Enliven will continue as the business of the combined organization.

We expect to devote significant time and resources to the completion of the Merger. However, there can be no assurances that such activities will result in the completion of the Merger. Further, the completion of the Merger may ultimately not deliver the anticipated benefits or enhance shareholder value. If the Merger is not completed, we will reconsider our strategic alternatives. We consider one of the following courses of action to be the most likely alternatives if the Merger is not completed:

- *Dissolve and liquidate our assets*. If, for any reason, the Merger does not close, our board of directors may conclude that it is in the best interest of stockholders to dissolve the Company and liquidate our assets. In that event, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims. There would be no assurances as to the amount or timing of available cash remaining to distribute to stockholders after paying our obligations and setting aside funds for reserves.
- *Pursue another strategic transaction*. We may resume the process of evaluating a potential strategic transaction in order to attempt another strategic transaction like the Merger.
- *Operate our business*. Our board of directors may elect to seek new product candidates for development.

Asset Purchase Agreement

Pursuant to the terms of the Asset Purchase Agreement, we agreed to sell tovinontrine and all of our other assets related to our PDE9 program to Cardurion. As consideration for the Asset Sale, in addition to $250,000 previously paid by Cardurion to us upon execution of a non-binding term sheet, the aggregate purchase price consisted of an upfront cash

payment of $34,750,000 upon closing of the transaction and a $10,000,000 potential future payment that may become payable if Cardurion achieves a proof of concept milestone or other specified clinical milestones and a $50,000,000 potential future payment that may become payable if Cardurion achieves specified regulatory and/or commercial milestone events, in each case as described in the Asset Purchase Agreement and subject to the terms of the Asset Purchase Agreement.

The Asset Purchase Agreement contains certain customary representations, warranties and covenants. The Asset Purchase Agreement also contains customary indemnification provisions pursuant to which the parties agree to indemnify each other for certain matters, including, among other things, breaches of certain representations, warranties and covenants in connection with the Asset Sale. At a special meeting of our stockholders held on November 9, 2022, our stockholders voted to approve the Asset Sale. On November 10, 2022, we announced the closing of the Asset Sale.

Merger Agreement

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, or the Effective Time, (a) each then-outstanding share of Enliven common stock (including shares of Enliven common stock issued upon conversion of Enliven preferred stock, which conversion will occur immediately prior to the Effective Time and shares of Enliven common stock issued in the Financing Transaction (as defined below)) will be converted into the right to receive a number of shares of our common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to the Reverse Stock Split (as defined below)) calculated in accordance with the Merger Agreement (the ratio of such conversion, the Exchange Ratio); and (b) each then-outstanding Enliven stock option to purchase Enliven common stock will be assumed by us, subject to adjustment as set forth in the Merger Agreement.

Subject to the terms and conditions of, and the calculation of the Exchange Ratio pursuant to, the Merger Agreement, it is currently anticipated that upon the closing of the Merger, our pre-Merger stockholders will own approximately 16% of the combined company and pre-Merger Enliven stockholders (including those purchasing Enliven shares in the Financing Transaction) will own approximately 84.1% of the combined company on a pro forma basis, based on the number of shares of our common stock expected to be issued in connection with the Merger.

The provisions for calculating the Exchange Ratio are set forth in the Merger Agreement, and assume a valuation for Enliven equal to $324.6 million, plus the proceeds of the Financing Transaction, and a valuation for us equal to our net cash as of the business day immediately prior to the closing date of the Merger, plus $10 million, in each case as further described in the Merger Agreement. The Exchange Ratio is also based on the relative capitalizations of the companies. For purposes of calculating the Exchange Ratio, shares of our common stock underlying our stock options outstanding immediately prior to the Effective Time with an exercise price per share of less than or equal to $10.00 (as adjusted for the Reverse Stock Split) will be deemed to be outstanding, and all shares of Enliven common stock underlying outstanding Enliven stock options, warrants and other derivative securities will be deemed to be outstanding.

In connection with the Merger, we will seek the approval of our stockholders at a special meeting expected to be held on February 22, 2023 to, among other things, (a) issue the shares of our common stock issuable in connection with the Merger under the rules of The Nasdaq Stock Market LLC, or Nasdaq, pursuant to the terms of the Merger Agreement, or the Required Voting Proposal, (b) amend our certificate of incorporation to (i) increase the number of authorized shares of our common stock from 200,000,000 shares to 400,000,000 shares and (ii) effect a reverse split of our common stock, at a ratio of not less than 1-for-3 and not more than 1-for-7 and to be determined prior to the Effective Time in accordance with the Merger Agreement, or the Reverse Stock Split, which is intended to ensure that Nasdaq listing requirements are satisfied and (c) amend certain terms of our equity incentive plans as described in the Merger Agreement.

Each of us and Enliven have agreed to customary representations, warranties and covenants in the Merger Agreement, including, among others, covenants relating to (1) using reasonable best efforts to obtain the requisite approvals of our respective stockholders, (2) non-solicitation of alternative acquisition proposals, (3) the conduct of our respective businesses during the period between the date of signing the Merger Agreement and the closing of the Merger, (4) us using reasonable best efforts to maintain the existing listing of our common stock on Nasdaq and causing the shares of our common stock to be issued in connection with the Merger to be approved for listing on Nasdaq prior to the closing of the Merger, (5) us filing with the U.S. Securities and Exchange Commission, or the SEC, and causing to become effective a registration statement to register the shares of our common stock to be issued in connection with the Merger, or the Registration Statement, and (6) each of us and Enliven filing a pre-merger notification requirement under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act.

Consummation of the Merger is subject to certain closing conditions, including, among other things, (1) approval by our stockholders of the Required Voting Proposal, (2) approval by the Enliven stockholders of the adoption of the Merger Agreement, (3) Nasdaq's approval of the listing of the shares of our common stock to be issued in connection with the Merger, (4) the effectiveness of the Registration Statement, (5) our net cash as determined in accordance with the Merger Agreement being between $75 million and $95 million, (6) the waiting period under the HSR Act having expired or been terminated and (7) our closing of the previously announced Asset Sale. The closing condition set forth in clause (2) above was satisfied on January 25, 2023, when the Enliven stockholders approved adoption of the Merger Agreement. The closing condition set forth in clause (4) above was satisfied when the Registration Statement was declared effective by the SEC on January 23, 2023. The closing condition set forth in clause (6) above was satisfied on November 28, 2022, when the waiting period under the HSR Act expired without extension or a request for additional information or documentary material. The closing condition set forth in clause (7) above was satisfied on November 10, 2022, when the Asset Sale was completed.

Each party's obligation to consummate the Merger is also subject to other specified customary conditions, including the representations and warranties of the other party being true and correct as of the date of the Merger Agreement and as of the closing date of the Merger, generally subject to an overall material adverse effect qualification, and the performance in all material respects by the other party of its obligations under the Merger Agreement required to be performed on or prior to the date of the closing of the Merger. Enliven's obligation to consummate the Merger is also subject to the completion of the Financing Transaction such that Enliven receives gross proceeds of at least $131.6 million and our obligation to consummate the Merger is subject to the completion of the Financing Transaction such that Enliven receives gross proceeds of at least $75.0 million.

The Merger Agreement contains certain termination rights of each of us and Enliven, including, subject to compliance with the applicable terms of the Merger Agreement, the right of each party to terminate the Merger Agreement to enter into a definitive agreement for a superior proposal. Upon termination of the Merger Agreement under specified circumstances, we may be required to pay Enliven a termination fee of $3.0 million and Enliven may be required to pay us a termination fee of $9.75 million. In addition, Enliven will be required to pay us a termination fee of $3.0 million if Enliven or we terminate the Merger Agreement at specified times with all conditions to closing of the Merger satisfied other than completion of the Financing Transaction such that Enliven receives gross proceeds of at least $131.6 million or $75 million, respectively.

At the Effective Time, the board of directors of the combined company is expected to consist of nine members, eight of whom will be designated by Enliven and one of whom will be designated by us. Enliven's designees are expected to be the current members of the board of directors of Enliven. Our designee is expected to be Rahul Ballal, our President and Chief Executive Officer.

Concurrently with the execution and delivery of the Merger Agreement, Enliven entered into a common stock purchase agreement, or the Purchase Agreement with certain new and existing Enliven investors, pursuant to which Enliven agreed to issue and sell to such investors, and such investors agreed to purchase from Enliven, shares of Enliven common stock for an aggregate purchase price of approximately $164.5 million, or the Financing Transaction. The closing of the Financing Transaction is conditioned on the satisfaction or waiver of the closing conditions to the Merger as set forth in the Merger Agreement and other customary closing conditions, and is expected to occur immediately prior to the closing of the Merger, in accordance with the terms of the Purchase Agreement. The shares of Enliven common stock to be issued in connection with the Financing Transaction will be converted into the right to receive a number of shares of our common stock in the Merger in accordance with the Exchange Ratio, or the Converted Financing Stock (subject to the payment of cash in lieu of fractional shares and after giving effect to the Reverse Stock Split).

At or prior to the Effective Time, we will enter into a Contingent Value Rights Agreement, or the CVR Agreement, with a rights agent, or the Rights Agent, pursuant to which our pre-Merger common stockholders will receive one contingent value right (each, a CVR) for each outstanding share of our common stock held by such stockholder on such date. Each CVR will represent the contractual right to receive payments upon the occurrence of certain events related to the Asset Sale, subject to and in accordance with the terms and conditions of, the CVR Agreement.

The contingent payments under the CVR Agreement, if they become payable, will become payable to the Rights Agent for subsequent distribution to the holders of the CVRs. In the event that no such proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that holders of CVRs will receive any amounts with respect thereto. The right to the contingent payments contemplated by the CVR Agreement is a contractual right only and will not be transferable, except in the limited circumstances specified in the CVR Agreement. The CVRs will not be evidenced by a certificate or any other instrument and will not be registered with the SEC. The CVRs will not have

any voting or dividend rights and will not represent any equity or ownership interest in us or any of our affiliates. No interest will accrue on any amounts payable in respect of the CVRs.

Financial Overview

Since our inception in 2016, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of tovinontrine. To date, we have funded our operations primarily through the sale of common stock and the sale of convertible preferred stock.

