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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

☐ **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 001-38537

AVROBIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-0710585**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Technology Square Sixth Floor Cambridge, Massachusetts	**02139**
(Address of principal executive offices)	**(Zip Code)**

(617) 914-8420
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	**AVRO**	**Nasdaq Global Select Market**

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 Section 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 registrant's common stock held by non-affiliates of the registrant was approximately $36,571,122 as of June 30, 2023 (based on a closing price of $0.95 share as quoted by the Nasdaq Global Select Market as of such date). In determining the market value of non-affiliate common stock, shares of the registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The registrant had 44,860,515 shares of Common Stock, $0.0001 par value per share, outstanding as of March 7, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

None.

AVROBIO, Inc.
Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2023
Table of Contents

Summary Risk Factors

The business of AVROBIO, Inc., or AVROBIO, is subject to numerous risks and uncertainties that you should be aware of in evaluating AVROBIO's business. These risks include, but are not limited to, the following, including risks related to the proposed merger (as defined below) with Tectonic Therapeutic, Inc., a Delaware corporation, or Tectonic:

- The exchange ratio (as defined below) will not change or otherwise be adjusted based on the market price of AVROBIO common stock as the exchange ratio depends on AVROBIO's net cash at the closing and not the market price of AVROBIO common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement (as defined below) was signed.
- Failure to complete the merger may result in either AVROBIO or Tectonic paying a termination fee to the other party, and could harm the AVROBIO common stock price and future business and operations of each company.
- Some AVROBIO and Tectonic directors and executive officers have interests in the merger that are different from AVROBIO stockholders and that may influence them to support or approve the merger without regard to AVROBIO stockholders' interests.
- AVROBIO stockholders and Tectonic stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger, including the issuance of Tectonic common stock in the private financings (as defined below).
- If the merger is not completed, AVROBIO's stock price may decline significantly.
- AVROBIO has incurred net losses since inception, expects to incur net losses for the foreseeable future and may never achieve or maintain profitability.
- If AVROBIO decides to resume development of its product candidates, AVROBIO will need additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force AVROBIO to delay, limit or terminate AVROBIO's product development efforts or other operations.
- Business interruptions resulting from the coronavirus disease, or COVID-19, pandemic or similar public health crises have caused and may in the future cause a disruption of the development of AVROBIO's product candidates and adversely impact AVROBIO's business.
- AVROBIO's hematopoietic stem cell, or HSC, lentiviral-based gene therapy product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development and of subsequently obtaining regulatory approval, should AVROBIO resume development of AVROBIO's product candidates.
- AVROBIO's product candidates and the process for administering AVROBIO's product candidates may cause undesirable side effects or have other properties that, should AVROBIO resume development of its product candidates, could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.
- Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials, should AVROBIO resume development of its product candidates.
- Should AVROBIO resume development of its product candidates, AVROBIO may find it difficult to enroll patients in AVROBIO's clinical trials, which could delay or prevent AVROBIO from proceeding with clinical trials of AVROBIO's product candidates.
- Should AVROBIO resume development of its product candidates, AVROBIO may encounter substantial delays in resuming its clinical trials or AVROBIO may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.
- Should AVROBIO resume development of its product candidates, even if AVROBIO completes the necessary preclinical and clinical studies, AVROBIO cannot predict whether or when AVROBIO would be able to obtain regulatory approval to commercialize a product candidate, and any approval could be for a narrower indication than anticipated.
- AVROBIO's commercially-scalable plato® platform has been used in only two of AVROBIO's clinical trials and clinical development has been halted.
- AVROBIO faces significant competition in AVROBIO's industry and, should AVROBIO resume development of its product candidates, there can be no assurance that AVROBIO's product candidates, if approved, will achieve

acceptance in the market over existing established therapies. In addition, AVROBIO's competitors may develop therapies that are more advanced or effective than AVROBIO's, which may adversely affect AVROBIO's ability to successfully market or commercialize any of AVROBIO's product candidates, should AVROBIO resume development of AVROBIO's product candidates.

- Gene therapies are novel, complex and difficult to manufacture. Should AVROBIO resume development of its product candidates, AVROBIO could experience production problems that result in delays in AVROBIO's development or commercialization programs or otherwise adversely affect AVROBIO's business.
- Should AVROBIO resume development of its product candidates, AVROBIO expects to rely on third parties to conduct some or all aspects of AVROBIO's vector production, product manufacturing, protocol development, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.
- AVROBIO has historically relied, and, should AVROBIO resume development of its product candidates, expects to continue to rely, on sole source suppliers for AVROBIO's automated, closed cell processing system; vector supply; plasmid supply; cell culture media supply; and drug product manufacturing. In addition, AVROBIO is dependent on a limited number of suppliers for some of AVROBIO's other components and materials used in AVROBIO's product candidates.
- Should AVROBIO resume development of its product candidates, third-party claims of intellectual property infringement may prevent or delay AVROBIO's development and commercialization efforts.
- AVROBIO's rights to develop and commercialize its product candidates, should AVROBIO resume development of its product candidates, are subject, in part, to the terms and conditions of licenses granted to AVROBIO by others.
- If AVROBIO experiences material weaknesses or deficiencies in the future, or otherwise fails to establish and maintain effective internal controls, AVROBIO may be unable to produce timely and accurate financial statements, and AVROBIO may conclude that its internal control over financial reporting is not effective, which could adversely impact AVROBIO's investors' confidence and AVROBIO's stock price.
- AVROBIO's failure to meet Nasdaq Global Select Market's, or Nasdaq, continued listing requirements could result in a delisting of AVROBIO common stock.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled "Risk Factors" and the other information set forth in this Annual Report on Form 10-K, including AVROBIO's consolidated financial statements and the related notes, as well as in other documents that AVROBIO files with the Securities and Exchange Commission, or the SEC. The risks summarized above or described in full below are not the only risks that AVROBIO faces. Additional risks and uncertainties not precisely known to AVROBIO, or that AVROBIO currently deems to be immaterial may also materially adversely affect AVROBIO's business, financial condition, results of operations and future growth prospects.

Forward-looking Information

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements may be identified by such forward-looking terminology as "aims," "anticipates," "believes," "continue," "could," "designed to," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "predicts," "projects," "seeks," "strives," "should," "will," and similar expressions or the negative of these terms. AVROBIO's forward-looking statements are based on a series of expectations, assumptions, estimates and projections about AVROBIO, are not guarantees of future results or performance and involve substantial risks and uncertainty. AVROBIO may not actually achieve the plans, intentions or expectations disclosed in AVROBIO's forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. AVROBIO's business and its forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in AVROBIO's statements regarding:

- the risk that the conditions to closing of the potential merger with Tectonic are not satisfied, including failure to obtain stockholder approval for the transactions;
- AVROBIO's ability to meet expectations regarding the timing and completion of the merger;

- uncertainties as to the timing and costs of the consummation of the transactions contemplated by the Merger Agreement and the ability of AVROBIO and Tectonic to consummate the transaction, including the private financings;
- the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the Merger Agreement;
- the fact that under the terms of the Merger Agreement, AVROBIO is restrained from soliciting other acquisition proposals during the pendency of the merger, except in certain circumstances;
- the effect of the announcement or pendency of the merger on AVROBIO's business relationships, operating results and business generally, including disruption of AVROBIO's management's attention from ongoing business operations due to the merger and potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transactions;
- the risk that the Merger Agreement may be terminated in circumstances that require AVROBIO to pay a termination fee;
- the outcome of any legal proceedings that may be instituted against AVROBIO, Tectonic or any of each company's respective directors or officers related to the Merger Agreement or the transactions contemplated thereby;
- the impact of the COVID-19 pandemic or any other public health crisis on AVROBIO's clinical trial programs, should AVROBIO resume development of its product candidates, clinical supply and business generally;
- should AVROBIO resume development of its product candidates, the timing, progress and results of preclinical studies and clinical trials for AVROBIO's programs and product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and AVROBIO's research and development programs;
- should AVROBIO resume development of its product candidates, the existence or absence of side effects or other properties relating to AVROBIO's product candidates which could delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences following any potential marketing approval;
- the durability of effects from AVROBIO's product candidates, should AVROBIO resume development of its product candidates;
- the timing, scope or likelihood of regulatory filings and approvals, should AVROBIO resume development of its product candidates;
- should AVROBIO resume development of its product candidates, the anticipated regulatory pathway for its product candidates and planned interactions with regulatory agencies;
- should AVROBIO resume development of its product candidates, AVROBIO's ability to develop and advance product candidates into, and successfully complete, clinical studies;
- should AVROBIO resume development of its product candidates, AVROBIO's expectations regarding the size of the patient populations for its product candidates, if approved for commercial use;
- the implementation of AVROBIO's business model and its strategic plans for its business, product candidates, should AVROBIO resume development of its product candidates, technology and plato platform;
- should AVROBIO resume development of its product candidates, AVROBIO's commercialization, marketing and manufacturing capabilities and strategy;
- should AVROBIO resume development of its product candidates, the pricing and reimbursement of AVROBIO's product candidates, if approved;
- should AVROBIO resume development of its product candidates, the scalability and commercial viability of AVROBIO's manufacturing methods and processes, including AVROBIO's move to a closed, automated system;
- should AVROBIO resume development of its product candidates, the rate and degree of market acceptance and clinical utility of its product candidates, in particular, and gene therapy, in general;
- AVROBIO's ability to establish or maintain collaborations or strategic relationships or obtain additional funding;

- AVROBIO's competitive position;
- the scope of protection AVROBIO and/or its licensors are able to establish and maintain for intellectual property rights covering its product candidates, should AVROBIO resume development of its product candidates, as well as any statements as to whether AVROBIO does or does not infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- AVROBIO's financial performance;
- AVROBIO's ability to retain the continued service of its key professionals and, should AVROBIO resume development of its product candidates, to identify, hire and retain additional qualified professionals;
- should AVROBIO resume development of its product candidates, developments and projections relating to its competitors and industry, including other lentiviral or HSC gene therapy companies;
- AVROBIO's expectations related to the use of its cash reserves;
- AVROBIO's estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- AVROBIO's ability to avoid any findings of material weaknesses or significant deficiencies in the future;
- AVROBIO's ability to satisfy the continued listing requirements of the Nasdaq, including a minimum bid price, and to maintain its common stock listing on Nasdaq or any stock exchange;
- the impact of laws and regulations, including without limitation recently enacted tax reform legislation; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

All of AVROBIO's forward-looking statements are as of the date of this Annual Report on Form 10-K only. In each case, actual results may differ materially from such forward-looking information. AVROBIO can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Annual Report on Form 10-K or included in AVROBIO's other public disclosures or its other periodic reports or other documents or filings filed with or furnished to the SEC could materially and adversely affect AVROBIO's business, prospects, financial condition and results of operations. Except as required by law, AVROBIO does not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report on Form 10-K, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by AVROBIO following this Annual Report on Form 10-K that modify or impact any of the forward-looking statements contained in this Annual Report on Form 10-K will be deemed to modify or supersede such statements in this Annual Report on Form 10-K.

Note Regarding Trademarks

All brand names or trademarks appearing in this report are the property of their respective holders.

PART I

Unless the context requires otherwise, references in this Annual Report on Form 10-K to the "Company," "AVROBIO," "we," "us," and "our" refer to AVROBIO, Inc. Our "board of directors" refers to the board of directors of AVROBIO, Inc.

Item 1. Business.

Overview

AVROBIO is a gene therapy company with a purpose to free people from a lifetime of genetic disease. AVROBIO has been focused on developing potentially curative HSC gene therapies to treat patients with rare diseases following a single dose treatment regimen. The gene therapies AVROBIO had been developing employ HSCs that are harvested from the patient and then modified with a lentiviral vector to insert the equivalent of a functional copy of the gene that is mutated in the target disease. AVROBIO believes that its approach, which is designed to transform stem cells from patients into therapeutic products, has the potential to provide curative benefit for a range of diseases. AVROBIO's development focus has been on a group of rare genetic diseases referred to as lysosomal disorders, some of which today are primarily managed with enzyme replacement therapies, or ERTs.

On July 12, 2023, following a comprehensive review of AVROBIO's business by the AVROBIO board of directors, or the AVROBIO Board, AVROBIO announced its intention to halt development of its programs and explore strategic alternatives focused on maximizing stockholder value, which may include, but is not limited to, an acquisition, a merger, business combination or divestiture. AVROBIO currently has a total of three gene therapy product candidates, none of which are currently in active clinical development, including AVR-RD-02 for the treatment of Gaucher disease type 1 and type 3, AVR-RD-03 for the treatment of Pompe disease and AVR-RD-01 for the treatment of Fabry disease.

After a comprehensive review of strategic alternatives, including identifying and reviewing potential candidates for a strategic transaction, on January 30, 2024, AVROBIO entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Alpine Merger Subsidiary, Inc., a direct, wholly owned subsidiary of AVROBIO, or Merger Sub, and Tectonic, pursuant to which Merger Sub will merge with and into Tectonic, with Tectonic surviving as AVROBIO's wholly-owned subsidiary, such transaction referred to hereinafter as the merger. The merger was unanimously approved by the AVROBIO Board, and the AVROBIO Board resolved to recommend approval of the Merger Agreement to AVROBIO stockholders. In connection with the merger, certain investors have agreed to purchase shares of Tectonic common stock at a purchase price of $12.39908 per share, subject to and immediately prior to the closing of the merger, pursuant to the terms of a subscription agreement entered into by such investors and Tectonic, or the Subscription Agreement, and certain investors have consummated or will consummate certain additional purchases of Tectonic common stock pursuant to the conversion of certain simple agreements for future equity, or SAFEs, entered into by such investors and Tectonic, or the Tectonic SAFEs, for an aggregate purchase price among the transactions contemplated by the Subscription Agreement and such Tectonic SAFEs of approximately $130.7 million, such transactions collectively, the private financings. At the effective time of the merger, each share of then-outstanding Tectonic common stock will be converted into the right to receive a number of shares of AVROBIO common stock, equal to the exchange ratio as set forth in the Merger Agreement, or the exchange ratio. Concurrently with the closing of the merger, and assuming approval by AVROBIO stockholders, AVROBIO anticipates effecting a reverse stock split, or the reverse stock split, at a ratio in the range between 1:3 to 1:30, inclusive. Additionally, at or prior to the effective time of the merger, AVROBIO and a rights agent will enter into a Contingent Value Rights Agreement, or CVR Agreement, pursuant to which AVROBIO stockholders of record as of immediately prior to such effective time (including holders of AVROBIO common stock issued upon settlement of the AVROBIO restricted stock units, or RSUs) will receive one non-transferable contingent value right, or CVR, for each outstanding share of AVROBIO common stock held by such stockholder on such date.

The closing of the merger is subject to approval by AVROBIO stockholders and Tectonic stockholders, as well as other customary closing conditions, including the effectiveness of a registration statement on Form S-4 filed with the SEC in connection with the transaction and Nasdaq's approval of the listing of the shares of the AVROBIO common stock to be issued in connection with the proposed merger. The closings of the private financings are conditioned upon the satisfaction or waiver of the conditions to the closing of the merger as well as certain other conditions. If the transactions are completed, the business of Tectonic will continue as the business of the combined company.

AVROBIO's future operations are highly dependent on the success of the merger and there can be no assurances that the merger will be successfully consummated. There can be no assurance that the strategic review process or any transaction relating to a specific asset, including the merger and any AVROBIO asset sale (as defined below), will result in AVROBIO pursuing such a transaction(s), or that any transaction(s), if pursued, will be completed on terms favorable to AVROBIO and its stockholders in the existing AVROBIO entity or any possible entity that results from a combination of entities. If the strategic review process is unsuccessful, and if the merger is not consummated, the AVROBIO Board may decide to pursue a dissolution and liquidation of AVROBIO.

AVROBIO's Product Candidates

AVROBIO's pipeline included three HSC gene therapy programs, none of which are in active clinical development, each targeting rare lysosomal disorders: AVR-RD-02 for the treatment of Gaucher disease type 1 and type 3, AVR-RD-03 for the treatment of Pompe disease and AVR-RD-01 for the treatment of Fabry disease.

AVR-RD-02 has been studied for the treatment of Gaucher disease type 1 in an AVROBIO-sponsored Phase 1/2 clinical trial, which AVROBIO refers to as the Guard1 clinical trial. Five patients were dosed in the Guard1 clinical trial.

AVR-RD-01 was AVROBIO's investigational gene therapy program for Fabry disease, which was deprioritized in January 2022. This decision was made due to several factors, including new clinical data showing variable engraftment patterns from the five most recently dosed patients in AVROBIO's Phase 2 clinical trial of AVR-RD-01 for the treatment of Fabry disease, which AVROBIO refers to as its FAB-GT clinical trial. The emergence of such new data would have significantly extended the program's development timeline. That development, coupled with an increasingly challenging market and regulatory environment for Fabry disease, were among the primary factors leading to AVROBIO's deprioritization of its Fabry program. As a result of the deprioritization, AVROBIO stopped enrollment of its FAB-GT clinical trial and focused on its other pipeline programs. A total of 14 patients had been dosed in AVROBIO's Fabry program, including nine patients in AVROBIO's FAB-GT clinical trial and five patients in a collaborator-sponsored Phase 1 clinical study of AVR-RD-01 for Fabry disease.

Resumption of the development of these product candidates, if that were to occur, would require the expenditure of significant resources to advance these candidates. Thereafter, if development of such product candidates were to be resumed and successfully advanced (of which there can be no assurance), it would be necessary to seek and obtain marketing approval to commercialize such product candidates, which could be expected to require the expenditure of significant additional resources and expenses related to regulatory, product sales, medical affairs, marketing, manufacturing and distribution.

Tectonic will assume AVROBIO's product candidates and related intellectual property rights as part of the merger.

Manufacturing

To support its HSC gene therapy programs, AVROBIO developed its plato® HSC gene therapy platform, incorporating multiple upgrades including a four-plasmid lentiviral vector designed to optimize vector copy number; transduction efficiency and resulting enzyme activity; a closed, automated manufacturing system designed to improve consistency and predictability of the drug product; and a personalized approach to conditioning. Six patients in AVROBIO's FAB-GT clinical trial of AVR-RD-01, for which enrollment was halted, and five patients in AVROBIO's Guard1 clinical trial of AVR-RD-02 were dosed with drug product manufactured utilizing the plato platform.

AVROBIO established manufacturing relationships that AVROBIO believes would provide AVROBIO with drug product manufacturing capabilities to support all aspects of the development and eventual commercialization of AVROBIO's gene therapies. AVROBIO's team leveraged their broad expertise in the manufacturing of gene and cellular therapies to build a network of contract manufacturing organizations, or CMO, partners for the development and manufacture of drug products and outsourced suppliers for the supply of vectors and plasmids. AVROBIO relies on sole source suppliers for drug product manufacturing, vector supply, plasmid supply and cell culture media.

To optimize production of AVROBIO's gene therapies, AVROBIO moved cell processing to an automated, closed system using disposable supplies, believing this industrialized manufacturing process facilitated a repeatable approach through which AVROBIO could design and manufacture commercially viable HSC gene therapies to potentially treat a large variety of genetic disorders.

Competition

AVROBIO's industry is highly competitive and subject to rapid and significant technological change. Potential competitors for AVROBIO's HSC gene therapy candidates include larger pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as academic institutions, government agencies and private and public research institutions. Key competitive factors affecting the commercial success of AVROBIO's gene therapies would likely include efficacy, safety and tolerability profile, reliability, convenience, price and reimbursement.

The market for treatment of lysosomal disorders is especially large and competitive. The gene therapies AVROBIO was developing, if approved, would have faced competition.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of AVROBIO's competitors. Accordingly, AVROBIO's competitors may be more successful than AVROBIO would have been in obtaining approval by the United States Food and Drug Administration, or FDA, for drugs and achieving widespread market acceptance. AVROBIO's competitors' products may be more effective, or

more effectively marketed and sold, than any product AVROBIO would have commercialized and may have rendered AVROBIO's gene therapies obsolete or non-competitive before AVROBIO could recover the expenses of developing and commercializing any of AVROBIO's gene therapies. AVROBIO's competitors may also obtain FDA or other regulatory approval for their products more rapidly than AVROBIO may have obtained approval for its products. AVROBIO anticipates that biotechnology companies will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases targeted by AVROBIO's gene therapies could render AVROBIO's gene therapies non-competitive or obsolete.

Licenses and Collaborations

Agreement with Lund University Rights Holders

In January 2017, AVROBIO entered into an exclusive license agreement with Prof. Stefan Karlsson and Dr. Maria Dahl, affiliates of Lund University, pursuant to which Prof. Karlsson and Dr. Dahl, and certain other relevant rights holders that may have an interest in intellectual property generated under a research project AVROBIO funded with Lund University, granted to AVROBIO an exclusive worldwide license, subject to certain retained rights, under certain intellectual property rights to develop, commercialize and sell products in any and all uses relevant to Gaucher disease. Intellectual property licensed to AVROBIO under this agreement relates to AVROBIO's Gaucher program.

As consideration for the license, AVROBIO is required to make payments in connection with the achievement of certain milestones up to an aggregate of $0.55 million.

AVROBIO's license agreement with the rights holders expires on the latest of (i) the twentieth anniversary of the end of a certain research project AVROBIO has funded pursuant to an agreement with Lund University, (ii) the expiration of the term of any patent filed on the licensed rights that covers a licensed product, (iii) the expiration of any applicable marketing exclusivity right and (iv) such time that neither AVROBIO nor any of AVROBIO's sublicensees or partners or contractors are commercializing a licensed product. Either AVROBIO or the rights holders acting together may terminate the license agreement if the other such party commits a material breach and fails to cure such breach within a certain period of time, or if the other party enters into liquidation, becomes insolvent, or enters into composition or statutory reorganization proceedings.

Agreement with BioMarin Pharmaceutical Inc.

In August 2017, AVROBIO entered into a license agreement with BioMarin Pharmaceutical Inc., or BioMarin, pursuant to which BioMarin granted AVROBIO an exclusive worldwide license under certain intellectual property rights related to GILT tags owned or controlled by BioMarin to develop, commercialize and sell retroviridae-based gene therapy products for use in the treatment of Pompe disease. This agreement was amended in February 2018 and again in January 2020 to, among things, provide that BioMarin would supply AVROBIO with certain materials related to the GILT tags technology. Under the terms of the agreement, AVROBIO must use commercially reasonable efforts to develop and commercialize one or more licensed products in the United States and certain European countries. In addition, AVROBIO is required to initiate an IND-enabling pharmacology/toxicology study of a licensed product within a specified period of time.

As consideration for the license, AVROBIO paid an initial license fee in the amount of $0.5 million and issued 233,765 shares of AVROBIO's Series B preferred stock to BioMarin at the time of AVROBIO's Series B financing. AVROBIO is also obligated to make payments to BioMarin upon achievement of certain milestones up to an aggregate of $13.0 million and pay to BioMarin a low single digit royalty percentage on net sales of licensed products covered by patent rights in a relevant country. AVROBIO's royalty obligation expires on a licensed product-by-licensed product and country-by-country basis upon the latest to occur of the expiration or termination of the last valid claim under the licensed patent rights in such country, which is currently projected to occur in 2029, the tenth anniversary of the first commercial sale of such licensed product in such country and the expiration of any applicable regulatory exclusivity in such country.

Unless terminated earlier, AVROBIO's license agreement with BioMarin will expire upon the expiration of AVROBIO's royalty obligation for all licensed products throughout the world. Either AVROBIO or BioMarin may terminate the license agreement if the other party commits a material breach and fails to cure such breach within a certain period of time. BioMarin may also terminate the agreement in the event of any challenge or opposition to the licensed patent rights or related actions brought by AVROBIO or AVROBIO's affiliates or sublicensees, or if AVROBIO, AVROBIO's affiliates or sublicensees knowingly assist a third party in challenging or otherwise opposing the licensed patent rights, except as required under a court order or subpoena. In addition, BioMarin may terminate the agreement upon our bankruptcy or insolvency. AVROBIO may terminate the agreement for any reason upon notice to BioMarin.

Governmental Regulation

In the United States, biological products, including gene therapy products, are subject to regulation under the Federal Food, Drug, and Cosmetic Act, as amended, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products. Each clinical study protocol for a gene therapy product must be reviewed by the FDA, and FDA approval must be obtained before the marketing of biological products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and AVROBIO may not be able to obtain the required regulatory approvals.

Within the FDA, the Center for Biologics Evaluation and Research, or CBER, regulates gene therapy products. The FDA and the United States National Institutes of Health, or NIH, have published guidance documents with respect to the development and submission of gene therapy protocols. The FDA has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing subjects involved in gene therapy studies for delayed adverse events, potency testing, and chemistry, manufacturing and control information in Investigational New Drug Applications, or INDs, for gene therapies.

Ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes AVROBIO may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that AVROBIO's products are unsafe or pose a hazard could prevent AVROBIO from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of AVROBIO's product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

U.S. Biological Products Development Process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical studies may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical study site before each study may be initiated;
- performance of adequate and well-controlled human clinical studies according to the FDA's regulations commonly referred to as GCPs and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a biologics license application, or BLA, for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical studies;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current Good Manufacturing Practices, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies); and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including a gene therapy product, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some

preclinical testing may continue even after the IND is submitted. An IND is a request for authorization from the FDA to ship an unapproved, investigational product in interstate commerce and to administer it to humans, and must become effective before clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees, or IBCs, as set forth in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

The FDA also may impose clinical holds on a biological product candidate at any time before or during clinical studies due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, AVROBIO cannot be sure that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such studies.

Clinical studies involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical studies are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical study will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical studies must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical study must be reviewed and approved by an IRB at or servicing each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Clinical studies typically are conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical studies are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for approval and product labeling.

Post-approval clinical studies, sometimes referred to as Phase 4 clinical studies, may be conducted after initial marketing approval. These clinical studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA recommends that sponsors, unless otherwise agreed by the FDA, observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire, of study subjects.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Annual progress reports detailing the results of the clinical studies must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor, acting on its own or based on a recommendation from the sponsor's data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Human gene therapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the study period, the number of patients the FDA will require to be enrolled in the studies in order to establish the safety, efficacy, purity and potency of human gene therapy products, or that the data generated in these studies will be acceptable to the FDA to support marketing approval. The NIH has a publicly accessible database, the Genetic Modification Clinical Research Information System which includes information on gene transfer studies and serves as an electronic tool to facilitate the reporting and analysis of adverse events on these studies.

Concurrent with clinical studies, companies usually complete additional animal studies and also must develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical studies of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. In most cases, the submission of a BLA is subject to a substantial application user fee, although the fee may be waived under certain circumstances. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original BLAs, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification. This review typically takes twelve months from the date the BLA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory

committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For a gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with GTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical studies were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a novel product (e.g., new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than AVROBIO interprets the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical studies, sometimes referred to as Phase 4 clinical studies, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the

same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of AVROBIO's products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if AVROBIO's product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

Expedited Development and Review Programs

The FDA has various programs, including Fast Track designation, breakthrough therapy designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the development and FDA review of drugs and biologics that are intended for the treatment of serious or life- threatening diseases or conditions. These programs do not change the standards for approval but may expedite the development or approval process. To be eligible for Fast Track designation, new drugs and biological products must be intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. One benefit of Fast Track designation, for example, is that the FDA may consider for review sections of the marketing application for a product that has received Fast Track designation on a rolling basis before the complete application is submitted.

Under the breakthrough therapy program, products intended to treat a serious or life-threatening disease or condition may be eligible for the benefits of the Fast Track program when preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies. Additionally, FDA will seek to ensure the sponsor of a breakthrough therapy product receives timely advice and interactive communications to help the sponsor design and conduct a development program as efficiently as possible.

Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, a platform technology incorporated within or utilized by a biological product is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a drug approved under a BLA; (2) preliminary evidence submitted by the sponsor of the licensed drug, or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a drug that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original BLA for a drug that uses or incorporates the platform technology. Designated platform technology status does not ensure that a drug will be developed more quickly or receive FDA approval. In addition, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation.

Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Under priority review, the FDA's goal is to review an application in six months, compared to ten months for a standard review.

Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. Under FDORA, the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved

under accelerated approval if, for example, the sponsor fails to conduct such studies in a timely manner and send the necessary updates to the FDA, or if a confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination of publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period.

Regenerative Medicine Advanced Therapies Designation

As part of the 21st Century Cures Act, enacted in December 2016, Congress amended the FD&C Act to facilitate an efficient development program for, and expedite review of regenerative medicine advanced therapies, which include cell and gene therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Regenerative medicine advanced therapies, or RMATs, do not include those human cells, tissues, and cellular and tissue based products regulated solely under Section 361 of the Public Health Service Act and 21 CFR Part 1271. This program is intended to facilitate efficient development and expedite review of regenerative medicine therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and qualify for RMAT designation. A drug sponsor may request that the FDA designate a drug as a RMAT concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the drug meets the criteria, including whether there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. Like the FDA's other expedited development programs, RMAT designation does not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP. AVROBIO has relied, and expects to continue to rely, should it resume development of its product candidates, on third parties for the production of clinical and commercial quantities of any products that AVROBIO may commercialize. Manufacturers of AVROBIO's products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

AVROBIO also must, if it were to resume development of its product candidates, comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with

doctors or other stakeholders, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on AVROBIO.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products, and those supplying products, ingredients, and components of them, are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterate products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of AVROBIO's product candidates, if AVROBIO were to resume development of its product candidates, some of AVROBIO's U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The United States Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, should AVROBIO resume development of its product candidates, AVROBIO may intend to apply for restoration of patent term for one of its patents, if and as applicable, to add patent life beyond its current expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant BLA.

A biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the biologic. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

The ACA, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted four- and 12-year exclusivity periods from the time of first licensure of the product. FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other

related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The first biological product determined to be interchangeable with a branded reference product for any condition of use is also eligible for a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the same reference product for any condition of use. The FDA may approve multiple "first" interchangeable products so long as they are all approved on the same first day of marketing. This exclusivity period, which may be shared amongst multiple first interchangeable products, lasts until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6).

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect AVROBIO's business. These and other laws govern AVROBIO's use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, AVROBIO's operations. If AVROBIO's operations result in contamination of the environment or expose individuals to hazardous substances, AVROBIO could be liable for damages and governmental fines. AVROBIO believes that it is in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on AVROBIO's business. AVROBIO cannot predict, however, how changes in these laws may affect its future operations.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which AVROBIO is subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Government Regulation Outside of the United States

Whether or not AVROBIO obtains FDA approval for a product, AVROBIO must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical studies. In the European Union, for example, a clinical trial agreement, or CTA, must be submitted for each clinical trial to each participating country's national competent authority and an independent ethics committee, much like the FDA and an IRB, respectively. Under the Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022, a single application is now made through the Clinical Trials Information System, or CTIS, for clinical trial authorization in up to 30 EU/European Economic Area, or EEA, countries at the same time and with a single set of documentation. The assessment of applications for clinical trials is divided into two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Member State concerned. The role of the relevant ethics committees in the assessment procedure continues to be governed by the national law of the concerned EU Member State, however overall related timelines are defined by the Clinical Trials Regulation. The Clinical Trials Regulation also provides for simplified reporting procedures for clinical trial sponsors.

The requirements and process governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical studies must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of a product in the European Union, AVROBIO must submit a marketing authorization application. The centralized procedure for obtaining a marketing authorization in the European Union is mandatory for certain types of products, such as products produced by biotechnological processes, orphan medicinal products, advanced-therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the European Union, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union. A centralized marketing authorization is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the European Union and in the additional Member States of the EEA (Iceland, Liechtenstein and Norway).

The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving a marketing authorization, innovative medicinal products approved on the basis of a complete and independent data package generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union, for a period of eight years from the date on which the reference product was first authorized in the European Union. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company could nevertheless also market another version of the product if such company obtained a marketing authorization based on an application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, is unlikely to generate sufficient return in the European Union to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication, during which a marketing authorization may not be granted in the European Union for a "similar medicinal product" to the authorized orphan product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar medicinal product for the same indication as an authorized orphan product at any time if:

- The second applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior;
- The marketing authorization holder for the authorized orphan product consents to a second orphan medicinal product application; or
- The marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product.

The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted,

but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The aforementioned European Union rules are generally applicable in the EEA.

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the European Union for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval. In October 2023, the European Parliament published draft reports proposing amendments to the legislative proposals, which will be debated by the European Parliament. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into European Union law.

The UK officially withdrew from the European Union on January 31, 2020 and the European Union and the UK signed a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and European Union pharmaceutical regulations. At present, Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the European Union regulatory framework currently continues to apply in Northern Ireland). The regulatory regime in Great Britain therefore aligns in many ways with current European Union regulations, however it is possible that these regimes will diverge more significantly in the future now that Great Britain's regulatory system is independent from the European Union. For example, the UK has implemented the now repealed Clinical Trials Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). However, the Medicines and Healthcare products Regulatory Agency, or MHRA, the UK's medicines regulator, published details of its legislative proposals designed to improve and strengthen the UK clinical trials legislation on March 21, 2023. The legislative proposals were published in response to a consultation which ran from January 17, 2022 to March 14, 2022. The MHRA will now work with lawyers to draft such new legislation. Great Britain is no longer covered by the European Union's procedures for the grant of marketing authorizations (Northern Ireland is covered by the centralized authorization procedure for the time being) and a separate marketing authorization is therefore required to market drugs in Great Britain. On January 1, 2024, a new international recognition framework was put in place by the MHRA, under which the MHRA may have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulators. The MHRA also has the power to have regard to marketing authorizations approved in EU Member States through decentralized or mutual recognition procedures with a view to more quickly granting a marketing authorization in the United Kingdom or Great Britain.

Since January 1, 2021, a separate process for orphan designation has applied in Great Britain. There is now no pre-marketing authorization orphan designation (as there is in the European Union) in Great Britain and the application for orphan designation will be reviewed by the MHRA at the time of a marketing authorization application for a UK or Great Britain marketing authorization. The criteria for orphan designation are the same as in the European Union, save that they apply to Great Britain only (e.g., there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in Great Britain, as opposed to the European Union, and the prevalence of the condition must be no more than 5 in 10,000 persons in Great Britain).

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework." This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK Government and the European Union will enact legislative measures to enact it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies must be conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If AVROBIO fails to comply with applicable foreign regulatory requirements, AVROBIO may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws and Compliance Requirements

In addition to FDA restrictions on the marketing of pharmaceutical products, AVROBIO may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, AVROBIO's business or financial arrangements and relationships through which AVROBIO markets, sells and distributes the gene therapies for which AVROBIO obtains approval. In addition, AVROBIO may be subject to patient privacy regulation by both the federal government and the states in which AVROBIO conducts its business. The laws that may affect AVROBIO's ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act, or FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, AVROBIO is subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if AVROBIO fails to comply with an applicable state law requirement AVROBIO could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of AVROBIO's business activities could be subject to challenge under one or more of such laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, imprisonment and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal FCA as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of AVROBIO's practices may be challenged under these laws. Efforts to ensure that AVROBIO's current and future business arrangements with third parties, and AVROBIO's business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that AVROBIO's business practices, including AVROBIO's arrangements with physicians and other healthcare providers, some of whom may receive stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against AVROBIO, and AVROBIO is not successful in defending itself or asserting AVROBIO's rights, those actions could have a significant impact on AVROBIO's business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of AVROBIO's operations, any of which could adversely affect AVROBIO's ability to operate AVROBIO's business and AVROBIO's results of operations. In addition, the approval and commercialization of any of AVROBIO's gene therapies outside the United States will also likely subject AVROBIO to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If any of the physicians or other healthcare providers or entities with whom AVROBIO does business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect AVROBIO's business.

Regulators globally are also imposing greater monetary fines for privacy violations. For example, non-compliance with the EU GDPR (as defined below) may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher.

European and UK Personal Data Collection

The collection and use of personal data (including health data) in the EEA and United Kingdom, or UK, is governed by the provisions of the EU General Data Protection Regulation, or EU GDPR, with respect to the EEA and the UK General Data Protection Regulation and UK Data Protection Act 2018 with respect to the UK, or UK GDPR, and collectively with the EU GDPR referred to as the GDPR, unless specified otherwise. The GDPR applies to any company established in the EEA and UK, as well as to those outside the EEA and UK, if they collect and use personal data in connection with the offering of goods or services to individuals in the European Union or the monitoring of their behavior. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to ensuring a legal basis or condition applies to the processing of personal data, stricter requirements relation to the processing of sensitive data (such as health data), providing information to individuals regarding data processing activities, where necessary obtaining consent from individuals to whom the data processing relates, responding to additional data subject requests, imposing notification of personal data breaches to the competent national data protection authorities, implementing safeguards in connection with the security and confidentiality of the personal data, accountability requirements and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA and UK to countries that do not ensure an adequate level of protection, like the United States in certain circumstances unless a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses, or the SCCs, and the UK International Data Transfer Agreement/Addendum, or UK IDTA), has been put in place. Where relying on the SCCs /UK IDTA for data transfers, AVROBIO may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. Further, the EU and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework, or Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. Non-compliance with the GDPR may result in enforcement action, including monetary penalties of up to €20 million (£ 17.5 million for the UK), or 4% of worldwide revenue, whichever is higher, 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. The GDPR, supplemental laws/regulations supplementing the GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase AVROBIO's cost of providing AVROBIO's products and services(including with respect to conducting clinical trial in the EEA and UK) or even prevent AVROBIO from offering certain services in jurisdictions that AVROBIO may operate in, should AVROBIO resume development of its product candidates.

Although the UK is regarded as a third country under the EU GDPR, the EEA and UK recognize one another as providing adequate protection under the EU GDPR and, therefore, transfers of personal data between the EEA and the UK remain unrestricted. The UK GDPR and EU GDPR are currently still closely aligned but operate independently from each other. The UK Government has introduced a Data Protection and Digital Information Bill into the UK legislative process to reform the UK data protection legal framework which may have an impact on the current alignment between the EU GDPR and UK GDPR if passed.

Healthcare Reform

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 medical products. For example, in 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjects drug manufacturers to annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; created a Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established the Center for Medicare Innovation at Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year,

which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.

- The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayment to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA - approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act, or IRA, includes several provisions that could impact AVROBIO's business to varying degrees, should AVROBIO resume development of its product candidates, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on AVROBIO's business and the healthcare industry in general is not yet known.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, the HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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.

AVROBIO expects that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that foreign federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for AVROBIO's products, if approved, or additional pricing pressures, should AVROBIO resume development of its product candidates.

Coverage and Reimbursement

While there have been some HSC gene therapies that have obtained coverage and reimbursement, significant uncertainty exists as to the coverage and reimbursement status of any gene therapies for which AVROBIO obtains regulatory approval. In the United States and markets in other countries, sales of any gene therapies for which AVROBIO receives regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurer sand other organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payor not to cover AVROBIO's gene therapies could reduce physician utilization of AVROBIO's products once approved and have a material adverse effect on AVROBIO's sales, results of operations and financial condition. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable AVROBIO to maintain price levels sufficient to realize an appropriate return on AVROBIO's investment in product development.

In addition, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate.

As a result, should AVROBIO resume development of its product candidates, the coverage determination process will require AVROBIO to provide scientific and clinical support for the use of AVROBIO's products to each payor separately and will be a time-consuming process. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost- effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product, AVROBIO may need to conduct expensive clinical trials in order to demonstrate the medical necessity and cost-effectiveness of such product, in addition to the costs required to obtain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Outside of the United States, the pricing of pharmaceutical products is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions.

Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

Human Capital Resources

As of March 7, 2024, AVROBIO had 13 full-time employees, two of whom have Ph.D. or M.D. degrees.
Of these full-time employees, two employees are engaged in research and development activities and 11 employees are engaged in finance, legal, human resources, facilities and general management. AVROBIO has no collective bargaining agreements with AVROBIO's employees and AVROBIO has not experienced any work stoppages. AVROBIO considers its relationship with its employees to be good.

AVROBIO's human capital resources objectives have included, as applicable, retaining and incentivizing its existing employees. The principal purposes of AVROBIO's incentive plans and retention awards have been to retain, incentivize and motivate selected employees through the granting of stock- and cash-based awards, as well as through severance benefits.

Available Information

AVROBIO is subject to the informational requirements of the Exchange Act and is required to file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read AVROBIO's SEC filings at the SEC's website at www.sec.gov. AVROBIO also maintains a website at www.avrobio.com. You may access, free of charge, AVROBIO's annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

Item 1A. Risk Factors.

Investing in AVROBIO common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this Annual Report on Form 10-K, including AVROBIO's consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as AVROBIO's other filings with the SEC, before investing in AVROBIO common stock. Any of the risk factors described below could adversely affect AVROBIO's business, financial condition or results of operations. The market price of AVROBIO common stock could decline if one or more of these risks or uncertainties were to occur, which may cause you to lose all or part of the money you paid to buy AVROBIO common stock. Additional risks that are currently unknown to AVROBIO or that AVROBIO currently believes to be immaterial may also impair AVROBIO's business. Certain statements below are forward-looking statements. See "Forward-Looking Information" in this Annual Report on Form 10-K.

Risks Related to the Merger with Tectonic

The exchange ratio will not change or otherwise be adjusted based on the market price of AVROBIO common stock as the exchange ratio depends on AVROBIO's net cash at the closing and not the market price of AVROBIO common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.