On April 1, 2021, we filed a shelf registration statement on Form S-3, or the Shelf, with the SEC in relation to the registration and potential future issuance of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof in the aggregate amount of up to $200.0 million. The Shelf was declared effective on April 8, 2021. We also simultaneously entered into a sales agreement, or Sales Agreement, with Cantor Fitzgerald & Co, LLC, or Cantor, as sales agent, providing for the offering, issuance and sale by us of up to an aggregate $75.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf. As of December 31, 2022, we have issued and sold 231,291 shares of common stock under the Sales Agreement, resulting in net proceeds of $1.4 million after deducting commissions and offering expenses. No sales were made under the sales agreement during the twelve months ended December 31, 2022.

On July 16, 2021, we completed a public offering of shares of our common stock and issued and sold 8,333,333 shares of common stock at a public offering price of $6.00 per share, resulting in net proceeds of $46.8 million after deducting underwriting discounts and commissions and estimated offering expenses.

Excluding the gain on the Asset Sale recognized in the current year, we have incurred significant operating losses since inception. Our losses from operations were $34.3 million and $51.4 million for years ended December 31, 2022, and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of approximately $146.0 million. In April 2022, we discontinued development of tovinontrine and implemented reduction in workforce, each of which was designed to substantially reduce our operating expenses while we undertake a comprehensive assessment of our strategic options. In September 2022, we entered into the Asset Purchase Agreement and on November 10, 2022, we announced the closing of the Asset Sale. In October 2022, we entered into the Merger Agreement. Notwithstanding these events, and subject to the closing of the Merger, we expect to continue to incur operating losses for the foreseeable future. In addition, our losses from operations may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the outcome of our strategic process and depending on whether we decide to pursue any future product development efforts.

We are not currently developing any product candidates and we do not have any products approved for sale. If the Merger does not close, if we decide to pursue any future product development efforts, we will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for any future product candidate. In addition, if we obtain regulatory approval for any product candidate and to the extent that it engages in commercialization activities on our own, we expect we will incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing, and distribution activities.

Moreover, if we decide to pursue any future product development efforts, we will need substantial additional funding to support our continuing operations and develop a growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we would expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into other arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when, needed, could have a material adverse effect on our business, results of operations, and financial condition. We will need to generate significant revenue to achieve profitability, and may never do so.

As of December 31, 2022 we had $88.2 million in cash and cash equivalents. We believe that our cash and cash equivalents as of December 31, 2022 will enable us to fund our operating expenses and capital expenditure requirements at least twelve months from the date of filing this Annual Report on Form 10-K. See "—Liquidity and Capital Resources."

Impact of COVID-19 Pandemic

In December 2019, a novel strain of coronavirus, called COVID-19, emerged and has now spread globally. The impact continues to evolve as of the date of this Annual Report on Form 10-K. We continue to actively monitor the impact of the COVID-19 pandemic on our financial condition, liquidity, operations, suppliers, industry and workforce.

Although we have not experienced any significant adverse impact from the COVID-19 pandemic on our financial condition, results of operations or liquidity as of the date of this Annual Report on Form 10-K, the COVID-19 pandemic has resulted in disruptions to our clinical trial operations. In addition, our employees are currently working remotely.

Our financial condition, results of operations and liquidity could be negatively impacted by the impact of the COVID-19 pandemic in future periods. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which remain uncertain and cannot be predicted, including new information that may emerge concerning the continued severity of COVID-19 and variants of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. As the impact of the COVID-19 pandemic continues, it may have an adverse effect on our results of future operations, financial position and liquidity, and on our ability to access capital. Even after the primary impact of the COVID-19 pandemic has subsided, we may continue to experience adverse impacts to our business as a result of any economic recession or depression that has occurred or may occur in the future.

Financial Operations Overview

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If we decide to pursue any future product development efforts and such efforts are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating Expenses

Research and Development. Research and development expenses consist primarily of costs incurred in connection with the preclinical and clinical development and manufacture of our products. We expect our future research and development expenses to decrease significantly as compared to research and development expenses in 2021 and the first half of 2022, as a result of our April 2022 decision to discontinue development of tovinontrine and our related reduction in workforce. For the year ended December 31, 2022, research and development expenses include:

- costs related to the impact of the COVID-19 pandemic;
- personnel-related expenses, including salaries, benefits and stock-based compensation expenses, for individuals involved in research and development activities;
- external research and development expenses incurred under agreements with contract research organizations, or CROs, investigative sites, and consultants that conducted our preclinical studies and clinical trials and other scientific development services;
- costs incurred under agreements with contract manufacturing organizations, or CMOs, who developed and manufactured material for our preclinical studies and clinical trials;
- costs related to compliance with regulatory requirements; and
- milestone fees incurred in connection with our license agreement with Lundbeck.

Historically, we expensed research and development costs as incurred. We recognized external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites. Payments for these activities were based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid expenses or accrued research and development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities were deferred and capitalized, even when there was no alternative future use for the research and development. The capitalized amounts were expensed as the related goods were delivered or the services are performed.

A significant portion of our research and development costs have been external costs, which we tracked after a clinical product candidate had been identified. Our internal research and development costs are primarily personnel-related costs and other indirect costs. Our research and development expenses to-date have been incurred in connection with our development of tovinontrine in SCD and β-thalassemia.

The following table summarizes our research and development expenses for the periods indicated:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
IMR-687	$ 13,600	$ 29,239
Personnel expenses (including stock-based compensation)	4,532	7,804
Other expenses	808	1,399
Total research and development expenses	$ 18,940	$ 38,442

If we were to decide to pursue any future product development efforts, the successful development of any product candidates is highly uncertain. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that would be necessary to complete the potential development and commercialization of any future product candidates. We are also unable to predict when, if ever, material net cash inflows would commence from the sale of potential future product candidates, if approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the impact of the COVID-19 pandemic and our response to it;
- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain research and development programs or to establish new ones;
- establishing an appropriate safety profile with investigational new drug application, or IND, enabling studies;
- successful patient enrollment in, and the initiation of, clinical trials;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration, or FDA, or any comparable foreign regulatory authority;
- the timing, receipt and terms of any regulatory approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

Any changes in the outcome of any of these variables with respect to the potential development of any future product candidates could mean a significant change in the costs and timing associated with the development of these product candidates. If we were to decide to pursue any future product development efforts, we may never obtain regulatory approval for any product candidates. Drug commercialization takes several years and millions of dollars in development costs and the potential success of such programs is difficult to predict and are often not successful.

General and Administrative. General and administrative expenses consist primarily of personnel-related expenses, including salaries, benefits, and stock-based compensation expenses for personnel in executive, finance, accounting, human resources, legal and other administrative functions. Other significant general and administrative expenses include the cost of director and officer insurance premiums, legal fees relating to patent, intellectual property and corporate matters, and fees paid for accounting, consulting and other professional services.

Our future general and administrative expenses will be significantly dependent on the outcome of our strategic process, including whether or not we successfully consummate the Merger, and on whether we decide to pursue any future product development efforts.

Total Other Income, Net

Total Other Income, Net. Total other income, net primarily consists of interest earned on our cash, cash equivalents and investments during the years ended December 31, 2022 and 2021.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Operating expenses:		
Research and development	$ 18,940	$ 38,442
General and administrative	15,330	13,000
Total operating expenses	34,270	51,442
Gain on Asset Sale	35,000	—
Income (loss) from operations	730	(51,442)
Total other income, net	846	58
Income Tax Provision	(88)	—
Net income (loss)	$ 1,488	$ (51,384)

Research and Development Expenses

Research and development expenses decreased by approximately $19.5 million from $38.4 million for the year ended December 31, 2021 to $18.9 million for the year ended December 31, 2022. The decrease in research and development expenses was primarily attributable to the following:

- a $15.6 million decrease in costs related to the development and manufacturing of clinical materials, clinical research and oversight of our clinical trials and investigative fees for tovinontrine following discontinuation of clinical development;
- a $3.3 million decrease in personnel-related costs; and
- a $0.6 million decrease in other research and development operational costs, including professional services, supplies, travel, and facilities.

General and Administrative Expenses

General and administrative expenses increased by approximately $2.3 million from $13.0 million for the year ended December 31, 2021 to $15.3 million for the year ended December 31, 2022. The increase in general and administrative expenses was primarily attributable to the following:

- a $2.2 million increase in consulting and professional fees, including legal fees incurred in connection with the Asset Sale, business development, accounting and audit fees; and
- a $0.1 million increase in stock-based compensation expense.

Total Other Income, Net

Total other income, net was $0.1 million for the year ended December 31, 2021, compared to total other income, net of $0.8 million for the year ended December 31, 2022. The increase during the year ended December 31, 2022 was primarily due to interest earned on our cash, cash equivalents and investments.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses on an aggregate basis. We have not yet commercialized or generated revenue from sales of any product candidate. Through December 31, 2022, we have funded our operations primarily through the issuance of common stock and convertible preferred stock.

On April 1, 2021, we filed the Shelf with the SEC in relation to the registration and potential future issuance of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof in the aggregate amount of up to $200.0 million. The Shelf was declared effective on April 8, 2021.We also simultaneously entered into the Sales Agreement with Cantor, as sales agent, providing for the offering, issuance and sale by us of up to an aggregate $75.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf. As of December 31, 2022, we have issued and sold 231,291 shares of common stock under the Sales Agreement, resulting in net proceeds of $1.4 million after deducting commissions and offering expenses. The extent to which we utilize the Sales Agreement as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, general market conditions, the extent to which we are able to secure funds from other sources, and restrictions on our ability to sell common stock pursuant to the Sales Agreement. Accordingly, we may not be able to sell shares under the Sales Agreement at prices or amounts that we deem acceptable, and there can be no assurance that we will sell any further common stock pursuant to the Sales Agreement.

On July 16, 2021, we completed a public offering of shares of our common stock and issued and sold 8,333,333 shares of common stock at a public offering price of $6.00 per share, resulting in net proceeds of $46.8 million after deducting underwriting discounts and commissions and estimated offering expenses.

As of December 31, 2022, we had $88.2 million in cash and cash equivalents.

While we do not currently expect that the COVID-19 pandemic will have a material adverse impact on our short-term or long-term liquidity, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. See "Impact of COVID-19 Pandemic."