The Merger Agreement has set an exchange ratio for Tectonic capital stock being converted into AVROBIO's common stock, and the exchange ratio is based on the outstanding capital stock of Tectonic and the outstanding common stock of AVROBIO, in each case immediately prior to the closing. Applying the exchange ratio formula in the Merger Agreement, and after giving further effect to the proposed private financings, AVROBIO securityholders as of immediately prior to the merger are expected to own approximately 22.3% of the outstanding shares of capital stock of the combined company, former Tectonic securityholders are expected to own approximately 39.8% of the outstanding shares of capital stock of the combined company, and purchasers of Tectonic common stock in the private financings are expected to represent approximately 38.0% of the outstanding shares of capital stock of the combined company, subject to certain assumptions. Under certain circumstances further described in the Merger Agreement, the ownership percentages may be adjusted up or down including, but not limited to, if AVROBIO's net cash as of closing is lower than $64.5 million or greater than $65.5 million. AVROBIO management currently anticipates AVROBIO's net cash as of closing will be approximately $65.0 million to $75.0 million and the currently estimated ownership percentages are based on an assumption of closing net cash of approximately $65.0 million. In the event AVROBIO's net cash is below $65.0 million, the exchange ratio will be adjusted such that the number of shares issued to the pre-merger Tectonic securityholders will be increased, and AVROBIO stockholders will own a smaller percentage of the combined company following the merger.

Any changes in the market price of AVROBIO common stock before the completion of the merger will not affect the number of shares Tectonic stockholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the merger, the market price of AVROBIO common stock increases from the market price on the date of the Merger Agreement, then Tectonic stockholders could receive merger consideration with substantially more value for their shares of Tectonic capital stock than the parties had negotiated when they established the exchange ratio. Similarly, if before the completion of the merger the market price of AVROBIO common stock declines from the market price on the date of the Merger Agreement, then Tectonic stockholders could receive merger consideration with substantially lower value. The Merger Agreement does not include a price-based termination right.

Failure to complete the merger may result in either AVROBIO or Tectonic paying a termination fee to the other party, and could harm the AVROBIO common stock price and future business and operations of each company.

If the merger is not completed, AVROBIO and Tectonic are subject to the following risks:

- if the Merger Agreement is terminated under specified circumstances, AVROBIO could be required to pay Tectonic a termination fee of $2,712,500, and Tectonic could be required to pay AVROBIO a termination fee of $4,900,000;
- if the Merger Agreement is terminated by AVROBIO or Tectonic due to AVROBIO stockholders voting on and failing to approve certain proposals, AVROBIO will be required to reimburse Tectonic for merger-related expenses up to $650,000. The expense reimbursement, to the extent paid, will be credited against any termination fee payable by AVROBIO in the transaction;
- the price of AVROBIO common stock may decline and could fluctuate significantly; and
- costs related to the merger, such as financial advisor, legal and accounting fees, a majority of which must be paid even if the merger is not completed.

If the Merger Agreement is terminated and the AVROBIO Board or the Tectonic board of directors, or Tectonic Board, determines to seek another business combination, there can be no assurance that either AVROBIO or Tectonic will be able to find another third party to transact a business combination with, yielding comparable or greater benefits.

If the conditions to the merger are not satisfied or waived the merger may not occur.

Certain proposals are a condition to completion of the merger. Therefore, the merger cannot be consummated without the approval of such proposals. If the AVROBIO stockholders do not approve such proposals, failure to consummate the merger may harm AVROBIO and/or Tectonic. Even if the merger is approved by the Tectonic stockholders and the requisite proposals are approved by the AVROBIO stockholders, specified conditions must be satisfied or, to the extent permitted by applicable law, waived to complete the merger, as set forth in the Merger Agreement. AVROBIO and Tectonic cannot provide any assurance that all of the conditions to the consummation of the merger will be satisfied or waived. If the conditions are not satisfied or waived, the merger may not occur or the closing may be delayed.

The merger may be completed even though a material adverse effect may result from the announcement of the merger, industry-wide changes or other causes.

In general, neither AVROBIO nor Tectonic is obligated to complete the merger if there is a material adverse effect affecting the other party between January 30, 2024 (the date of the Merger Agreement), and the closing of the merger. However, certain types of causes are excluded from the concept of a "material adverse effect." Such exclusions include but are not limited to changes in general economic or political conditions, industry wide changes, changes resulting from the announcement of the merger, natural disasters, pandemics (including the COVID-19 pandemic), other force majeure events, acts or threat of terrorism or war and changes in GAAP. Therefore, if any of these events were to occur and adversely affect AVROBIO or Tectonic, the other party would still be obliged to consummate the closing notwithstanding such material adverse effect. If any such adverse effects occur and AVROBIO and Tectonic consummate the closing, the stock price of the combined company may suffer. This in turn may reduce the value of the merger to the AVROBIO stockholders, Tectonic stockholders or both.

If AVROBIO and Tectonic complete the merger, the combined company will need to raise additional capital by issuing equity securities or additional debt or through licensing arrangements, which may cause significant dilution to the combined company's stockholders or restrict the combined company's operations.

On January 30, 2024, Tectonic entered into the Subscription Agreement with certain investors named therein, pursuant to which such investors agreed to purchase shares of Tectonic common stock, at a purchase price currently estimated at approximately $96.6 million in the aggregate, for an aggregate purchase price among the transactions contemplated by the Subscription Agreement and the Tectonic SAFEs of approximately $130.7 million. The closings of the private placement financings are conditioned upon the satisfaction or waiver of the conditions to the closing as well as certain other conditions. The shares of AVROBIO common stock upon the exchange at closing of the private financing shares issued in the private financings will result in dilution to all securityholders of the combined company (i.e., both the pre-merger AVROBIO securityholders and former Tectonic securityholders).

Additional financing may not be available to the combined company when it is needed or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such financing will cause additional dilution to all securityholders of the combined company, including AVROBIO's pre-merger securityholders and Tectonic's former securityholders. It is also possible that the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to the combined company.

Some AVROBIO and Tectonic directors and executive officers have interests in the merger that are different from AVROBIO stockholders and that may influence them to support or approve the merger without regard to AVROBIO stockholders' interests.

Directors and executive officers of AVROBIO and Tectonic may have interests in the merger that are different from, or in addition to, the interests of other AVROBIO stockholders generally. These interests with respect to AVROBIO's directors and executive officers may include, among others: acceleration or vesting of certain AVROBIO stock options or AVROBIO RSUs, retention bonus payments, extension of exercisability periods of previously issued AVROBIO stock option grants, severance payments if employment is terminated in a qualifying termination in connection with the merger and rights to continued indemnification, expense advancement and insurance coverage. One member of the AVROBIO Board will continue as a director of the combined company after the effective time, and, following the closing, will be eligible to be compensated as a non-employee director of the combined company. All of AVROBIO's 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 the officers and directors of AVROBIO and cause them to view the merger differently from how AVROBIO stockholders generally may view it.

Tectonic's directors and executive officers may also have interests in the merger that are different from, or in addition to, the interests of other AVROBIO stockholders generally. Such interests may include, among others, certain of Tectonic's directors and executive officers have options, subject to vesting, to purchase shares of Tectonic common stock which, after the effective time, will be converted into and become options to purchase shares of the common stock of the combined company, Tectonic's executive officers are expected to continue as executive officers of the combined company after the effective time and all of Tectonic's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement.

Current members of the Tectonic Board may continue as directors of the combined company after the effective time, and, following the closing, will be eligible to be compensated as non-employee directors of the combined company pursuant to the combined company's non-employee director compensation policy.

The AVROBIO Board and Tectonic Board were aware of and considered those interests, among other matters, in reaching their decisions to approve and adopt the Merger Agreement, approve the merger, and recommend the approval of the Merger Agreement to AVROBIO and Tectonic stockholders. These interests, among other factors, may have influenced the directors and executive officers of AVROBIO and Tectonic to support or approve the merger.

AVROBIO stockholders and Tectonic stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger, including the issuance of Tectonic common stock in the private financings.

If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the merger, AVROBIO stockholders and Tectonic stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the merger.

If the merger is not completed, AVROBIO's stock price may decline significantly.

The market price of AVROBIO common stock is subject to significant fluctuations. Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market price of AVROBIO common stock will likely be volatile based on whether stockholders and other investors believe that AVROBIO can complete the merger or otherwise raise additional capital to support AVROBIO's operations if the merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market price of AVROBIO common stock has been and is expected to continue to be exacerbated by low trading volume. Additional factors that may cause the market price of AVROBIO common stock to fluctuate include:

- the entry into, or termination of, key agreements, including strategic licensing or commercial partner agreements;
- announcements by partners or competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the loss of key employees;
- future sales of its common stock;
- general and industry-specific economic conditions that may affect its research and development expenditures;
- the failure to meet industry analyst expectations; and
- period-to-period fluctuations in financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of AVROBIO common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

AVROBIO and Tectonic securityholders will generally have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the merger as compared to their current ownership and voting interests in the respective companies.

After the completion of the merger, the current AVROBIO stockholders and Tectonic stockholders will generally own a smaller percentage of the combined company than their ownership of their respective companies prior to the merger. Following the merger and after giving further effect to the proposed private financings, AVROBIO securityholders as of immediately prior to the merger are expected to own approximately 22.3% of the outstanding shares of capital stock of the combined company, former Tectonic securityholders are expected to own approximately 39.8% of the outstanding shares of capital stock of the combined company, and purchasers of Tectonic common stock in the private financings are expected to represent approximately 38.0% of the outstanding shares of capital stock of the combined company, subject to certain assumptions. Under certain circumstances further described in the Merger Agreement, the ownership percentages may be adjusted up or down including, but not limited to, if AVROBIO's net cash as of closing is lower than $64.5 million or greater than $65.5 million. AVROBIO management currently anticipates AVROBIO's net cash as of closing will be approximately $65.0 million to $75.0 million and the currently estimated ownership percentages are based on an assumption of AVROBIO's net cash of approximately $65.0 million at closing.

The Chief Executive Officer of Tectonic will serve as the Chief Executive Officer of the combined company following the completion of the merger. In addition, the board of directors of the combined company will initially include one member of the AVROBIO Board. Consequently, former securityholders of AVROBIO will not be able to exercise the same influence over the management and policies of the combined company following the closing of the merger than they currently exercise over the management and policies of AVROBIO.

The Merger Agreement contains provisions that limit AVROBIO's and Tectonic's ability to pursue alternatives to the merger, could discourage a potential competing acquiror of AVROBIO or Tectonic from making an alternative transaction proposal and, in specified circumstances, could require AVROBIO or Tectonic to pay a termination fee, which could significantly harm the market price of AVROBIO's common stock and negatively affect the financial condition, future business and operations of each company.

Covenants in the Merger Agreement impede the ability of AVROBIO and Tectonic to make acquisitions during the pendency of the merger, subject to specified exceptions. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, seeking, initiating or knowingly encouraging, inducing or facilitating the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry (each as defined in the Merger Agreement) or taking any action that could reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Any such transactions could be favorable to such party's stockholders, but the parties may be unable to pursue them.

If the merger is not completed and the Merger Agreement is terminated under certain circumstances, AVROBIO may be required to pay Tectonic a termination fee of $2,712,500, or Tectonic may be required to pay AVROBIO a termination fee of $4,900,000. Additionally, if the Merger Agreement is terminated by AVROBIO or Tectonic due to AVROBIO stockholders voting on and failing to approve certain proposals, AVROBIO will be required to reimburse Tectonic for merger-related expenses up to $650,000. The expense reimbursement, to the extent paid, will be credited against any termination fee payable by AVROBIO in the transaction. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, each of AVROBIO and Tectonic will have incurred significant fees and expenses, which must be paid whether or not the merger is completed. Further, if the proposed merger is not completed, it could significantly harm the market price of AVROBIO common stock.

In addition, if the Merger Agreement is terminated and AVROBIO or Tectonic determines to seek another business combination, there can be no assurance that either AVROBIO or Tectonic will be able to find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement.

Because the lack of a public market for Tectonic common stock makes it difficult to evaluate the fair market value of Tectonic's capital stock, the value of the AVROBIO common stock to be issued to Tectonic stockholders may be more or less than the fair market value of Tectonic common stock.

The outstanding capital stock of Tectonic is privately held and is not traded in any public market. The lack of a public market makes it difficult to determine the fair market value of Tectonic's capital stock. Because the percentage of AVROBIO equity to be issued to Tectonic stockholders was determined based on negotiations between the parties, it is possible that the value of the AVROBIO common stock to be issued to Tectonic stockholders will be more or less than the fair market value of Tectonic's capital stock.

The tax treatment of the CVRs is subject to substantial uncertainty.

There is substantial uncertainty as to the U.S. federal income tax treatment of the CVRs and payments (if any) thereon. There is no legal authority directly addressing the U.S. federal income tax treatment of the receipt of, holding of, or payments

under, the CVRs, and there can be no assurance that the Internal Revenue Service, or the IRS, would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs.

AVROBIO does not intend to report the issuance of the CVRs as a current distribution of property with respect to its stock, but it is possible that the IRS could assert that AVROBIO stockholders are treated as having received a distribution of property equal to the fair market value of the CVRs on the date the CVRs are distributed, which could be taxable to AVROBIO stockholders without the corresponding receipt of cash. In addition, it is possible that the IRS or a court could determine that the issuance of the CVRs (and/or any payments thereon) and the reverse stock split constitute a single "recapitalization" for U.S. federal income tax purposes with the CVRs constituting taxable "boot" received in such recapitalization exchange. In such case, the tax consequences of the CVRs and the reverse stock split would differ from the anticipated consequences, including with respect to the timing and character of income.

Risks Related to the Proposed Reverse Stock Split

The reverse stock split may not increase the combined company's stock price over the long-term.

The principal purposes of the reverse stock split are to (i) increase the per-share market price of AVROBIO common stock above the Nasdaq minimum bid price requirement so that the listing of AVROBIO and the shares of AVROBIO common stock being issued in the merger on Nasdaq will be approved and (ii) increase the number of authorized and unissued shares available for future issuance in connection with the merger. It cannot be assured, however, that the reverse stock split will accomplish any increase in the per-share market price of AVROBIO common stock for any meaningful period of time. While it is expected that the reduction in the number of outstanding shares of common stock will proportionally increase the market price of AVROBIO common stock, it cannot be assured that the reverse stock split will increase the market price of its common stock by a multiple of the reverse stock split ratio mutually agreed by AVROBIO and Tectonic, or result in any permanent or sustained increase in the market price of AVROBIO common stock, which is dependent upon many factors, including AVROBIO's business and financial performance, general market conditions and prospects for future success. Thus, while the stock price of AVROBIO common stock might meet the listing requirements for Nasdaq initially after the reverse stock split, it cannot be assured that it will continue to do so.

The reverse stock split may decrease the liquidity of the combined company's common stock.

Although the AVROBIO Board believes that the anticipated increase in the market price of the combined company's common stock resulting from the proposed reverse stock split could encourage interest in its common stock and possibly promote greater liquidity for its stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the reverse stock split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for the combined company's common stock. In addition, the reverse stock split may not result in an increase in the combined company's stock price necessary to satisfy Nasdaq's initial listing requirements for the combined company.

The reverse stock split may lead to a decrease in the combined company's overall market capitalization.

Should the market price of the combined company's common stock decline after the reverse stock split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the reverse stock split. A reverse stock split is often viewed negatively by the market and, consequently, can lead to a decrease in the combined company's overall market capitalization. If the per share market price does not increase in proportion to the reverse stock split ratio, then the value of the combined company, as measured by its stock capitalization, will be reduced. In some cases, the per-share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of the combined company's common stock will remain the same after the reverse stock split is effected, or that the reverse stock split will not have an adverse effect on the combined company's stock price due to the reduced number of shares outstanding after the reverse stock split.

Risks Related to AVROBIO's Strategic Alternative Process and Potential Strategic Transaction

Failure to complete, or delays in completing, the proposed merger with Tectonic could materially and adversely affect AVROBIO's results of operations, business, financial results and/or stock price.

In July 2023, AVROBIO announced that it was undertaking a comprehensive exploration of strategic alternatives focused on maximizing stockholder value, which may include, but are not limited to, an acquisition, a merger, business combination or divestiture. After a comprehensive review of strategic alternatives, including identifying and reviewing potential candidates for the merger, on January 30, 2024, AVROBIO entered into the Merger Agreement with Tectonic and Merger Sub, pursuant to which, subject to the satisfaction or waiver of the conditions therein, Merger Sub will merge with and into Tectonic, with Tectonic continuing as the surviving company and a wholly-owned subsidiary of AVROBIO. The closing is subject to approval by the AVROBIO stockholders and Tectonic stockholders as well as other customary closing

conditions, including the effectiveness of a registration statement filed with the SEC in connection with the transaction. If the merger is completed, the business of Tectonic will continue as the business of the combined company. Any failure to satisfy a required condition to closing may prevent, delay or otherwise materially and adversely affect the completion of the transaction, which could materially and adversely affect AVROBIO's results of operations, business, financial results and/or stock price. AVROBIO cannot predict with certainty whether or when any of the required closing conditions will be satisfied or if another uncertainty may arise and cannot assure you that the proposed merger will be successfully consummated or that AVROBIO will be able to successfully consummate the proposed merger as currently contemplated under the Merger Agreement or at all.

AVROBIO's efforts to complete the merger could cause substantial disruptions in, and create uncertainty surrounding, AVROBIO's business, which may materially adversely affect AVROBIO's results of operations and AVROBIO's business. Uncertainty as to whether the merger will be completed may affect AVROBIO's ability to recruit prospective employees or to retain and motivate existing employees. Employee retention may be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following the transaction. A substantial amount of AVROBIO's management's and employees' attention is being directed toward the completion of the transaction and thus is being diverted from AVROBIO's day-to-day operations. Uncertainty as to AVROBIO's future could adversely affect AVROBIO's business and AVROBIO's relationship with collaborators, suppliers, vendors, regulators and other business partners. For example, vendors, collaborators and other counterparties may defer decisions about working with AVROBIO or seek to change existing business relationships with AVROBIO. Changes to, or termination of, existing business relationships could adversely affect AVROBIO's results of operations and financial condition, as well as the market price of AVROBIO's common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction or termination of the Merger Agreement.

Risks related to the failure to consummate, or delay in consummating, the proposed merger with Tectonic include, but are not limited to, the following:

- AVROBIO may not realize any or all of the potential benefits of the merger, which could have a negative effect on AVROBIO's results of operations, business or stock price;
- under some circumstances, AVROBIO may be required to pay a termination fee to Tectonic of $2,712,500;
- if the Merger Agreement is terminated by AVROBIO or Tectonic due to AVROBIO stockholders voting on and failing to approve certain proposals, AVROBIO will be required to reimburse Tectonic for merger-related expenses up to $650,000. The expense reimbursement, to the extent paid, will be credited against any termination fee payable by AVROBIO in the transaction;
- AVROBIO would remain liable for significant transaction costs, including legal, accounting, financial advisory and other costs relating to the merger regardless of whether the merger is consummated;
- the trading price of AVROBIO common stock may decline to the extent that the current market price for AVROBIO common stock reflects a market assumption that the merger will be completed;
- the attention of AVROBIO's management and employees may have been diverted to the merger rather than to AVROBIO's operations and the pursuit of other opportunities that could have been beneficial to AVROBIO;
- AVROBIO could be subject to litigation related to any failure to complete the merger;
- AVROBIO could potentially lose key personnel during the pendency of the merger as employees and other service providers may experience uncertainty about their future roles with AVROBIO following completion of the merger; and
- under the Merger Agreement, AVROBIO is subject to certain customary restrictions on the conduct of AVROBIO's business prior to completing the merger, which restrictions could adversely affect AVROBIO's ability to conduct AVROBIO's business as AVROBIO otherwise would have done if AVROBIO was not subject to these restrictions.

The occurrence of any of these events individually or in combination could materially and adversely affect AVROBIO's results of operations, business, and AVROBIO's stock price.

AVROBIO cannot be sure if or when the merger will be completed.

The consummation of the merger is subject to the satisfaction or waiver of various conditions, including the authorization of the merger by AVROBIO stockholders and Tectonic stockholders. AVROBIO cannot guarantee that the closing conditions set forth in the Merger Agreement will be satisfied. If AVROBIO is unable to satisfy certain closing conditions or if other mutual closing conditions are not satisfied, Tectonic will not be obligated to complete the merger.

Under certain circumstances, AVROBIO would be required to pay Tectonic a termination fee of $2,712,500. Additionally, if the Merger Agreement is terminated by AVROBIO or Tectonic due to AVROBIO stockholders voting on and failing to approve certain proposals, AVROBIO will be required to reimburse Tectonic for merger-related expenses up to $650,000. The expense reimbursement, to the extent paid, will be credited against any termination fee payable by AVROBIO in the transaction. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, AVROBIO will have incurred significant fees and expenses, which must be paid whether or not the merger is completed.

If the merger is not completed, the AVROBIO Board, in discharging its fiduciary obligations to AVROBIO stockholders, would evaluate other strategic alternatives or financing options that may be available, which alternatives may not be as favorable to AVROBIO stockholders as the merger, including a liquidation and dissolution. Any future sale or merger, financing or other transaction, including a liquidation or dissolution, may be subject to further stockholder approval. AVROBIO may also be unable to find, evaluate or complete other strategic alternatives, which may have a materially adverse effect on AVROBIO's business.

Until the merger is completed, the Merger Agreement restricts Tectonic and AVROBIO from taking specified actions without the consent of the other party, and requires AVROBIO to operate in the ordinary course of business consistent with past practice. These restrictions may prevent Tectonic and AVROBIO from making appropriate changes to AVROBIO respective businesses or pursuing attractive business opportunities that may arise prior to the completion of the merger. Further, if AVROBIO's net cash at closing is lower than anticipated, either because expenses exceed current estimates or due to delays prior to closing, then the pre-merger AVROBIO stockholders will own less of the combined company pursuant to the exchange ratio adjustment set forth in the Merger Agreement.

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.

Lawsuits may be filed against AVROBIO and the members of the AVROBIO Board 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 AVROBIO, the AVROBIO Board, Tectonic, the Tectonic Board and others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, and AVROBIO may not be successful in defending against any such future claims. Lawsuits that may be filed against AVROBIO, the AVROBIO Board, Tectonic or the Tectonic Board could delay or prevent the merger, divert the attention of AVROBIO's management and employees from AVROBIO's day-to-day business and otherwise adversely affect AVROBIO's financial condition. Litigation may also impact AVROBIO's ability to consummate a potential strategic transaction or the ultimate value its stockholders receive in any such transaction.

In connection with the proposed merger, one action has been filed in the United States District Court for the Southern District of New York captioned *Garofalo v. Avrobio, Inc. et al*., 24-cv-1493 (filed February 27, 2024). The foregoing complaint is referred to as the "Merger Action."

The Merger Action alleges that the Form S-4 registration statement filed by AVROBIO on February 14, 2024 in connection the merger misrepresents and/or omits certain purportedly material information relating to the analyses performed by AVROBIO and the financial advisor to AVROBIO in connection with the merger, potential conflicts of interest of AVROBIO's officers and directors, and the events that led to the signing of the Merger Agreement. The Merger Action asserts violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder against all defendants (AVROBIO and the AVROBIO Board) and violations of Section 20(a) of the Exchange Act against AVROBIO's directors. The Merger Action seeks, among other things, an injunction enjoining the consummation of the merger, costs of the action, including plaintiff's attorneys' fees and experts' fees, and other relief the court may deem just and proper.

Also in connection with the Merger Agreement, AVROBIO has received demand letters from four purported AVROBIO stockholders demanding that AVROBIO disclose certain additional information relating to the merger, or the Demands.

AVROBIO cannot predict the outcome of the Merger Action or the Demands. AVROBIO believes that the allegations and claims asserted in the Merger Action and the Demands are without merit and intends to defend against them vigorously. Additional lawsuits and demand letters arising out of the merger may also be filed or received in the future, though AVROBIO will not provide additional disclosures unless those new complaints or letters contain material differences from those received to date.

AVROBIO stockholders potentially may not receive any payment on the CVRs and the CVRs may otherwise expire valueless.

The Merger Agreement contemplates that, at or prior to the effective time, AVROBIO, the holders' representative and a rights agent will execute and deliver the CVR Agreement, pursuant to which AVROBIO stockholders of record as of immediately prior to the effective time (including holders of shares of AVROBIO common stock issued upon settlement of the AVROBIO RSUs) will receive one non-transferable CVR for each outstanding share of AVROBIO common stock held by such stockholder on such date, subject to and in accordance with the terms and conditions of the CVR Agreement. Pursuant to the CVR Agreement, each CVR holder is entitled to certain rights to receive a pro rata portion of 80% of the net proceeds (as defined in the CVR Agreement), if any, received by AVROBIO as a result of an AVROBIO disposition (including a license) of AVROBIO's pre-closing assets after the effective date and prior to the 18-month anniversary of the closing, received within a 10-year period following the closing; provided that no contingent payment will be payable to any holder of the CVRs until such time as the then-outstanding and undistributed proceeds exceeds $350,000 in the aggregate. Such proceeds are subject to certain permitted deductions, including for applicable tax payments, certain expenses incurred by AVROBIO or its affiliates, losses incurred or reasonably expected to be incurred by AVROBIO or its subsidiaries due to a third party proceeding in connection with a disposition and certain wind-down costs. 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 proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that any holders of CVRs will receive payments with respect thereto.

The CVR Agreement provides that AVROBIO will use commercially reasonable efforts (as defined in the CVR Agreement) during the 18-month period following the closing to effect dispositions of AVROBIO's pre-closing assets to a third party that has delivered inbound interest (as defined in the CVR Agreement) with respect to such assets. As a result, AVROBIO will have no obligations to affirmatively sell or market such assets, in the absence of such inbound interest.

AVROBIO 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.

If AVROBIO does not successfully consummate the merger or another strategic transaction, the AVROBIO Board may decide to pursue a dissolution and liquidation of AVROBIO. In such an event, the amount of cash available for distribution to AVROBIO stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities, as to which AVROBIO can give you no assurance.

There can be no assurance that the merger will be completed. If the merger is not completed, the AVROBIO Board may decide to pursue a dissolution and liquidation of AVROBIO. In such an event, the amount of cash available for distribution to AVROBIO 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 AVROBIO funds its operations while pursuing the merger. In addition, if the AVROBIO Board were to approve and recommend, and AVROBIO stockholders were to approve, a dissolution and liquidation of the company, AVROBIO would be required under Delaware corporate law to pay AVROBIO's outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to stockholders. AVROBIO's commitments and contingent liabilities may include obligations under AVROBIO's employment and related 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 the company, litigation against AVROBIO, and other various claims and legal actions arising in the ordinary course of business, and other unexpected and/or contingent liabilities. As a result of this requirement, a portion of AVROBIO's assets would need to be reserved pending the resolution of such obligations.

In addition, AVROBIO may be subject to litigation or other claims related to a dissolution and liquidation of AVROBIO. If a dissolution and liquidation were to be pursued, the AVROBIO Board, in consultation with AVROBIO's advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of AVROBIO common stock could lose all or a significant portion of their investment in the event of liquidation, dissolution or winding up of the company. A liquidation would be a lengthy and uncertain process with no assurance of any value ever being returned to AVROBIO stockholders.

AVROBIO is substantially dependent on AVROBIO's remaining employees to facilitate the consummation of the merger.