Cash Flows

The following table provides information regarding our cash flows for the periods indicated:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (35,568)	$ (46,771)
Net cash provided by (used in) investing activities	76,515	(1,632)
Net cash provided by (used in) financing activities	(1,233)	49,101
Net increase in cash, cash equivalents, and restricted cash	$ 39,714	$ 698

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 was $35.6 million primarily due to realized gain on the Asset Sale of $35.0 million and net cash outflows from the change in operating assets and liabilities of $5.4 million, partially offset by net income of $1.5 million, stock-based compensation expense of $2.6 million, depreciation expense of $0.6 million, and amortization of $0.1 million on our short-term investments.

Net cash used in operating activities for the year ended December 31, 2021 was $46.8 million primarily due to our net loss of $51.4 million, partially offset by stock-based compensation expense of $3.8 million, depreciation expense of $0.1 million, amortization of $0.2 million on our short-term investments, and net cash inflows from the change in operating assets and liabilities of $0.5 million.

Net Cash Provided by and Used in Investing Activities

Net cash provided by investing activities for the year ended December 31, 2022 was $76.5 million primarily due to proceeds of $35.0 million from the Asset Sale, proceeds of $41.9 million from maturities and sales, which were partially offset by purchases of property and equipment of $0.4 million.

Net cash used in investing activities for the year ended December 31, 2021 was $1.6 million primarily due to purchases of marketable securities of $47.6 million, partially offset by proceeds from sales and maturities of short-term investments of $45.9 million.

Net Cash Used in and Provided by Financing Activities

Net cash used in financing activities for the year ended December 31, 2022 was $1.2 million, primarily due to payment of transaction costs.

Net cash provided by financing activities for the year ended December 31, 2021 was $49.1 million, primarily due to $46.8 million of net proceeds after deducting underwriting discounts and commissions and payment of issuance costs from our July 2021 offering, $1.4 million of net proceeds after deducting underwriting discounts and commissions and payment of issuance costs from the sale of common stock under the Sales Agreement with Cantor, and $0.9 million of proceeds received from the exercise of stock options.

Funding Requirements

Based on our current operating plan, we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of filing of this Annual Report on Form 10-K. However, we have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

Our future capital requirements will depend on the results of our ongoing strategic evaluation, including whether we complete the Merger. If the Merger is not completed, we will reconsider our strategic alternatives which may include a dissolution of the company, pursuit of another strategic transaction or the pursuit of future product development. If the Merger does not close, or if we decide to pursue any future product development efforts, our future funding requirements would depend on, and could increase significantly as a result of, many factors, including:

- our ability to consummate an alternative strategic transaction and the nature and type of such transaction;
- our ability to bring any product candidates through preclinical and clinical development, and the timing and scope of these research and development activities;
- the costs of obtaining clinical and commercial supplies of any product candidates we may seek to develop;
- our ability to successfully commercialize any product candidates we may develop;
- the manufacturing, selling and marketing costs associated with any product candidates we may develop, including the cost and timing of establishing our sales and marketing capabilities;
- the amount and timing of sales and other revenues from any product candidates we may identify and develop, including the sales price and the availability of coverage and adequate third-party reimbursement;
- the time and cost necessary to respond to technological and market developments;
- the extent to which we may acquire or in-license other product candidates and technologies;
- our ability to attract, hire and retain qualified personnel;
- the impact of the COVID-19 pandemic and our response to it;
- the costs of maintaining, expanding and protecting our intellectual property portfolio; and
- the costs associated with operating as a public company and maintaining compliance with exchange listing and SEC requirements.

A change in the outcome of any of these or other variables with respect to the development of any product candidate we may develop in the future could significantly change the costs and timing associated with the development of that product candidate. Further, our need for additional funds is heavily dependent on the outcome of our ability to complete a strategic transaction, including the Merger.

Moreover, if we decide to pursue future product development, until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of cash-on-hand, equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We currently have no credit facility or committed sources of capital. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the

ownership interests of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of such stockholders. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research program or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

In the normal course of business**,** we enter into agreements that contain contractual obligations, of which the most significant to date included our former licensing agreement with Lundbeck. In connection with the Asset Sale, our license agreement with Lundbeck was assigned to Cardurion.

Our license agreement with Lundbeck, as well as certain other agreements, required us to pay third parties upon achievement of certain development, regulatory or commercial milestones. Amounts related to contingent payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory and commercial milestones that may not be achieved. We have not included payments contingent upon the achievement of certain development, regulatory or commercial milestones on our consolidated balance sheets. For further information regarding our former license agreement with Lundbeck, please see Note 7 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Further, on October 13, 2022, we entered into the Merger Agreement with Enliven. The closing of the Merger is subject to approval by our stockholders and the stockholders of Enliven and other customary closing conditions. If we are unable to satisfy certain closing conditions under the Merger Agreement, or if other mutual closing conditions are not satisfied, Enliven will not be obligated to complete the Merger. The Merger Agreement contains certain termination rights of each of us and Enliven. Under certain circumstances detailed in the Merger Agreement, we could be required to pay Enliven a termination fee of $3.0 million or Enliven could be required to pay us a termination fee of $9.75 million. In addition, Enliven will be required to pay us a termination fee of $3.0 million if Enliven or we terminate the Merger Agreement at specified times with all conditions to closing of the Merger satisfied other than the conditions related to the completion of the Enliven pre-closing financing such that, in the case of Enliven's condition, Enliven receives gross proceeds of at least $131.6 million, and in the case of our condition, Enliven receives gross proceeds of at least $75 million.

Critical Accounting Policies and Estimates

This management's discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reported periods. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our critical accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates. See Note 2 of the notes to our annual consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a description of our other significant accounting policies.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued third-party research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Stock-Based Compensation

We measure stock-based compensation issued to employees and non-employees based on the grant date fair value of the stock-based awards and recognize stock-based compensation expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period of the respective award. We have also granted stock-based awards with performance-based vesting conditions. We recognize compensation expense for awards with performance-based vesting conditions over the remaining service period using the accelerated attribution method when the performance condition is deemed to be probable. We account for forfeitures as they occur.

We classify stock-based compensation expense in our consolidated statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified. In future periods, we expect stock-based compensation expense to increase, due in part to our existing unrecognized stock-based compensation expense and as we grant additional stock-based awards to continue to attract and retain our employees.

We determine the fair value of stock-based awards based on the fair value of our common stock on the date of grant. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. Given our limited trading history as a public company, we determine the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted-average of the historical volatility measures of this group of guideline companies. We expect to continue to do so until we have adequate historical data regarding the volatility of our own traded stock price. The expected term of our stock options granted to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. Prior to our IPO, the expected term of our stock options granted to non-employees also used the "simplified" method. Following our IPO, the expected term of options granted to non-employees is determined by contractual term. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. We have not paid, and do not anticipate paying, dividends on our common stock; therefore, the expected dividend yield is assumed to be zero.

Following our IPO, we have determined the fair value of our common stock based on the quoted market price of our common stock on the Nasdaq Global Select Market.

Emerging Growth Company Status

We are an "emerging growth company," or EGC, under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107 of the JOBS Act provides that an EGC can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as private entities.

As an EGC, we may take advantage of certain exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an EGC:

- we may present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations within registration statements;
- we may avail ourselves of the exemption from providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- we may avail ourselves of the exemption from complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis;
- we may provide reduced disclosure about our executive compensation arrangements; and
- we may not require nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments.

We will remain an EGC until the earliest of (i) December 31, 2025, (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous rolling three-year period, or (iv) the date on which we are deemed to be a large accelerated filer under the Securities Exchange Act of 1934, as amended.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are in the form of money market funds that are invested in U.S. Treasury securities. We also hold investments in corporate debt securities and commercial paper. As of December 31, 2022, we had cash and cash equivalents of $88.2 million. Interest income is sensitive to changes in the general level of interest rates; however, due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors that are located in Europe and Asia, who we may pay in local currency. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the report of our independent registered public accounting firm, are presented beginning on page F-1 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer and Chief Operating Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our Chief Executive Officer and Chief Financial Officer and Chief Operating Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control system was designed to provide reasonable assurance to our management and our board of directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, our management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013 (COSO criteria). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2022. This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm because we are exempt from this requirement pursuant to rules of the Securities and Exchange Commission.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2022, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

As previously disclosed, in order to induce Enliven to enter into the Merger Agreement, on October 13, 2022, certain of our stockholders entered into support agreements with Enliven. Pursuant to the terms of the support agreements, such stockholders agreed not to sell or transfer their shares of our common stock (or securities convertible into shares of our common stock) until the earlier of the termination of the Merger Agreement and the completion of the Merger, subject to certain exceptions. On January 27, 2023, we entered into a letter agreement, or the Letter Agreement, with Rahul Ballal, our Chief Executive Officer, Michael Gray, our Chief Financial Officer, and Enliven, pursuant to which Enliven agreed to waive the restriction on sales of our common stock with respect to certain sales by Dr. Ballal and Mr. Gray to the extent required to cover their respective statutory withholding obligations in connection with (i) any vesting prior to the closing of the Merger of any restricted stock units held by Dr. Ballal and Mr. Gray pursuant to the terms of grant and (ii) any acceleration of vesting effected by us or our board of directors consistent with the terms of the Merger Agreement. The foregoing description of the Letter Agreement is qualified in its entirety by reference to the full text of the Letter Agreement, which is attached hereto as Exhibit 10.24 and incorporated herein by reference

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except to the extent provided below, the information required by this Item 10 will be included in our definitive proxy statement to be filed with the Securities and Exchange Commission, or the SEC, with respect to our 2023 Annual Meeting of Stockholders within 120 days of the end of the fiscal year to which this report relates, which information is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of the code on the "Corporate Governance" section of the "Investors" section of our website, www.imaratx.com. In addition, we intend to post on our website all disclosures that are required by law or Nasdaq listing standards concerning any amendments to, or waivers from, any provision of the code.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in the section captioned "Executive Compensation" in our definitive proxy statement for our 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates, which information is incorporated herein by reference.

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

The information required by this Item 12 will be included in the section captioned "Security Ownership of Certain Beneficial Owners and Management" in our definitive proxy statement for our 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates, which information is incorporated herein by reference.

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

The information required by this Item 13 will be included in the sections captioned "Related Person Transactions," "Policies and Procedures for Related Person Transactions" and "Board Determination of Independence" in our definitive proxy statement for our 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates, which information is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included in the section captioned "Audit Fees and Services" our definitive proxy statement for our 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates, which information is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(1) The financial statements listed below are filed as part of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm (PCAOB ID: 00042) F-2

Consolidated Balance Sheets F-3

Consolidated Statements of Operations and Comprehensive Income (Loss) F-4

Consolidated Statements of Stockholders' Equity F-5

Consolidated Statements of Cash Flows F-6

Notes to Consolidated Financial Statements F-7

(2) All financial statement schedules have been omitted because they are not applicable, not required, or the information required is shown in the consolidated financial statements or the notes thereto.

(3) The following is a list of exhibits filed as part of this Annual Report on Form 10-K

Exhibit Index

Exhibit Number	Description
2.1†	Asset Purchase Agreement, dated September 6, 2022, between the Registrant and Cardurion Pharmaceuticals, Inc. (incorporated by reference as Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on September 7, 2022).
2.2	Agreement and Plan of Merger, dated as of October 13, 2022, by and among the Registrant, Iguana Merger Sub, Inc. and Enliven Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 13, 2022)
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 16, 2020)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed with the SEC on March 16, 2020)
4.1	Specimen stock certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1, filed with the SEC on February 14, 2020)
4.2	Amended and Restated Investors' Rights Agreement, dated as of March 15, 2019, by and among the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1, filed with the SEC on February 14, 2020)
10.1	Sales Agreement by and between the Registrant and Cantor Fitzgerald & Co. dated as of April 1, 2021 (incorporated by reference to Exhibit 1.2 to the Registrant's universal shelf registration statement on Form S-3 filed with the SEC on April 1, 2021).
10.2#	2016 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1/A, filed with the SEC on March 3, 2020).
10.3#	Form of Incentive Stock Option Agreement under the 2016 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1, filed with the SEC on February 14, 2020).
10.4#	Form of Nonstatutory Stock Option Agreement under the 2016 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1, filed with the SEC on February 14, 2020).

10.5# 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1/A, filed with the SEC on March 3, 2020).

10.6# Form of Stock Option Agreement under the 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1, filed with the SEC on February 14, 2020).

10.7# Form of Restricted Stock Unit Agreement under the 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 15, 2022).

10.8# 2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1/A, filed with the SEC on March 3, 2020)

10.9# Amended and Restated Letter Agreement, dated as of September 23, 2019, by and between the Registrant and Rahul D. Ballal, Ph.D. (incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1, filed with the SEC on February 14, 2020)

10.10# First Amendment to the Amended and Restated Letter Agreement, dated as of November 5, 2021, by and between the Registrant and Rahul D. Ballal, Ph.D. (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 9, 2021)

10.11# Retention Agreement, dated as of May 5, 2022, by and between the Registrant and Rahul D. Ballal, Ph.D. (incorporated by reference as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 6, 2022).

10.12# Amendment to Retention Agreement, dated as of May 5, 2022, by and between the Registrant and Rahul D. Ballal, Ph.D. (incorporated by reference as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 7, 2022).

10.13# Amended and Restated Letter Agreement, dated as of September 23, 2019, by and between the Registrant and Michael P. Gray (incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1, filed with the SEC on February 14, 2020)

10.14# First Amendment to the Amended and Restated Letter Agreement, dated as of November 5, 2021, by and between the Registrant and Michael P. Gray (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 9, 2021)

10.15# Amended and Restated Retention Agreement, dated as of May 18, 2022, by and between the Registrant and Michael P. Gray (incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 3, 2022).

10.16# Amendment to Amended and Restated Retention Agreement, dated as of May 18, 2022, by and between the Registrant and Michael P. Gray (incorporated by reference as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on September 7, 2022).

10.19# Form of Indemnification Agreement with directors and executive officers (incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1, filed with the SEC on February 14, 2020).

10.20 Form of Contingent Value Rights Agreement (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on October 13, 2022).

10.21 Form of Enliven Support Agreement (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on October 13, 2022).

10.22 Form of Imara Support Agreement (incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K, filed with the SEC on October 13, 2022).

10.23 Form of Lock-Up Agreement (incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K, filed with the SEC on October 13, 2022).

10.24*# Letter Agreement, dated as of January 27, 2023, by and among the Registrant, Rahul Ballal, Michael Gray and Enliven Therapeutics, Inc.

21.1	List of Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Registration Statement on Form S-4, filed with the SEC on November 10, 2022).
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm
31.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2022, has been formatted in Inline XBRL.

* Filed herewith.

\# Indicates a management contract or any compensatory plan, contract or arrangement.

† Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the Registrant if disclosed.

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.

IMARA INC.

Date: February 10, 2023

By: /s/ Rahul D. Ballal

Rahul D. Ballal, Ph.D.
President and Chief Executive Officer
(Principal Executive 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/ Rahul D. Ballal **Rahul D. Ballal, Ph.D.**	President and Chief Executive Officer, Director (Principal Executive Officer)	February 10, 2023
/s/ Michael P. Gray **Michael P. Gray**	Chief Financial Officer and Chief Operating Officer (Principal Financial and Accounting Officer)	February 10, 2023
/s/ David M. Mott **David M. Mott**	Chairman of the Board	February 10, 2023
/s/ David Bonita **David Bonita, M.D.**	Director	February 10, 2023
/s/ Mark Chin **Mark Chin**	Director	February 10, 2023
/s/ Edward Conner **Edward Conner, M.D.**	Director	February 10, 2023
/s/ Barbara J. Dalton **Barbara J. Dalton, Ph.D.**	Director	February 10, 2023
/s/ Carl Goldfischer **Carl Goldfischer, M.D.**	Director	February 10, 2023
/s/ Laura Williams **Laura Williams, M.D., MPH**	Director	February 10, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm (PCAOB ID: 00042) F-2

Consolidated Balance Sheets F-3

Consolidated Statements of Operations and Comprehensive Income (Loss) F-4

Consolidated Statements of Stockholders' Equity F-5

Consolidated Statements of Cash Flows F-6

Notes to Consolidated Financial Statements F-7

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of IMARA Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of IMARA Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.

Boston, Massachusetts
February 10, 2023

IMARA INC.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 88,198	$ 48,309
Short-term investments	—	41,969
Prepaid expenses and other current assets	1,438	2,418
Total current assets	89,636	92,696
Property and equipment, net	—	250
Right of use assets - operating leases	—	525
Other assets	2,323	175
Total assets	$ 91,959	$ 93,646
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	149	2,360
Accrued expenses and other current liabilities	1,681	4,604
Operating lease liability, current	—	246
Total current liabilities	1,830	7,210
Operating lease liability, non-current	—	406
Total liabilities	$ 1,830	$ 7,616
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 10,000,000 shares authorized; no shares issued or outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, par value of $0.001 per share; 200,000,000 shares authorized; 26,287,264 shares issued and outstanding as of December 31, 2022 and 2021	27	27
Additional paid-in capital	236,111	233,516
Accumulated other comprehensive (loss) income	—	(16)
Accumulated deficit	(146,009)	(147,497)
Total stockholders' equity	90,129	86,030
Total liabilities and stockholders’ equity	$ 91,959	$ 93,646

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

IMARA INC.
Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands, except share and per share data)

	Years ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 18,940	$ 38,442
General and administrative	15,330	13,000
Total operating expenses	$ 34,270	$ 51,442
Gain on Asset Sale	$ 35,000	$ —
Income (loss) from operations	730	(51,442)
Total other income, (net):		
Interest income	943	233
Other income (expense)	(97)	(175)
Total other income, (net)	$ 846	$ 58
Net income (loss) before income tax provision	$ 1,576	$ (51,384)
Income tax provision	$ (88)	$ —
Net income (loss) attributable to common stockholders—basic and diluted	$ 1,488	$ (51,384)
Net income (loss) per share applicable to common stockholders—basic and diluted	$ 0.06	$ (2.37)
Weighted-average common shares outstanding—basic	26,287,264	21,661,450
Weighted-average common shares outstanding—diluted	26,385,567	21,661,450
Comprehensive income (loss):		
Net income (loss)	1,488	(51,384)
Other comprehensive income (loss):		
Unrealized gain (loss) on investments	—	(20)
Realized gain (loss) on investments	16	—
Comprehensive income (loss)	$ 1,504	$ (51,404)

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

IMARA INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share and per share data)

	COMMON STOCK $0.001 PAR VALUE		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2020	17,548,263	$ 18	$ 180,526	$ 4	$ (96,113)	$ 84,435
Issuance of common stock under ATM and July 2021 offering, net of issuance costs of $579	8,564,624	9	48,231	—	—	48,240
Exercise of stock options and issuance of stock under the Employee Stock Purchase Plan	174,377	—	914	—	—	914
Stock-based compensation expense	—	—	3,845	—	—	3,845
Unrealized loss on investments	—	—	—	(20)	—	(20)
Net loss	—	—	—	—	(51,384)	(51,384)
Balance at December 31, 2021	26,287,264	27	233,516	(16)	(147,497)	86,030
Stock-based compensation expense	—	—	2,595	—	—	2,595
Realized gain on investments	—	—	—	16	—	16
Net income	—	—	—	—	1,488	1,488
Balance at December 31, 2022	26,287,264	$ 27	$ 236,111	$ —	$ (146,009)	$ 90,129

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

IMARA Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net income (loss)	$ 1,488	$ (51,384)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation expense	2,595	3,845
Depreciation expense	611	99
Amortization and accretion on investments	109	155
Non-cash lease expense	(11)	—
Gain on Asset Sale	(35,000)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	980	(235)
Accounts payable	(2,213)	389
Accrued expenses and other current liabilities	(4,013)	393
Operating lease assets and liabilities, net	(114)	(33)
Net cash used in operating activities	(35,568)	(46,771)
Cash flows from investing activities:		
Proceeds from maturities and sales of short-term investments	41,878	45,937
Proceeds from Asset Sale	35,000	—
Purchases of short-term investments	—	(47,557)
Purchases of property and equipment	(363)	(12)
Net cash provided by (used in) investing activities	76,515	(1,632)
Cash flows from financing activities:		
Proceeds from July 2021 Offering, net of underwriting discounts and commissions	—	47,000
Proceeds from ATM offering, net of underwriting discounts and commissions	—	1,819
Proceeds from exercise of options	—	860
Payment of transaction costs	(1,233)	(578)
Net cash (used in) provided by financing activities	(1,233)	49,101
Net increase in cash, cash equivalents and restricted cash	39,714	698
Cash, cash equivalents and restricted cash, beginning of period	48,484	47,786
Cash, cash equivalents and restricted cash, end of period	$ 88,198	$ 48,484
Supplemental disclosure of non-cash investing and financing activities:		
Offering costs included in accounts payable and accrued expenses	$ 1,090	$ 1
Right of use asset obtained in exchange for lease liabilities	$ 1,886	$ —
Unrealized gain (loss) on investments	$ —	$ (20)
Realized gain (loss) on investments	$ 16	$ —

The following table provides a reconciliation of the cash, cash equivalents, and restricted cash balances as of each of the dates shown below:

	December 31,	
	2022	2021
Cash and cash equivalents	$ 88,198	$ 48,309
Restricted cash (included in other assets)	—	175
Total cash, cash equivalents and restricted cash	$ 88,198	$ 48,484

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

1. Nature of the Business

IMARA Inc. ("IMARA" or the "Company") is a biopharmaceutical company that has been dedicated to developing and commercializing novel therapeutics to treat patients suffering from serious diseases. The Company was incorporated in January 2016 under the laws of the State of Delaware, and its principal offices are in Brookline, Massachusetts.