AVROBIO's ability to consummate a strategic transaction depends upon its ability to retain its employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In January 2022, and then between July 2023 and February 2024, AVROBIO implemented reductions in force that significantly reduced its workforce in order to conserve its capital resources. As of March 7, 2024, AVROBIO had only 13

full-time employees. AVROBIO's ability to successfully complete the merger depends in large part on AVROBIO's ability to retain certain remaining personnel. Despite AVROBIO's efforts to retain these employees, one or more may terminate their employment with AVROBIO on short notice. AVROBIO's cash conservation activities may yield other unintended consequences, such as attrition beyond its planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. The loss of the services of certain employees could potentially harm AVROBIO's ability to consummate the merger, to run AVROBIO's day-to-day business operations and to fulfill AVROBIO's reporting obligations as a public company.

Risks Related to AVROBIO's Financial Position and Need for Additional Capital in Event the Merger is Not Consummated

AVROBIO has incurred net losses since inception, expects to incur net losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, with the exception of the current year, AVROBIO has incurred annual net losses. AVROBIO incurred net income (loss) of $12.2 million and $(105.9) million for the years ended December 31, 2023 and 2022, respectively. AVROBIO historically financed AVROBIO's operations primarily through private placements of AVROBIO preferred stock and, more recently, AVROBIO's initial public offering, or IPO, and follow-on public offerings of AVROBIO common stock, as well as sales of AVROBIO common stock under AVROBIO's "at-the-market" facility, or the ATM facility. Although AVROBIO had established its ATM facility, as of the filing date of its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, AVROBIO had not made any sales under its ATM facility, and AVROBIO will not make sales under its ATM facility unless and until a new shelf registration statement on Form S-3 is filed and declared effective. In addition, on November 2, 2021, AVROBIO entered into the Loan and Security Agreement, or the Term Loan Agreement, by and among AVROBIO, the lenders party thereto from time to time and Silicon Valley Bank or its successor, Silicon Valley Bank, a division of First-Citizens Bank & Trust company. In May 2023, AVROBIO announced that it had entered into an asset purchase agreement, or the Asset Purchase Agreement, with Novartis Pharma AG and Novartis Pharmaceuticals Corporation, collectively referred to herein as Novartis, providing for the sale of AVROBIO's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of AVROBIO specifically related to this program for an aggregate cash payment of $87.5 million upon closing of the transaction, or the Asset Sale. In June 2023, AVROBIO announced the closing of this transaction, as well as the pay-off of all outstanding amounts due and owed, including principal, interest and other charges, under the Term Loan Agreement and the termination thereof.

AVROBIO has devoted substantially all of AVROBIO's efforts to research and development, including clinical and preclinical development of AVROBIO's product candidates, as well as assembling AVROBIO's team. In July 2023, AVROBIO announced the decision to halt further development of AVROBIO's programs and to conduct a comprehensive exploration of strategic alternatives, and as such, AVROBIO's research and development expenses have decreased. Should AVROBIO resume development of AVROBIO's product candidates, AVROBIO expects that research and development costs would increase significantly, that it would be several years, if ever, before AVROBIO commercializes any product candidates, and that AVROBIO would continue to incur significant expenses and increasing operating losses for the foreseeable future thereafter. AVROBIO also anticipates that its expenses would increase substantially should AVROBIO resume development of AVROBIO's product candidates and if, and as, AVROBIO:

- resumes clinical enrollment activities, particularly if and as AVROBIO commences and continues clinical-stage activities for AVROBIO's product candidates;
- initiates additional clinical trials and preclinical studies for AVROBIO's product candidates, if any;
- experiences delays or interruptions in preclinical studies, clinical trials, or AVROBIO's supply chain due to the COVID-19 pandemic;
- seeks to identify and develop or in-license additional product candidates;
- seeks marketing approvals for AVROBIO's product candidates that successfully complete clinical trials, if any;
- establishes a sales, marketing and distribution infrastructure to commercialize any product candidates for which AVROBIO may obtain marketing approval;
- continues AVROBIO's implementation of AVROBIO's plato® platform as AVROBIO seeks to industrialize its HSC gene therapy approach into a robust, scalable and, if approved, commercially viable process;
- hires and retains additional personnel, such as clinical, quality control, regulatory and scientific personnel;

- expands AVROBIO's office space, infrastructure and facilities as needed to accommodate AVROBIO's employee base, including adding equipment and physical infrastructure to support AVROBIO's research and development; and
- continues to incur additional public company-related costs.

AVROBIO expects to continue to incur costs and expenditures in connection with AVROBIO's strategic alternatives process. Should AVROBIO resume development of its product candidates, to become and remain profitable, it must successfully develop and eventually commercialize product candidates with significant market potential and acceptance. This will require AVROBIO to be successful in a range of challenging activities, and its expenses will increase substantially as AVROBIO seeks to resume, initiate, conduct and complete preclinical and clinical trials of AVROBIO's product candidates, and manufacture, market and sell these or any future product candidates for which AVROBIO may obtain marketing approval, if any, and satisfy any post-marketing requirements. Should AVROBIO resume development of its product candidates, AVROBIO may never succeed in any or all of these activities and, even if AVROBIO does, AVROBIO may never generate revenues that are significant or large enough to achieve profitability. If AVROBIO does achieve profitability, AVROBIO may not be able to sustain or increase profitability on a quarterly or annual basis. AVROBIO's failure to become and remain profitable would decrease the value of AVROBIO and could impair their ability to raise capital, maintain their research and development efforts, expand their business or continue operations. A decline in the value of AVROBIO also could cause you to lose all or part of your investment.

In July 2023, AVROBIO announced that it was undertaking a comprehensive exploration of strategic alternatives focused on maximizing stockholder value, and in January 2024 AVROBIO announced its proposed merger with Tectonic. There can be no assurance that the proposed merger with Tectonic, or any other course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value. Further, if AVROBIO does not obtain additional funding and/or if a strategic transaction is not completed and are unable to continue as a going concern, AVROBIO may have to liquidate its assets and the values AVROBIO receives for the assets in liquidation or dissolution could be significantly lower than the values reflected in AVROBIO's consolidated financial statements.

AVROBIO has never generated revenue from product sales and does not expect to do so for the next several years, if ever.

AVROBIO's ability to generate revenue from product sales and achieve profitability depends on AVROBIO's ability, alone or with collaborative partners, to successfully resume and complete the development of, and obtain the regulatory approvals necessary to commercialize, AVROBIO's product candidates. AVROBIO does not anticipate generating revenues from product sales for the next several years, if ever. Should AVROBIO resume development of its product candidates, AVROBIO's ability to generate future revenues from product sales depends heavily on AVROBIO's success in:

- re-initiating and completing research and preclinical and clinical development of AVROBIO's product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which AVROBIO completes clinical trials;
- launching and commercializing product candidates for which AVROBIO obtains regulatory and marketing approval by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- qualifying for adequate coverage and reimbursement by government and third-party payors for AVROBIO's product candidates;
- establishing and maintaining supply and manufacturing processes and relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the commercial market demand for AVROBIO's product candidates, if approved;
- obtaining market acceptance of AVROBIO's product candidates, if approved, as a viable treatment option;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which AVROBIO may enter and performing AVROBIO's obligations under such arrangements; and
- attracting, hiring and retaining qualified personnel.

Should AVROBIO resume development of its product candidates, and one or more of the product candidates that AVROBIO develops is approved for commercial sale, AVROBIO anticipates incurring significant costs associated with commercializing any approved product candidate. AVROBIO's expenses could increase beyond expectations if AVROBIO

is required by the FDA, or other foreign regulatory authorities to perform clinical and other studies in addition to those that AVROBIO currently anticipates would be required. Even if AVROBIO is able to generate revenues from the sale of any approved products, AVROBIO may not become profitable and may need to obtain additional funding to continue operations.

If AVROBIO decides to resume development of its product candidates, AVROBIO will need additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force AVROBIO to delay, limit or terminate AVROBIO's product development efforts or other operations.

Should AVROBIO resume development of its product candidates, particularly if AVROBIO continues the research and development of, initiate further clinical trials of and seek marketing approval for, AVROBIO's product candidates and continue to enhance and optimize AVROBIO's vector technology and manufacturing processes, AVROBIO expects its expenses would increase in connection with such activities. In July 2023, AVROBIO announced it was halting further development of its programs. Following such announcement, in September 2023 AVROBIO terminated its agreements with the University of Manchester, or the MPSII License Agreement, for the license and development of a gene therapy for MPSII, or Hunter syndrome, and discontinued AVROBIO's AVR-RD-05, a Hunter syndrome gene therapy program. Previously, in June 2023, AVROBIO sold its cystinosis gene therapy program to Novartis. AVROBIO currently has a total of three gene therapy product candidates, for Gaucher, Pompe and Fabry diseases, none of which is currently in clinical development. Resumption of the development of these product candidates, if that were to occur, would require AVROBIO to expend significant resources to advance these candidates. In addition, should AVROBIO resume development of its product candidates and thereafter obtains marketing approval for any of AVROBIO's product candidates, AVROBIO expects to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution. Though AVROBIO has halted further development of its programs to conduct a comprehensive exploration of strategic alternatives and has conducted reductions in force, AVROBIO may incur significant costs in connection with a comprehensive review of strategic alternatives, and AVROBIO has incurred, and may in the future incur, significant costs related to this continued evaluation. AVROBIO may also incur additional unanticipated expenses in connection with this process. Furthermore, AVROBIO expects to continue to incur additional costs associated with operating as a public company. Accordingly, should AVROBIO resume development of its product candidates, AVROBIO will need to obtain substantial additional funding in connection with AVROBIO's continuing operations. If AVROBIO is unable to raise capital when needed or on reasonable terms, and/or if a strategic transaction is not completed, AVROBIO may have to liquidate its assets. AVROBIO's future capital requirements will depend on many factors, including:

- AVROBIO's exploration of strategic alternatives to maximize stockholder value, including whether AVROBIO is able to identify and implement any potential strategic alternatives, in a timely manner or at all, whether AVROBIO realizes all or any of the anticipated benefits of any such transaction and whether any such transactions would generate value for stockholders;
- should AVROBIO resume development of its product candidates, the scope, progress, results and costs of drug discovery, laboratory testing, preclinical development and clinical trials for AVROBIO's product candidates, including the extent of any impacts from the COVID-19 pandemic or similar public health crisis on these activities;
- should AVROBIO resume development of its product candidates, the costs, timing and outcome of regulatory review of AVROBIO's product candidates;
- the costs of future activities, including, should AVROBIO resume development of its product candidates, product sales, medical affairs, marketing, manufacturing and distribution, for any of AVROBIO's product candidates for which AVROBIO receives marketing approval;
- should AVROBIO resume development of AVROBIO's product candidates, the costs associated with AVROBIO's manufacturing process development and evaluation of third-party manufacturers;
- revenue, if any, should AVROBIO resume development of its product candidates, received from commercial sale of AVROBIO's products, should any of AVROBIO's product candidates receive marketing approval;
- the amounts, if any, raised from potential financings and capital raising activities should AVROBIO resume development of its product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing AVROBIO's intellectual property rights and defending intellectual property-related claims;
- the costs of defending against and resolving adverse litigation, if any;
- the terms of AVROBIO's current and any future license agreements and collaborations; and

- the extent to which AVROBIO acquires or in-license other product candidates, technologies and intellectual property.

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 should AVROBIO resume development of its product candidates, AVROBIO may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, AVROBIO's product candidates, if approved, may not achieve commercial success. AVROBIO's product revenues, if any, will be derived from or based on sales of products that may not be commercially available for many years, if at all. Accordingly, AVROBIO will need to continue to rely on additional financing to achieve AVROBIO's business objectives. Adequate additional financing may not be available to AVROBIO on acceptable terms, or at all.

Entry into an acquisition, merger, business combination, or other strategic transaction, or raising additional capital may cause dilution to AVROBIO's existing stockholders, restrict AVROBIO's operations or cause AVROBIO to relinquish valuable rights.

In July 2023, AVROBIO announced its intention to explore strategic alternatives, including a potential acquisition, merger, business combination, or other strategic transaction, and in January 2024 announced entrance into the Merger Agreement with Tectonic. If the merger with Tectonic is not consummated, the terms of any other strategic transaction that AVROBIO might enter into, if any, could result in the issuance of securities in the company, such as AVROBIO common stock, which could result in significant dilution to AVROBIO stockholders. Additionally, in connection with any other such strategic alternatives, AVROBIO may seek to raise additional capital through a combination of public and private equity offerings or other financing arrangements. To the extent that AVROBIO enters into any other strategic transaction and/or raises additional capital through the sale of equity, convertible debt securities or other equity-based derivative securities, stockholders' ownership interest will be diluted and the terms may include liquidation or other preferences that adversely affect rights of stockholders. Any indebtedness AVROBIO incurs would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on AVROBIO's ability to incur additional debt, limitations on AVROBIO's ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact AVROBIO's ability to conduct AVROBIO's business. Furthermore, the issuance of additional securities, whether equity or debt, by AVROBIO, or the possibility of such issuance, may cause the market price of AVROBIO common stock to decline and existing stockholders may not agree with AVROBIO's strategic or financing plans or the terms of such strategic transaction or financings. If AVROBIO raises additional funds through strategic partnerships and alliances and licensing arrangements with third parties, AVROBIO may have to relinquish valuable rights to AVROBIO's technologies, or AVROBIO's product candidates, or grant licenses on terms unfavorable to AVROBIO. Adequate additional financing may not be available to AVROBIO on acceptable terms, or at all.

AVROBIO's limited operating history may make it difficult to evaluate the success of AVROBIO's business to date and to assess AVROBIO's future viability.