On April 5, 2022, the Company announced the results from interim analyses of its Ardent Phase 2b clinical trial of tovinontrine (IMR-687) in patients with sickle cell disease ("SCD") and Forte Phase 2b clinical trial of tovinontrine in patients with ß-thalassemia. Based on the data generated by these interim analyses, the Company decided to discontinue the Ardent and Forte trials as well as the further development of tovinontrine in SCD and ß-thalassemia. The Company also decided to discontinue development of tovinontrine in heart failure with preserved ejection fraction, as well as its development plans with respect to IMR-261. In connection with these events, the Company's Board of Directors approved a reduction in workforce designed to substantially reduce the Company's operating expenses while it undertakes a comprehensive assessment of its strategic options to maximize stockholder value. The workforce reduction was completed as of September 30, 2022 and the Company incurred approximately $2.1 million of expenses comprised of notice and employee severance and retention payments.

On September 6, 2022, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Cardurion Pharmaceuticals, Inc. ("Cardurion"), discussed further in Note 7, providing for the sale of tovinontrine and all other assets of the Company related to its PDE9 program (the "Asset Sale") in exchange for a $35.0 million upfront payment and future contingent payments. The Company completed the Asset Sale on November 10, 2022.

On October 13, 2022, the Company, Iguana Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Merger Sub"), and Enliven Therapeutics, Inc., a Delaware corporation ("Enliven"), entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Enliven, with Enliven continuing as a wholly owned subsidiary of IMARA and the surviving corporation of the merger (the "Merger"). If the Merger is completed, the business of Enliven will continue as the business of the combined organization. Consummation of Merger Agreement is subject to customary closing conditions, including, without limitation, approval of the sale by the Company's stockholders.

Liquidity

The Company has incurred recurring negative operating cash flows since inception and has funded its operations primarily from the sale of convertible preferred stock and proceeds from the IPO and subsequent common stock offerings. As of December 31, 2022, the Company had cash and cash equivalents of $88.2 million and an accumulated deficit of $146.0 million. The Company expects to incur operating losses and negative operating cash flows to in the foreseeable future.

On April 1, 2021, the Company filed a Registration Statement on Form S-3 (the "Shelf") with the SEC in relation to the registration and potential future issuance of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof in the aggregate amount of up to $200.0 million. The Shelf was declared effective on April 8, 2021. The Company also simultaneously entered into a sales agreement with Cantor Fitzgerald & Co, LLC, as sales agent, providing for the offering, issuance and sale by the Company of up to an aggregate $75.0 million of its common stock from time to time in "at-the-market" offerings under the Shelf. As of December 31, 2022, the Company had issued and sold 231,291 shares of common stock under the sales agreement, resulting in net proceeds of $1.4 million after deducting commissions and offering expenses. No sales were made under the sales agreement during the twelve months ended December 31, 2022.

On July 16, 2021, the Company completed a public offering of shares of its common stock. In connection with the offering, the Company issued and sold 8,333,333 shares of common stock at a public offering price of $6.00 per share, resulting in net proceeds of $46.8 million after deducting underwriting discounts and commissions and offering expenses.

As described above, the Company made the decision to discontinue development of tovinontrine in sickle cell disease, β-thalassemia and heart failure with preserved ejection fraction, as well to discontinue its development plans with respect to

IMR-261. As a result, the Company believes its cash and cash equivalents as of December 31, 2022 will be sufficient to fund its operating expense requirements for at least twelve months from the date of filing of this Annual Report on Form 10-K.

In the event that the Company does not complete the Merger, the Company (i) may elect to pursue a dissolution and liquidation of the Company, (ii) may pursue another strategic transaction or (iii) may resume research and development activities. If the Company decides to pursue any future product development efforts, it will need additional funding to support its planned operating activities. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

2. Summary of Significant Accounting Policies

Basis of presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and as amended by Accounting Standards Updates of the FASB.

Principles of Consolidation

The accompanying consolidated financial statements of the Company include the accounts of its wholly owned subsidiaries, Iguana Merger Sub, Inc., IMARA Security Corporation and IMARA E.U. Limited, the latter of which was dissolved in July 2021. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, accrued research and development expenses, and stock-based compensation expense. Actual results could differ materially from those estimates.

Segments

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources. All of the Company's long-lived assets are held in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash with original maturities of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held in money market funds. Cash equivalents are stated at cost, which approximates market value.

Restricted Cash

Restricted cash of $0.2 million as of December 31, 2021 represents a letter of credit held as collateral in support of the Company's operating lease at 116 Huntington Avenue in Boston, Massachusetts, which was terminated in July 2022. Restricted cash is included as a component of other assets on the Company's consolidated balance sheets.

Investments

The Company's investments are maintained by investment managers and consist of corporate debt securities and commercial paper with original maturities of over 90 days, all of which are considered available-for-sale securities. The Company classifies its available-for-sale securities as short-term investments on the consolidated balance sheets, even though the stated maturity date may be one year or more beyond the current balance sheet date, as the Company views those securities as available for use in current operations, if needed.

Available-for-sale securities are carried at fair value with their unrealized gains and losses included in accumulated other comprehensive income within stockholders' equity (deficit), until such gains and losses are realized in other income (expense) within the consolidated statements of operations and comprehensive loss or until an unrealized loss is considered other-than-temporary.

The Company evaluates its investments with unrealized losses for other-than-temporary impairment. When assessing investments for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions. If the Company determines from this analysis that it does not expect to receive cash flows sufficient to recover the entire amortized cost of the security, a credit loss exists, the impairment is considered other-than-temporary and is recognized in the consolidated statements of operations and comprehensive loss.

Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity issuances as deferred offering costs until such equity issuances are consummated. After consummation of the equity issuance, these costs are recorded as a reduction in the capitalized amount associated with the equity issuance. Should the equity issuance be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss. There were $2.3 million of deferred offering costs capitalized and included in other assets on our consolidated balance sheet as of December 31, 2022.No deferred offering costs were capitalized as of December 31, 2021.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and investments. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and have not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Such deposits have and will continue to exceed federally insured limits. The Company has not experienced any losses on its cash deposits. The Company's available-for-sale investments primarily consist of high-grade corporate debt and commercial paper, and potentially subject the Company to concentrations of credit risk. The Company has adopted an investment policy that limits the amounts the Company may invest in any one type of investment and requires all investments held by the Company to be highly rated, thereby reducing credit risk exposure.

As of December 31, 2022 and 2021, the Company had no off-balance sheet risk such as foreign exchange contracts, option contracts, or other hedging arrangements.

Comprehensive Income (Loss)

Comprehensive income (loss) includes net loss and certain changes in stockholders' equity that are excluded from net loss. For the years ended December 31, 2022 and 2021, as a result of the Company's investments in available-for-sale securities, the Company's comprehensive income (loss) includes unrealized losses on those available-for-sale securities.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

An entity may choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings.

The carrying amounts reflected in the consolidated balance sheets for prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to their short-term nature of these assets and liabilities.

Property and Equipment, Net

Property and equipment is stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which are as follows:

	Estimated Useful Life
Computer equipment and software	3 years
Furniture and fixtures	5 years
Laboratory equipment	5 years
Leasehold improvements	Shorter of useful life or remaining lease term

Purchased assets that are not yet in service are recorded to construction-in-process and no depreciation expense is recorded. Once they are placed in service they are reclassified to the appropriate asset class. Upon the retirement or sale of an asset, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is recorded to other income (expense), net. Expenditures for maintenance and repairs are expensed as incurred.

Leases

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). This standard established a right-of-use model that requires all lessees to recognize on their balance sheets right-of-use assets and lease liabilities that arise from leases as well as provide disclosures with respect to certain qualitative and quantitative information related to a company's leasing arrangements to meet the objective of allowing users of financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. The FASB subsequently issued the following amendments to ASU 2016-02 that have the same effective date and transition date: ASU No. 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842, ASU No. 2018-10, Codification Improvements to Topic 842, Leases, ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, ASU No. 2018-20, Narrow-Scope Improvement for Lessors, and ASU No. 2019-01, Leases (Topic 842): Codification Improvements. The Company early adopted these amendments with ASU 2016-02 (collectively, the "new leasing standards"), effective January 1, 2021.

The Company adopted the new leasing standards using the modified retrospective transition approach, with no restatement of prior periods and there was no cumulative adjustment to retained earnings. Upon adoption, the Company elected the package of transition practical expedients, which allowed the Company to not reassess the following: (i) whether any expired or existing contracts are or contain leases, (ii) the lease classification for any expired or existing leases and (iii) the treatment of initial direct costs for existing leases. The Company made an accounting policy election to not recognize short-term leases with an initial term of twelve months or less within its consolidated balance sheets and to recognize those lease payments on a straight-line basis in its consolidated statements of operations over the lease term. Upon adopting the new leasing standards, the Company recognized an operating lease right-of-use asset of $0.7 million and a corresponding

current and non-current operating lease liability of $0.3 million and $0.6 million, respectively, which are included in its consolidated balance sheets. The adoption of the new leasing standards did not have a material impact on the Company's consolidated statements of operations.

As further discussed in Note 8, the Company terminated its sole office lease, effective August 7, 2022. Prior to such termination, the Company's operating leases were reflected in operating lease right-of-use assets and in current operating lease liabilities and long-term operating lease liabilities in its consolidated balance sheets. The Company's operating lease right-of-use asset as of December 31, 2021 did not include any material lease incentives. Prior to the termination of the office lease, the lease expense for future lease payments was recognized on a straight-line basis over the lease term.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs, depreciation, third-party license fees, and external costs of outside vendors engaged to conduct preclinical development activities and clinical trials as well as to manufacture research and development materials. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are expensed as the goods are delivered or the related services are performed or until it is no longer expected that the goods will be delivered, or the services rendered.

Costs incurred in obtaining technology licenses are recognized as research and development expense as incurred if the technology licensed has not reached technological feasibility and has no alternative future uses.

As of December 31, 2022, the Company had discontinued its research and development efforts while undertaking a comprehensive assessment of its strategic options to maximize stockholder value.

Accrued Research and Development Expenses

The Company has entered into various research and development related contracts with parties both inside and outside of the United States, including contracts with third-party contract research organizations and contract manufacturing organizations. These agreements are cancelable, and related payments are recognized as research and development expenses as incurred. The Company records accrued liabilities for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes the progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. To date, the Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure and are classified as general and administrative expenses. Following the completion of the Asset Sale and discontinuation of IMR-261, as of December 31, 2022 the Company had ceased active prosecution of patents and patent applications.

Stock-Based Compensation

The Company accounts for all stock-based awards granted to employees and non-employees as stock-based compensation expense at fair value. For stock-based awards issued to employees and members of the Company's board of directors (the "Board") for their services as a member of the Board, the Company measures the estimated fair value of the stock-based award on the date of grant.

Since the Company's initial public offering in March 2020, the fair value of the common stock has been determined based on the closing price of the Company's stock on the Nasdaq Global Select Market on the date of grant. Prior to the Company's initial public offering, the Company determined the fair value of the underlying common stock based on input from management and approved by the Board, which utilized the valuation of the Company's enterprise value determined utilizing various methods including the back-solve method, the option-pricing method ("OPM") or a hybrid of the probability-weighted expected return method ("PWERM") and the OPM. The total enterprise value was then allocated to the various outstanding equity instruments, including the underlying common stock, utilizing the OPM.

For employee and non-employee awards, the Company recognizes compensation expense over the requisite service period, which is generally the vesting period of the respective award based on the grant date fair value of the award. For awards that include performance-based vesting conditions expense is recognized using the accelerated attribution method when the performance condition is deemed to be probable. The Company accounts for forfeitures as they occur. The Company determines the fair value of restricted stock awards in reference to the fair value of its common stock less any applicable purchase price.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option and the Company's expected dividend yield. The fair value of each restricted stock award is determined on the date of grant based on the fair value of the Company's common stock on that same date. Given the Company's limited trading history as a public company, the Company determines the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted-average of the historical volatility measures of this group of guideline companies. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options granted to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. Under the simplified method, the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to lack of historical exercise data and the plain nature of its stock-based awards. Prior to the Company's IPO, the expected term of stock options granted to non-employees also used the "simplified" method. Following the Company's IPO, the expected term of options granted to non-employees is determined by contractual term. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common stock; therefore, the expected dividend yield is assumed to be zero.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's cash compensation costs are classified.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or the Company's tax returns. Under this method, deferred tax assets and liabilities are determined based on the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established.

The Company accounts for uncertain tax positions recognized in the consolidated financial statements by prescribing a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net Income (Loss) per Share

Basic net income (loss) per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. Net income (loss) per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. Net income (loss) attributable to common stockholders and participating preferred shares are allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods in which a net loss is recorded.

Diluted net income (loss) per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of common shares included in the computation of diluted net income (loss) effect to all potentially dilutive common equivalent shares, including outstanding stock options and Preferred Stock. Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net income (loss) attributable to common stockholders, diluted net income (loss) per share attributable to common stockholders is generally the same as basic net income (loss) per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recently Issued Accounting Pronouncements

In March 2020, the FASB issued "ASU 2020-03", Codification Improvements to Financial Instruments, ("ASU 2020-03") which addressed, among other topics, Amendments related to ASU 2016-13 Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). The amendments align the contractual term under Topic 326 and Topic 842 (Leases) to be consistent, and also clarifies when an entity should record an allowance for credit losses in accordance with Topic 326. For public business entities that meet the definition of a SEC filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, the standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, the standard is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of this new guidance on the Company's consolidated financial statements and related disclosures but does not expect the adoption of ASU 2020-03 or ASU 2016-13 to be material.

3. Fair Value of Financial Assets and Liabilities

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	December 31, 2022			
Description	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
Assets:				
Money market funds, included in cash and cash equivalents	$ 53,511	$ 53,511	$ —	$ —
Total financial assets	$ 53,511	$ 53,511	$ —	$ —

	December 31, 2021			
Description	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
Assets:				
Money market funds, included in cash and cash equivalents	$ 24,798	$ 24,798	$ —	$ —
Marketable securities:				
Commercial Paper	26,131	—	26,131	—
Corporate debt securities	15,838	—	15,838	—
Total financial assets	$ 66,767	$ 24,798	$ 41,969	$ —

As of December 31, 2022 and 2021, the Company's cash equivalents consisted of money market funds, classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment. The financial assets valued based on Level 2 inputs as of December 31, 2021 consist of corporate debt securities and commercial paper, which consist of investments in highly-rated investment-grade securities. The Company estimates the fair values of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for

which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. The Company validates the prices provided by its third-party pricing sources by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

During the years ended December 31, 2022 and 2021, there were no transfers between fair value measurement levels.

4. Investments

As of December 31, 2022, the Company held no investments. As of December 31, 2021, the Company had short-term investments consisting of corporate debt securities and commercial paper, which are considered to be available-for-sale investments. These are included in short-term investments on the consolidated balance sheets, even though the stated maturity date may be one year or more beyond the current balance sheet date, as the Company views those securities as available for use in current operations, if needed. The following table summarizes the Company's investments as of December 31, 2021 (in thousands):

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
Current:				
Commercial paper	$ 26,131	$ —	$ —	$ 26,131
Corporate debt securities	15,854	—	(16)	15,838
Total	$ 41,985	$ —	$ (16)	$ 41,969

As of December 31, 2021, the Company held seven available-for-sale securities with an aggregate value of approximately $15.8 million in an unrealized loss position for less than twelve months. The Company held these securities until their final maturity date and determined there was no other-than-temporary impairment as of December 31, 2022 and 2021.

5. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Property and equipment:		
Leasehold improvements	$ 376	$ 336
Furniture and fixtures	464	143
Property and equipment	$ 840	$ 479
Less: accumulated depreciation	(840)	(229)
Property and equipment, net	$ —	$ 250

Depreciation expense was $0.6 million and $0.1 million for the years ended December 31, 2022 and 2021, respectively. In July 2022, the Company entered into a second amendment and termination of office lease agreement (the "Termination Agreement") to terminate the lease under the May 2019 Lease Agreement, as amended by the June 2021 Amended Lease Agreement. The Company revised the estimated useful lives of the existing leasehold improvements and furniture placed in service at its premises, which are included as component of property and equipment, net on its consolidated balance sheets and are fully depreciated as of December 31, 2022.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Accrued research and development expenses	$ 85	$ 2,288
Accrued compensation and benefits	127	2,024
Accrued professional services	1,100	249
Accrued other	369	43
Total accrued expenses	$ 1,681	$ 4,604

7. License and Purchase Agreements

Tovinontrine (IMR-687) – Exclusive License Agreement with Lundbeck

In April 2016, the Company entered into a license agreement with Lundbeck (the "Lundbeck Agreement") pursuant to which Lundbeck, among other things, granted the Company an exclusive, royalty-bearing license to certain patent rights and certain know-how owned or otherwise controlled by Lundbeck to research, develop, make, use, sell, and commercialize products from PDE9 inhibitors, which included tovinontrine. In November 2022, the Lundbeck Agreement was assigned to Cardurion in connection with the Asset Sale.

Prior to the assignment to Cardurion, the Company made cash payments to Lundbeck of $2.0 million consisting of an upfront payment and ongoing milestone payments of which $0.3 million was paid during the year ended December 31, 2022. Such payments were recorded as research and development expense. No payments were made during the year ended December 31, 2021. As partial consideration for the license, the Company issued 167,523 shares of common stock to Lundbeck in 2016, which represented 8.0% of the Company's then outstanding equity pursuant to a restricted stock agreement. The shares were fully vested on the date of issuance.

Sale of Tovinontrine (IMR-687) and the PDE9 program

In November 2022, the Company completed the Asset Sale to Cardurion pursuant to the Asset Purchase Agreement entered into in September 2022. In advance of executing the Asset Purchase Agreement, Cardurion paid the Company $0.3 million upon the execution of a non-binding term sheet as a reimbursement to the Company for fees it paid to Lundbeck related to its license agreement with Lundbeck. In accordance with the Asset Purchase Agreement the Company sold the license, know-how, patent rights, clinical research organization and clinical manufacturing organization contracts, inventory for its research and development, and other intangible assets related to tovinontrine and its PDE9 program to Cardurion in exchange for an up-front cash payment of $34.8 million. In addition, the Asset Purchase Agreement includes future milestone payments if Cardurion achieves a proof-of-concept milestone and if Cardurion achieves a regulatory and/or commercial milestone. Specifically, if Cardurion achieves the proof-of-concept milestone it will pay the Company a $10.0 million milestone payment, and if Cardurion achieves the regulatory and/or commercial milestone it will pay the Company a $50.0 million milestone payment. These milestone payments are a form of contingent consideration as the Company's receipt of these payments is contingent upon the achievement of the future milestones. The Company has excluded these payments from the transaction price at closing, and will recognize a gain contingency when the milestones are achieved.

As a result of the Asset Sale, the Company recognized a gain on the Asset Sale equal to $35.0 million, which is included in the Consolidated Statements of Operations and Comprehensive Income (Loss) for the year ended December 31, 2022. Additionally, as part of the asset sale process, the Company incurred costs of $2.5 million for legal, accounting and transaction services. $2.0 million of these costs were incurred during the third quarter 2022, and the remaining $0.5 million were incurred in the fourth quarter 2022. The Company recognized these costs within the General and administrative line of the Condensed Consolidated Statements of Operations and Comprehensive loss for the periods ended September 30, 2022, and the Consolidated Statements of Operations and Comprehensive Income (Loss) for the year ended December 31, 2022.