AVROBIO was founded in November 2015. AVROBIO's operations to date have been limited to corporate organization, recruiting key personnel, business planning, raising capital, acquiring rights to AVROBIO's technology, identifying potential product candidates, undertaking preclinical studies and planning and supporting clinical trials of certain of AVROBIO's product candidates and establishing research and development and manufacturing capabilities. AVROBIO has not yet demonstrated the ability to complete clinical trials of AVROBIO's product candidates, obtain marketing approvals, manufacture products on a commercial scale or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about AVROBIO's future success or viability, should AVROBIO resume development of its programs, may not be as accurate as they could be if AVROBIO had a longer operating history. In addition, as an early-stage company, AVROBIO may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect AVROBIO's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Uncertainty remains over liquidity concerns in the broader financial services industry, and if any of AVROBIO's contract organizations, vendors, suppliers or other parties with whom AVROBIO conducts business are unable to access funds pursuant to their own arrangements with such a financial institution, such party's ability to perform their obligations could be adversely affected. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, Federal Deposit Insurance Corporation, or the FDIC, and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although AVROBIO assesses its banking relationships as AVROBIO believes necessary or appropriate, AVROBIO's access to funding sources and other credit arrangements in amounts adequate to finance or capitalize AVROBIO's current and projected future business operations could be significantly impaired by factors that affect AVROBIO's company, the financial institutions with which AVROBIO has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which AVROBIO has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on AVROBIO's current and projected business operations and AVROBIO's financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and/or delays, inability or reductions in the company's ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require AVROBIO to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in AVROBIO's credit agreements or credit arrangements;
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for AVROBIO to acquire financing on acceptable terms or at all. Any decline in available funding or access to AVROBIO's cash and liquidity resources could, among other risks, adversely impact AVROBIO's ability to meet AVROBIO's operating expenses, financial obligations or fulfill AVROBIO's other obligations, result in breaches of AVROBIO's financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on AVROBIO's liquidity and AVROBIO's current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by AVROBIO's contract organizations, vendors, suppliers or other parties with whom AVROBIO conducts business, which in turn, could have a material adverse effect on AVROBIO's current and/or projected business operations and results of operations and financial condition. For example, contract organizations, vendors, suppliers or other parties with whom AVROBIO conducts business could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on AVROBIO's company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any bankruptcy or insolvency involving AVROBIO's contract organizations, vendors, suppliers

or other parties with whom AVROBIO conducts business, or any breach or default by such parties, or the loss of any significant relationships with such parties, could result in a material adverse impact on AVROBIO's business.

Risks Related to AVROBIO's Business if Merger is Not Consummated

AVROBIO may not be successful in completing the merger, and any strategic transactions that it may consummate in the future could have negative consequences.

AVROBIO is exploring strategic transactions regarding any product candidates and related assets, including, without limitation, licensing transactions and asset sales. There can be no assurance that AVROBIO will be able to successfully consummate the merger or that the merger will be completed on attractive terms, within the anticipated timing, or at all. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and AVROBIO has incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. AVROBIO may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in its business.

In addition, any strategic business combination or other transactions that AVROBIO may consummate in the future could have a variety of negative consequences and it may implement a course of action or consummate a transaction that yields unexpected results that adversely affects its business and decreases the remaining cash available for use in its business or the execution of its strategic plan. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value or achieve the anticipated results. Any potential transaction would be dependent on a number of factors that may be beyond its control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with AVROBIO, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with AVROBIO on reasonable terms. Any failure of such a potential transaction to achieve the anticipated results could significantly impair its ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to its stockholders.

If AVROBIO is not successful in setting forth a new strategic path for AVROBIO, or if its plans are not executed in a timely fashion, this may cause reputational harm with its stockholders and the value of its securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of AVROBIO could cause its stock price to fluctuate significantly.

If AVROBIO is successful in completing the merger, it may be exposed to other operational and financial risks.

Although there can be no assurance that the merger will be completed, the negotiation and consummation of the merger has required and will continue to require significant time on the part of its management, and the diversion of management's attention may disrupt its business.
The negotiation and consummation of the merger may also require more time or greater cash resources than AVROBIO anticipates and exposes AVROBIO to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with its operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of AVROBIO or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on its business, financial condition and prospects.

AVROBIO's corporate restructuring and the associated reduction in workforce may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt its business.

In January 2022, and then between July 2023 and February 2024, AVROBIO implemented reductions in force that significantly reduced its workforce in order to conserve its capital expenditures. AVROBIO may not realize, in full or in part, the anticipated benefits, savings and improvements in its cost structure from its restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If AVROBIO is unable to realize the expected operational efficiencies and cost savings from the restructuring, its operating results and financial condition will be adversely affected. Furthermore, its restructuring plan may be disruptive to its operations. For example, its headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing its business strategy, including retention of its remaining employees. Employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

Any future growth of AVROBIO's business would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to its limited resources, AVROBIO may not be able to effectively manage its operations or recruit and retain qualified personnel, which may result in weaknesses in its infrastructure and operations, risks that AVROBIO may not be able to comply with legal and regulatory requirements, loss of employees and reduced productivity among remaining employees.

The impact and results of AVROBIO's ongoing strategic process are uncertain and may not be successful.

The AVROBIO Board remains dedicated to diligent deliberations and the making of informed decisions that the directors believe are in the best interests of the company and its stockholders. There can be no assurance, however, that the company's current strategic direction, or the AVROBIO Board's evaluation of strategic alternatives, will result in any initiatives, agreements, transactions or plans that will further enhance stockholder value.
In addition, given the substantial restructuring of AVROBIO's operations over the past several years, it may be difficult to evaluate its current business and future prospects on the basis of historical operating performance.

Risks Related to the Discovery and Development of AVROBIO's Product Candidates

Business interruptions resulting from the COVID-19 pandemic or similar public health crises have caused and may in the future cause a disruption of the development of AVROBIO's product candidates and adversely impact AVROBIO's business.

Public health crises such as pandemics, epidemics, or any outbreak of an infectious disease or similar public health crises could adversely impact AVROBIO's business. For example, the COVID-19 pandemic disrupted normal business operations both in and outside of affected areas and has had significant negative impacts on businesses and financial markets worldwide. While AVROBIO currently has no ongoing clinical development activities following AVROBIO's decision to halt its clinical development programs while AVROBIO considers strategic alternatives, AVROBIO continues to monitor AVROBIO's operations and follow applicable government recommendations, and the majority of AVROBIO's employees have adopted a "hybrid" work schedule which generally limits the number of people in AVROBIO's office at any particular time. Notwithstanding these measures, the COVID-19 pandemic, including potential outbreaks of new variants, or any other public health crisis could affect the health and availability of AVROBIO's workforce as well as those of the third parties on which AVROBIO relies. If members of AVROBIO's management and other key personnel are unable to perform their duties or have limited availability due to any outbreak of an infectious disease or similar public health crises, AVROBIO may not be able to execute on AVROBIO's business strategy and/or AVROBIO's operations may be negatively impacted.

In addition, clinical trial activities, should AVROBIO resume any such activities, including patient enrollment and data collection, are dependent upon global clinical trial sites which were adversely affected by the COVID-19 pandemic. For example, as the global healthcare community responded to the fluctuations in COVID-19 cases and hospitalizations, many hospitals, including AVROBIO's clinical sites, temporarily paused elective procedures, which included dosing of new patients with AVROBIO's investigational gene therapies. While AVROBIO substantially resumed data collection and dosing of new patients until halting AVROBIO's development programs in July 2023, AVROBIO's ability to continue clinical activities without further delay or interruption, should AVROBIO resume development of its programs, will depend on future developments that are highly uncertain and cannot be accurately predicted.

Additional factors from any public health crisis that may delay or otherwise adversely affect enrollment in or the progress of the clinical trials of AVROBIO's product candidates if AVROBIO resumes development of its programs, as well as AVROBIO's business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as AVROBIO's clinical trial investigators, hospitals serving as AVROBIO's clinical trial sites and hospital staff supporting the conduct of AVROBIO's clinical trials;

- limitations on travel that could interrupt key trial activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that may impact the ability or willingness of patients, employees or contractors to travel to AVROBIO's clinical trial sites or secure visas or entry permissions, any of which could delay or adversely impact the conduct or progress of AVROBIO's clinical trials;
- interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in AVROBIO's clinical trials;
- business disruptions caused by workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact AVROBIO's business operations or those of third party service providers, contractors, or suppliers on whom AVROBIO relies, impair the productivity of AVROBIO's personnel, subject AVROBIO to additional cybersecurity risks, create data accessibility problems, cause AVROBIO to become more susceptible to communication disruptions, or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors;
- business disruptions involving AVROBIO's third parties on whom AVROBIO relies, including contract research organizations, or CROs, and other collaborators for the conduct of AVROBIO's clinical trials or AVROBIO's third party suppliers or manufacturers, which could impact their ability to perform adequately or disrupt AVROBIO's supply chain; and
- changes in hospital or research institution policies or government regulations, which could delay or adversely impact AVROBIO's ability to conduct AVROBIO's clinical trials.

These and other factors arising from the public health crises could reemerge or worsen and adversely impact AVROBIO's ability to conduct clinical trials and AVROBIO's business generally, and could have a material adverse impact on AVROBIO's operations and financial condition and results. The extent to which any public health crisis impacts AVROBIO's operations or those of AVROBIO's third party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the public health crisis, the efficacy and safety of vaccines, including against emerging variants, the ability of third parties to manufacture and distribute vaccines, among others.

AVROBIO's HSC lentiviral-based gene therapy product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development and of subsequently obtaining regulatory approval, should AVROBIO resume development of AVROBIO's product candidates.

AVROBIO has concentrated AVROBIO's research and development efforts on AVROBIO's HSC gene therapy approach, and should AVROBIO resume development of its product candidates AVROBIO's future success would depend on AVROBIO's successful development of viable gene therapy product candidates. There can be no assurance that AVROBIO will not experience problems or delays in developing new product candidates, should AVROBIO resume development of its product candidates, and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. For example, timely enrollment in AVROBIO's clinical trials is dependent upon global clinical trial sites which were adversely affected by the COVID-19 pandemic. In addition, AVROBIO may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial, additional or alternative partners, which should AVROBIO resume development of its product candidates may prevent AVROBIO from completing clinical studies or commercializing AVROBIO's products on a timely or profitable basis, if at all. For example, as of July 12, 2023, the date on which AVROBIO announced that AVROBIO was halting all further development activities in AVROBIO's programs, AVROBIO had dosed 11 patients using AVROBIO's plato platform, including six patients in AVROBIO's FAB-GT clinical trial (for which AVROBIO previously halted enrollment) and five patients in AVROBIO's Guard1 clinical trial. AVROBIO's implementation of the LV2 lentiviral vector or of AVROBIO's cell processing to an industrialized, automated closed system using disposable supplies may not be successful or may experience unforeseen delays, should AVROBIO resume development of its product candidates, which may cause shortages or delays in the supply of AVROBIO's products available for clinical trials and future commercial sales, if any, or impair AVROBIO's research and development efforts, including those in any future clinical trials. In addition, there is no assurance that products using AVROBIO's proprietary LV2 lentiviral vector or manufactured using this automated system will ultimately achieve the same favorable preliminary results observed to date. Furthermore, the FDA generally prefers that clinical trials be double-blinded and potentially include sham controls. Such a trial design could be challenging to implement due to the nature of the treatment regimen of HSC gene therapy.

In addition, the clinical trial requirements of the FDA and other foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type,

complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as AVROBIO's can be more expensive and take longer than for other, better known or more extensively studied product candidates. To date, only a limited number of HSC gene therapies have received marketing authorization from the FDA or foreign regulatory authorities. Should AVROBIO resume development of its product candidates, it is difficult to determine how long it would take or how much it would cost to obtain regulatory approvals for those product candidates in the United States, Canada, Europe, Japan or other major markets or how long it would take to commercialize those product candidates, if any were to be approved. Approvals by foreign regulatory authorities may not be indicative of what the FDA may require for approval, and vice versa.

Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the NIH also are subject to the NIH Guidelines, under which supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or the IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical trial can begin at any institution, its IRB and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of AVROBIO's product candidates should AVROBIO resume their development. Similarly, foreign regulatory authorities may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that AVROBIO complies with these new guidelines.

The FDA, NIH and the EMA have each expressed interest in further regulating biotechnology, including gene therapy and genetic testing. For example, the EMA advocates a risk-based approach to the development of a gene therapy product. Agencies at both the federal and state level in the United States, as well as the U.S. congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. For example, in 2016, the FDA established the Office of Tissues and Advanced Therapies, or the OTAT, within the CBER to consolidate the review of gene therapy and related products, and to advise the CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products, or the OTP, and elevation of OTP to a "Super Office" to meet its growing cell and gene therapy workload. Although FDA has indicated that this change of name and responsibilities is intended to, among other things, increase review capabilities and enhance expertise on new cell and gene therapies, AVROBIO cannot be certain that this approach will improve the time and cost associated with navigating gene therapy regulatory requirements, AVROBIO's regulatory strategy or the potential success of AVROBIO's product candidates. Such regulatory action and developments could, instead, delay, impede or even prevent commercialization of some or all of AVROBIO's product candidates.

These regulatory review committees and advisory groups and any new guidelines they promulgate may lengthen the regulatory review process, require AVROBIO to perform additional studies, increase AVROBIO's development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. Should AVROBIO resume development of AVROBIO's product candidates, AVROBIO will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. If AVROBIO fails to do so, AVROBIO may be required to delay or discontinue development of certain of those product candidates. These additional processes may result in a review and approval process that is longer than AVROBIO otherwise would have expected. Should AVROBIO resume development of its product candidates, the delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease AVROBIO's ability to generate sufficient product revenue, and AVROBIO's business, financial condition, results of operations and prospects would be materially and adversely affected.

The FDA continues to develop its guidance for assessing gene and cell therapy products. For example, the agency has released a series of draft and final guidance documents relating to, among other topics, various aspects of gene therapy product development, review, and approval, including aspects relating to clinical and manufacturing issues related to gene therapy products. In January 2020, the FDA released a final guidance with recommendations for long-term follow-up studies of patients following human gene therapy administration due to the increased risk of undesirable and unpredictable outcomes with gene therapies that may present as delayed adverse events. Foreign regulatory agencies also may have requirements for long term follow-up studies of patients following human gene therapy administration.