8. Commitments and Contingencies

Lease Agreements

In May 2019, the Company entered into a new operating lease agreement for office space totaling 4,210 square feet, located in Boston, Massachusetts with a 62-month term (the "May 2019 Lease Agreement). The lease included a rent escalation clause which resulted in cash rental payments of approximately $0.3 million annually. Rent expense was recognized on a straight-line basis over the expected lease term. In addition to the base rent, the Company was also responsible for its share of operating expenses, electricity and real estate taxes, in accordance with the terms of the May 2019

Lease Agreement. The Company provided a security deposit of approximately $0.1 million during the year ended December 31, 2019, which was included as a component of other assets on the Company's consolidated balance sheets for the year ended December 31, 2021.

In June 2021, the Company entered into an amendment to the May 2019 Lease Agreement (the "June 2021 Amended Lease Agreement"). Under the terms of the June 2021 Amended Lease Agreement, the Company expanded its leased premises by an additional 5,026 square feet, bringing the total office space to 9,236 square feet. The term of the June 2021 Amended Lease Agreement commenced in February 2022 and, prior to the early termination of the lease discussed below, was set to expire on March 31, 2027. Upon commencement of the term of the June 2021 Amended Lease Agreement, the annual base rent obligation was approximately $0.6 million, with a total cash obligation for base rent over the initial five-year term of the lease of approximately $3.1 million. In addition to the base rent, the Company was also responsible for its share of operating expenses, electricity and real estate taxes. Upon execution of the June 2021 Amended Lease Agreement, the Company provided an additional security deposit in the amount of $0.1 million, with security deposits under the May 2019 Lease Agreement and June 2021 Amended Lease Agreement totaling $0.2 million.

In July 2022, the Company entered into a second amendment and termination of office lease agreement (the "Termination Agreement") to terminate the lease under the May 2019 Lease Agreement, as amended by the June 2021 Amended Lease Agreement. The termination of the lease became effective on August 7, 2022 as a result of the landlord entering into a new lease agreement with a third-party tenant for the premises covered by the lease. As part of the Termination Agreement the Company paid a lease termination fee of $0.3 million, which was comprised of forfeiture of its $0.2 million security deposit and an additional fee of $0.1 million. In connection with this termination the Company remeasured its right of use assets and operating lease liabilities and recorded a gain of less than $0.1 million. The Company revised the estimated useful lives of the existing leasehold improvements and furniture placed in service at its premises, which are included as component of property and equipment, net on its consolidated balance sheets and are fully depreciated as of December 31, 2022.

The Company recorded rent expense of approximately $0.5 million and $0.3 million during the years ended December 31, 2022 and 2021, respectively.

There are no future lease payments due under the June 2021 Amended Lease Agreement following termination.

Legal Proceedings

The Company may from time to time be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the years ended December 31, 2022 and 2021, and no material legal proceedings are currently pending or, to the best of its knowledge, threatened.

Indemnification Agreements

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to the indemnification agreements, the Company agrees to indemnify, hold harmless, and to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third-party with respect to the Company's products. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

9. Stockholders' Equity (Deficit)

On August 13, 2019, the Company's board of directors, and on February 26, 2020, the Company's stockholders, approved the Company's restated certificate of incorporation, which became effective upon closing of the IPO on March 16, 2020, to authorize 10,000,000 shares of undesignated preferred stock, $0.001 per share par value, and to increase the number of authorized shares of common stock from 100,000,000 to 200,000,000 shares, $0.001 per share par value.

Common stockholders are entitled to receive dividends, as may be declared by the Board, if any, subject to the preferential dividend rights of any preferred stock then outstanding. Through December 31, 2022, no cash dividends have been declared or paid.

As of December 31, 2022, 10,000,000 shares of preferred stock were authorized and no shares of preferred stock were issued or outstanding.

As of December 31, 2022 and December 31, 2021, the Company has reserved for future issuance the following shares of common stock:

	December 31, 2022	December 31, 2021
Shares reserved for future issuance under the 2020 Equity Incentive Plan	2,627,945	1,216,532
Shares reserved for future issuance under the 2020 Employee Stock Purchase Plan	438,539	175,667
	3,066,484	1,392,199

10. Stock-Based Compensation

2016 Stock Incentive Plan

The Company's 2016 Stock Incentive Plan, (the "2016 Plan") provided for the grant of restricted stock, restricted stock units, stock appreciation rights, incentive stock options, non-statutory stock options and other stock-based awards to employees, officers, members of the Board, consultants and advisors of the Company.

As of the effective date of the 2020 Equity Incentive Plan, no shares remained available for future issuance under the 2016 Plan. Any options or awards outstanding under the 2016 Plan remained outstanding and effective.

2020 Equity Incentive Plan

On October 1, 2019, the Company's board of directors adopted, and on February 26, 2020 the Company's stockholders approved, the 2020 Equity Incentive Plan (the "2020 Plan"), which became effective on March 11, 2020. The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares reserved for issuance under the 2020 Plan is the sum of: (1) 1,220,283 shares of the Company's common stock; plus (2) the number of shares (up to a maximum of 2,091,969 shares) equal to the sum of (x) 228,852 shares, which represents the Company's common stock reserved for issuance under the 2016 Plan that remained available for grant under the 2016 Plan as of March 11, 2020 and (y) the number of shares of the Company's common stock subject to outstanding awards granted under the 2016 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right. The number of shares reserved shall be annually increased on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021 and continuing until, and including, the fiscal year ending December 31, 2030, equal to the lesser of (i) 4% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (ii) an amount determined by the Company's board of directors. On January 1, 2021, 701,930 additional shares were reserved for issuance under the 2020 Plan pursuant to this provision. On January 1, 2022, a further 1,051,490 shares were reserved for future under the 2020 Plan pursuant to this provision. No more than 8,541,982 shares of common stock may be issued as incentive stock options under the 2020 Plan. The shares of common stock underlying any awards that expire, terminate, or are otherwise surrendered, cancelled, forfeited or repurchased by the Company under the 2016 Plan or the 2020 Plan will be added back to the shares of common stock available for issuance under the 2020 Plan.

As of December 31, 2022, there were 2,627,945 shares available for future issuance under the 2020 Plan.

The following table summarizes the Company's stock option activity:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	2,373,024	$ 9.63	8.19	$ —
Granted	501,839	1.35		
Exercised	-			
Forfeited	(1,075,205)	10.00		
Outstanding as of December 31, 2022	1,799,658	$ 7.10	7.17	$ 1,006
Options vested and exercisable as of December 31, 2022	1,291,257	$ 7.03	6.79	$ 428

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the common stock as of the end of the period.

The weighted-average grant date fair value of the Company's stock options granted during the years ended December 31, 2022 and 2021 was $1.02 and $7.00, respectively.

The assumptions that the Company used to determine the grant date fair value of stock options granted to employees, non-employees and members of the Board during the years ended December 31, 2022 and 2021 were as follows, presented on a weighted-average basis:

	Year Ended December 31,	
	2022	2021
Expected term (in years)	6.16	6.20
Expected volatility	91.18%	81.0%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	1.83%	0.81%

Restricted Stock Units

In January 2022, the Company granted 425,289 restricted stock units to employees under the 2020 Plan, which will vest over a four year term. A summary of the restricted stock unit ("RSU") activity and related information is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2021	—	$ —
Granted	425,289	1.38
Vested	—	—
Forfeited	(211,846)	1.38
Unvested as of December 31, 2022	213,443	$ 1.38

Performance-based awards

The Company granted stock options to purchase an aggregate of 220,928 shares of common stock to certain employees, officers and consultants and advisors of the Company on May 16, 2019, June 5, 2019 and June 21, 2019, which contain performance-based vesting criteria. Vesting of these options was contingent on the closing of the second tranche of Series B Preferred Stock financing. Stock-based compensation expense associated with performance-based stock options is recognized if the performance conditions are considered probable of being achieved, using management's best estimates. As a result of the performance condition being met on February 25, 2020, these options vested as to 25% of the shares underlying each option on February 25, 2021 and vest as to the remainder of the shares in equal quarterly installments for

three years thereafter. The Company recognized stock-based compensation expense of less than $0.1 million and $0.2 million for these options during the years ended December 31, 2022 and December 31, 2021, respectively.

Stock-Based Compensation

Stock-based compensation expense included in the Company's consolidated statements of operations and comprehensive loss is as follows (in thousands):

	Year Ended December 31,	
	2022	2021
General and administrative	$ 2,398	$ 2,441
Research and development	197	1,404
Total stock-based compensation expense	$ 2,595	$ 3,845

As of December 31, 2022, total unrecognized compensation cost related to the unvested stock-based awards was $2.3 million, to be recognized over a weighted-average period of 1.89 years.

2020 Employee Stock Purchase Plan

On October 1, 2019, the Company's board of directors adopted, and on February 26, 2020, the Company's stockholders approved the 2020 Employee Stock Purchase Plan (the "2020 ESPP"), which became effective on March 11, 2020. The 2020 ESPP permits eligible employees who elect to participate, in six-month offering periods, to purchase shares of common stock through payroll deductions at a price equal to 85% of the fair market value of the common stock on the first or last business day of each applicable six-month offering period, whichever is lower. Purchase dates under the ESPP occur on or about June 14 and December 14 each year.

The 2020 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 193,216 shares of the Company's common stock. The number of shares of the Company's common stock reserved for issuance under the 2020 ESPP will automatically increase on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2021 and continuing until, and including, the fiscal year commencing on January 1, 2031, in an amount equal to the lowest of (i) 386,432 shares of the Company's common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (iii) an amount determined by the Company's board of directors. The Company's board of directors decided not to increase the number of shares of the Company's common stock reserved for issuance under the 2020 ESPP for the 2021 fiscal year. On January 1, 2022, 262,872 additional shares were reserved for issuance under the 2020 ESPP pursuant to this provision.

The Company did not withhold any amount from employees during the year ended December 31, 2022 and did not issue any shares. During the year ended December 31, 2021, less than $0.1 million was withheld from employees, on an after-tax basis, in order to purchase 15,696 shares of the Company's common stock. The Company recorded no stock-based compensation expense related to the 2020 ESPP for the year ended December 31, 2022 and less than $0.1 million for the year ended December 31, 2021. As of December 31, 2022, 438,539 shares of the Company's common stock remained available for issuance under the 2020 ESPP.

11. Income Taxes

For the year ended December 31, 2022, the Company recorded pre-tax book income of approximately $1.6 million, due substantially to the Asset Sale discussed in Note 7 above. As a result, the Company recorded tax expense of approximately $88.0 thousand in 2022, as the Company's taxable income for the year is not able to be fully offset with current and prior year tax attributes. In 2021, the Company did not record a current or deferred income tax expense or benefit due to current and historical losses incurred by the Company. The Company's income and losses before income taxes consist solely of income and losses from domestic operations.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The Cares Act includes provisions relating to refundable payroll tax credits, deferment of the employer portion of certain payroll taxes, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The

CARES Act also established a Paycheck Protection Program whereby certain small businesses are eligible for a loan to fund payroll expenses, rent, and related costs.

The CARES Act provided for an Employee Retention Credit ("ERC"), which is a refundable payroll tax credit that encouraged businesses to keep employees on the payroll during the COVID-19 pandemic. Eligible employers are entitled to a refundable tax credit equal to 50% of qualified wages paid to employees between March 13, 2020, and December 31, 2020, up to a maximum of $5,000 credit per employee. In late December 2020 Congress expanded and amended the CARES Act by enacting Public Law 116-260. Per the amendment to the CARES Act, eligible employers are entitled to a refundable tax credit equal to 70% of the qualified wages paid to employees between January 1, 2021, and June 30, 2021, up to a maximum of$10,000 of wages per employee per quarter, with a maximum of $7,000 per employee per calendar quarter. Congress further extended the credit with the American Rescue Plan signed into law on March 11, 2021; the American Rescue Plan extended the credit for the period July 1, 2021 to December 31, 2021 with the same limitations as the prior amendment (i.e., tax credit equal to 70% of qualified wages up to a maximum of $10,000 of wages per employee per quarter). However, on November 15, 2021, President Biden signed into law the Infrastructure Investment and Jobs Act which redacted the credit for calendar quarter 4 of 2021. Qualified Wages must be paid on or after March 13, 2020 and before October 1, 2021, and may include wages paid to employees, as well as so much of the employer's qualified health plan expenses as are properly allocable to such wages, not to exceed $10,000 per employee for calendar year 2020 or $10,000 per employee per calendar quarter in quarter 1, 2, or 3 of 2021 ("2021 Eligible Quarter"). The Retention Credit may be claimed for up to $5,000 per employee for calendar year 2020 (i.e., 50% of the $10,000 maximum in Qualified Wages for calendar year 2020) or $7,000 per employee per 2021 Eligible Quarter (i.e., 70% of the $10,000 maximum in Qualified Wages per 2021 Eligible Quarter). Therefore, the maximum Retention Credit per employee in 2020 is $5,000 and in 2021 is $21,000.

Based on the Company's evaluation of this provision and pandemic-related impact on its operations in 2020 and 2021, it was determined that the Company qualified to claim ERC in the second, third and fourth calendar quarters of 2020, as well as in both the first, second, and third calendar quarters of 2021. The Company recognized an ERC of approximately $1.0 million as an offset to payroll tax expenses for the year ended December 31, 2021, in its consolidated statements of operations.

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the consolidated financial statements is as follows:

	2022	2021
Income taxes at U.S. statutory rate	21%	21%
State income taxes	15.0	6
Permanent items	-3.2	0
Tax Credit	-142.9	5
Equity Compensation	70.9	0
Other	0.1	0
Change in valuation allowance	44.7	(32)
Total provision for income taxes	5.6%	0%

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities as of December 31, 2022 and 2021 are comprised of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Deferred tax assets		
Net operating loss carryforwards	$ 32,931	$ 37,411
Tax credits carryforwards	8,930	6,968
Capitalized Sec. 174 Costs	4,591	—
Stock-based compensation	673	1,268
Amortization	323	493
Accruals	—	545
Lease incentive liability	—	—
Lease liability	—	175
Unrealized gains/losses on investments	—	4
Other	5	31
Total deferred tax assets	47,453	46,895
Valuation allowance	(47,453)	(46,742)
Net deferred tax assets	—	153
Deferred tax liabilities		
Tenant improvement allowance	—	(12)
Unrealized gains/losses on investments	—	—
Right of Use Asset	—	(141)
Less Valuation Allowance	—	—
Total deferred tax liabilities	—	(153)
Net deferred taxes	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which are comprised primarily of net operating loss carryforwards and tax credits. Management has considered the Company's history of cumulative net losses in the United States, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its U.S. federal and state deferred tax assets. Accordingly, a full valuation allowance has been established against these net deferred tax assets as of December 31, 2022 and 2021, respectively. The Company reevaluates the positive and negative evidence at each reporting period. The Company's valuation allowance increased during 2022 by approximately $0.7 million primarily due to capitalized section 174 costs that were generated in the current year partially offset by utilization of net operating losses because of current year taxable income.

As of December 31, 2022 and 2021, the Company had U.S. federal net operating loss carryforwards of $122.8 million and $139.2 million, respectively, which may be available to offset future income tax liabilities. The 2017 Tax Cuts and Jobs Act ("TCJA") will generally allow losses incurred after 2017 to be carried over indefinitely but will generally limit the net operating loss deduction to the lesser of the net operating loss carryover or 80% of a corporation's taxable income (subject to Section 382 of the Internal Revenue Code of 1986, as amended). Also, there will be no carryback for losses incurred after 2017. Losses incurred prior to 2018 will generally be deductible to the extent of the lesser of a corporation's net operating loss carryover or 100% of a corporation's taxable income and be available for twenty years from the period the loss was generated. The Company has federal net operating losses generated following 2017 of $115.9 million, which do not expire. The federal net operating losses generated prior to 2018 of $7.9 million will expire at various dates through 2037.With the exception of the current year, the Company has been generating losses since its inception.

As of December 31, 2022 and 2021, the Company also had U.S. state net operating loss carryforwards of $113 million and $129.4 million, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2041.

As of December 31, 2022 and 2021, the Company had federal tax credit carryforwards of approximately $8.3 million and $6.5 million, respectively, available to reduce future tax liabilities which expire at various dates through 2042. As of December 31, 2022 and 2021, the Company had state research and development tax credit carryforwards of approximately $0.8 million and $0.6 million, respectively, available to reduce future tax liabilities which expire at various dates through 2037.

The utilization of our net operating loss carryforwards and research tax credit carryovers are subject to annual limitations under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state tax provisions, due to ownership change limitations that have occurred previously and that could occur in the future. These ownership changes limit the amount of net operating loss carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percent points over a three-year period. The Company has conducted an analysis of an ownership change under section 382. The impact of the Company's Section 382 study, which was conducted this year, has resulted in a reduction of the amount of tax attributes available to the Company to offset taxable income and income tax liabilities.

The Company has not, as of yet, conducted a study of research and development and orphan drug credit carryovers. Such a study, once undertaken by the Company, may result in an adjustment to the Company's research and development and orphan drug credit carryovers; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development and orphan drug credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment were required

At December 31, 2022 and December 31, 2021, the Company did not have any significant uncertain tax positions. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2022 and 2021, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company’s statement of operations. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

The Company files tax returns in the United States and Massachusetts. The Company is subject to U.S. federal and state examinations by tax authorities for years 2018 through the present. In addition, all of the Company’s tax years will remain open for examination by the federal and state taxing authorities to the extent that the Company's tax attributes are utilized in future years to offset income or income taxes.

12. Net Income (Loss) Per Share

The following table sets forth the computation of the Company’s basic and diluted net income (loss) per share for the years ended December 31, 2022 and 2021 (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2022	2021
Numerator:		
Net income (loss) attributable to common stockholders—basic and diluted	$ 1,488	$ (51,384)
Denominator:		
Weighted-average common shares outstanding—basic	26,287,264	21,661,450
Weighted-average common shares outstanding—diluted	26,385,567	21,661,450
Net income (loss) per share applicable to common stockholders—basic	$ 0.06	$ (2.37)
Net income (loss) per share applicable to common stockholders—diluted	$ 0.06	$ (2.37)

The Company excluded the following potential common shares from the computation of diluted net income (loss) per share attributable to common stockholders for the years ended December 31, 2022 and 2021 because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2022	2021
Options to purchase common stock	1,740,158	2,373,024
Unvested restricted shares	124,768	—
Shares reserved for future issuance under the ESPP	—	175,667

13. Related Party Transactions

Lundbeck

Lundbeckfond Invest A/S is one of the Company's stockholders and participated in all tranches of the Series A convertible preferred stock ("Series A Preferred Stock") financing and both tranches of the Series B Preferred Stock financing. Prior to the conversion of the Company's preferred stock, Lundbeckfond Invest A/S owned 5,470,492 shares of Series A Preferred Stock as of December 31, 2019, and 478,749 shares of Series Seed convertible preferred stock as of December 31, 2019. Lundbeckfond Invest A/S owned 1,326,111 shares of Series B Preferred Stock as of December 31, 2019. All shares of preferred stock converted into shares of common stock upon closing of the IPO. Lundbeckfond Invest A/S also purchased 187,500 shares of common stock in the IPO. This reflects a 5.1% and a 5.0% ownership interest on a fully diluted basis as of December 31, 2022 and 2021, respectively. Mette Kirstine Agger, who was a member of the Company's board of directors until June 29, 2021, is a Managing Partner at Lundbeckfonden Ventures, which is an affiliate of Lundbeckfond Invest A/S.

Lundbeck, an affiliate of Lundbeckfond Invest A/S, is also one of the Company's stockholders and participated in the fourth tranche of the Company's Series A Preferred Stock financing. Prior to the conversion of the Company's preferred stock, Lundbeck owned 499,069 shares of Series A Preferred Stock as of December 31, 2019, as well as 443,271 shares of common stock issued in conjunction with the Lundbeck Agreement (See Note 7). All shares of preferred stock converted into shares of common stock upon closing of the IPO. This reflects a 1.9% and a 1.8% ownership interest on a fully diluted basis as of December 31, 2022 and 2021, respectively. Lundbeck did not participate in the Series B Preferred Stock financing.

To date, pursuant to the Lundbeck Agreement, the Company has made cash payments to Lundbeck of $2.0 million consisting of an upfront payment and ongoing milestone payments which are recorded as research and development expense.

14. Benefit Plans

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code effective as of January 2019. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the plan may be made at the discretion of the Board. The Company contributed a match of $0.1 million and $0.2 million to the plan during the years ended December 31, 2022 and 2021, respectively.

(This page intentionally left blank)