AVROBIO's product candidates and the process for administering AVROBIO's product candidates may cause undesirable side effects or have other properties that, should AVROBIO resume development of its product candidates,

could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients may experience changes in their health, including illnesses, injuries, discomforts or a fatal outcome. It is possible that as AVROBIO tests AVROBIO's product candidates in larger, longer and more extensive clinical programs, or as use of AVROBIO's product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier clinical trials, as well as conditions that did not occur or went undetected in previous clinical trials, will be reported by patients. Additionally, any early access to AVROBIO's investigational therapies, such as through expanded or Right to Try access or compassionate use, may lead to discovery of undesirable side effects, or other negative consequences that could have adverse impacts on AVROBIO's development programs for AVROBIO's product candidates. Gene therapies are also subject to the potential risk that occurrence of adverse events will be delayed following administration of the gene therapy due to persistent biological activity of the genetic material or other components of the vectors used to carry the genetic material. Many times, side effects are only detectable after investigational products are tested in larger scale, pivotal clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. FDA guidance advises that patients treated with gene therapies undergo long-term follow-up observation for potential adverse events for as long as 15 years, unless otherwise agreed by the FDA. If additional clinical or long-term follow-up experience indicates that any of AVROBIO's product candidates have side effects or cause serious or life-threatening side effects, AVROBIO may be unable to resume its development programs and any further development of the product candidate may ultimately fail or be delayed.

Gene therapy is still a relatively new approach to disease treatment and adverse side effects could develop. A safety concern for gene therapies using lentiviral vectors has been the possibility of insertional oncogenesis, leading to malignant transformation of transduced cells and cellular outgrowth. As more patients are dosed with HSC gene therapies, it is expected that very rare cases of insertional oncogenesis may occur. For example, several patients with cerebral adrenoleukodystrophy treated in a third-party lentiviral gene therapy clinical trial have been diagnosed with treatment-related myelodysplastic syndrome to date. In addition, persistent clonal dominance due to vector integration has been observed in third-party HSC gene therapy clinical trials. While AVROBIO's HSC gene therapy approach has been designed to avoid insertional oncogenesis, there can be no assurance that patients will not experience such adverse effects, including death. Should AVROBIO resume development of its gene therapy product candidates and any of those product candidates demonstrates adverse side effects at unacceptable rates or degrees of severity, AVROBIO may decide or be required to halt or delay clinical development of such product candidates.

In addition to side effects caused by AVROBIO's product candidates, the conditioning, administration process or related procedures, also can cause adverse side effects. A gene therapy patient is generally administered one or more myeloablative drugs to remove stem cells from the bone marrow to create sufficient space in the bone marrow for the modified gene-corrected stem cells to engraft and produce their progeny. This procedure causes side effects and, among other potential risks, can transiently compromise the patient's immune system, known as neutropenia, and reduce blood clotting, known as thrombocytopenia.

In 2019, AVROBIO began transitioning, in connection with AVROBIO-sponsored clinical trials, towards a new conditioning regimen for AVROBIO's product candidates utilizing busulfan as the myeloablative conditioning agent instead of the melphalan that AVROBIO previously used. The use of this conditioning regimen AVROBIO designed to utilize a precision dosing program to achieve a balance between the removal of a sufficient amount of bone marrow cells from a patient to aid engraftment of AVROBIO's genetically modified cells against potential risks, such as toxicity or graft failure. AVROBIO's conditioning regimens may not be successful or may nevertheless result in adverse side effects. For example, busulfan, the myeloablative agent most recently used in AVROBIO's conditioning regimen, has been known to carry certain safety risks, including the risk of impairment to fertility in both men and women, and such impairment has been reported in some patients in AVROBIO's clinical trials. Moreover, in each of AVROBIO's previous clinical trials several adverse events, including suppression of neutrophils and platelet counts following the conditioning process, have been observed. While such adverse events in connection with conditioning are expected, if in the future any such adverse events caused by the conditioning process or related procedures continue at unexpected rates or degrees of severity, the FDA or other foreign regulatory authorities could order the cessation of development of, or deny approval of, product candidates for any or all targeted indications. There have been cases of therapy-related myelodysplastic syndrome, a type of blood disorder that is a potential precursor to acute myeloid leukemia, in patients with preexisting cancer where busulfan treatment was posited to be a contributing factor to this secondary malignancy. Even if AVROBIO is able to demonstrate that adverse events are not product-related, such occurrences could adversely affect patient recruitment (should AVROBIO resume development of its product candidates) or the ability of enrolled patients to complete the clinical trial, and lead to a decline in AVROBIO's stock price.

Additionally, if AVROBIO resume development of its programs and any of AVROBIO's product candidates receives marketing approval, the FDA could require AVROBIO to adopt a REMS to ensure that the benefits outweigh its risks, which

may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, and restrictions on how or where the product can be distributed, dispensed or used. Furthermore, if AVROBIO or others later identify undesirable side effects caused by AVROBIO's product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional or boxed warnings on the label;
- AVROBIO may be required to change the way a product candidate is distributed, dispensed, or administered or conduct additional clinical trials;
- AVROBIO could be sued and held liable for harm caused to patients; and
- AVROBIO's reputation may suffer.

Any of these events could prevent AVROBIO from achieving or maintaining market acceptance of AVROBIO's product candidates, lead to a decline in AVROBIO's stock price, and significantly harm AVROBIO's business, prospects, financial condition and results of operations.

AVROBIO has never completed a pivotal or registrational clinical trial, and may be unable to do so for any product candidates AVROBIO may develop, should AVROBIO resume development of its product candidates.

AVROBIO is at an early stage of development for all of AVROBIO's product candidates, and has currently halted further development of AVROBIO's programs. Twenty-five patients were dosed in AVROBIO's clinical trials, which includes 14 patients from AVROBIO's Fabry program that AVROBIO deprioritized in January 2022, six patients in AVROBIO's cystinosis program that AVROBIO sold to Novartis in June 2023, and five patients in AVROBIO's Gaucher disease type 1 program. Should AVROBIO resume development of its product candidates, further clinical trials must be completed in order to obtain FDA or other regulatory approval to market these product candidates. AVROBIO has limited experience in preparing, submitting and prosecuting regulatory filings, and has not previously submitted a BLA for any product candidate. Carrying out later-stage clinical trials is a complicated and lengthy process, and AVROBIO does not expect that all data from patients participating in the clinical trials will be relevant or meaningful.

In addition, across AVROBIO-sponsored clinical trials AVROBIO has dosed only four patients in the United States, and AVROBIO's interactions with the FDA have generally been limited. AVROBIO cannot be certain how many additional clinical trials of any of AVROBIO's product candidates would be required or how such trials should be designed, should AVROBIO resume development of its programs. In order to commence a clinical trial in the United States, AVROBIO is required to seek FDA acceptance of an IND for each of AVROBIO's product candidates. AVROBIO cannot be sure any IND AVROBIO submits to the FDA, or any similar CTA AVROBIO submits in other countries, will be accepted. Should AVROBIO resume development of its product candidates, there can be no assurance that AVROBIO would be able to submit and secure similar clearances for any of AVROBIO's other product candidates. AVROBIO may also be required to conduct additional preclinical testing prior to filing an IND for any of AVROBIO's product candidates, and the results of any such testing may not be positive. Consequently, AVROBIO may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to a BLA submission and approval of any of AVROBIO's product candidates. AVROBIO may require more time and incur greater costs than AVROBIO's competitors and may not succeed in obtaining regulatory approvals of product candidates that AVROBIO develops. Failure to commence or complete, or delays in, the necessary clinical trials, could prevent AVROBIO from or delay AVROBIO in commercializing any of AVROBIO's product candidates.

Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials, should AVROBIO resume development of its product candidates.

Results from preclinical studies or early clinical trials are not necessarily predictive of future clinical trial results and are not necessarily indicative of final results. There can be no assurance that prior results, such as signals of safety, activity or durability of effect, observed from preclinical studies or clinical trials will be replicated or will continue in ongoing or future studies or trials, should AVROBIO resume development of any of its programs. Furthermore, preliminary results may not be indicative of the final results of a trial after all data have been collected and analyzed. For example, in January 2022 AVROBIO announced the deprioritization of AVROBIO's Fabry program due to several factors, including new clinical data showing variable engraftment patterns from the five most recently dosed Phase 2 FAB-GT patients. Although previously reported data from 13 patients treated across AVROBIO's clinical-stage programs had shown durable engraftment out 9 to 54 months, the new data from the five most recently dosed Phase 2 FAB-GT patients were discordant with these other data and showed variable engraftment. Should AVROBIO resume development of its product candidates, there can be no assurance

that similar engraftment or other issues will not occur in clinical trials of AVROBIO's other product candidates, which are all based on AVROBIO's technology and the same HSC approach utilized for AVR-RD-01.

There is a high failure rate for gene therapy and biologic product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, the design of a pivotal clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. AVROBIO has limited experience in designing and conducting clinical trials and AVROBIO may be unable to design and execute a clinical trial to support regulatory approval, should AVROBIO resume development of its product candidates.

AVROBIO also may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy or the approval of competitive therapies during the period of AVROBIO's product candidate development. Should AVROBIO resume development of any of AVROBIO's product candidates, those product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies. Any such failure would cause AVROBIO to abandon the product candidate.

Additionally, the clinical trials performed to date have been open-label studies and have been conducted at a limited number of clinical sites on a limited number of patients. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware that patients have received treatment and may interpret the information more favorably given this knowledge. As is typical in open-label studies in which interim reports are provided, the safety and efficacy data are regularly reviewed and validated. As a result, certain data may change over time, including reductions or increases in the number of reported safety events, as well as the characterization of the severity or relatedness of safety events, until the database is locked at the end of the study.

Should AVROBIO resume development of its product candidates, AVROBIO may find it difficult to enroll patients in AVROBIO's clinical trials, which could delay or prevent AVROBIO from proceeding with clinical trials of AVROBIO's product candidates.

Should AVROBIO resume development of its product candidates, the timing and success of AVROBIO's patient enrollment and clinical trial activities would depend on AVROBIO's ability to recruit patients to participate as well as the completion of required follow-up periods. Patients may be unwilling to participate in AVROBIO's gene therapy clinical trials because of negative publicity from adverse events related to the biotechnology or gene therapy fields, competitive clinical trials for similar patient populations, clinical trials in product candidates employing AVROBIO's vectors, the existence of current treatments or for other reasons. In addition, the indications that AVROBIO has targeted and may in the future target are rare diseases, which may limit the pool of patients that may be enrolled in AVROBIO's clinical trials. Should AVROBIO resume development of its product candidates, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of AVROBIO's product candidates may be delayed, which could result in increased costs, delays in advancing AVROBIO's product candidates, delays in testing the effectiveness of AVROBIO's product candidates or termination of the clinical trials altogether. Should AVROBIO resume development of its product candidates, AVROBIO may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics, to complete AVROBIO's clinical trials in a timely manner or at all. There can be no assurance AVROBIO will achieve that goal or any of AVROBIO's other patient enrollment goals should AVROBIO resume development of its product candidates.

Patient enrollment and trial completion is affected by factors including the:

- size of the patient population and process for identifying patients;
- design of the trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidate under study;

- perceived risks and benefits of gene therapy-based approaches to treatment of diseases, including any required pretreatment conditioning regimens;
- availability of competing therapies and clinical trials;
- severity of the disease under investigation;
- availability of genetic testing for potential patients;
- proximity and availability of clinical trial sites for prospective patients;
- ability to obtain and maintain subject consent;
- risk that enrolled patients will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

AVROBIO historically expanded AVROBIO's patient enrollment activities to include patients who reside in a country other than the country where the applicable clinical site is located, and who are required to travel for some or all of the clinical testing and procedures required for patients in the applicable clinical trial. AVROBIO has encountered and, should AVROBIO resume development of its product candidates, in the future may continue to encounter logistical and regulatory challenges that could delay or prevent any such international patients from successfully enrolling and completing clinical trial procedures, including delays in processing or obtaining patient travel visas or denials of entry at borders, potential travel disruptions, or de-prioritization or unavailability of resources at clinical sites for non-resident international clinical trial participants, any of which could delay AVROBIO's progress and completion of planned clinical trials and which would have an adverse effect on AVROBIO's business. In addition, once these international patients return to their home country, they may need to travel back to the country where the applicable clinical site is located. If these patients are unwilling or unable to return to the clinical site for testing and procedures, progress and completion of the clinical trial could be delayed or prevented.

AVROBIO's product candidates were being developed to treat rare conditions. Should AVROBIO resume development of its product candidates, AVROBIO would expect to seek initial marketing approvals in the United States, Europe and certain other major markets, including Japan. However, AVROBIO may not be able to resume, initiate or continue clinical trials if AVROBIO cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by FDA or other foreign regulatory authorities. AVROBIO's ability to successfully resume, initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs clinical study sites and physicians;
- different standards for the conduct of clinical trials;
- the absence in some countries of established groups with sufficient regulatory expertise for review of gene therapy protocols;
- AVROBIO's inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

Should AVROBIO resume development of its product candidates and if AVROBIO has difficulty enrolling a sufficient number of patients to conduct AVROBIO's clinical trials, AVROBIO may need to delay, limit or terminate the resumption or continuation of clinical trials, any of which would have an adverse effect on AVROBIO's business, financial condition, results of operations and prospects.

Should AVROBIO resume development of its product candidates, AVROBIO may encounter substantial delays in resuming its clinical trials or AVROBIO may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of AVROBIO's product candidates, AVROBIO must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. Should AVROBIO resume development of its product candidates, AVROBIO cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent

successful or timely completion of clinical development, should AVROBIO resume any clinical development programs, include:

- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites;
- delays in obtaining required IRB approval at each clinical study site;
- delays in recruiting suitable patients to participate in AVROBIO's clinical studies;
- imposition of a clinical hold by regulatory agencies, after an inspection of AVROBIO's clinical study operations or study sites;
- failure by AVROBIO's CROs, other third parties or AVROBIO to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's GCP or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of AVROBIO's product candidates to the clinical sites;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- clinical study sites or patients dropping out of a study;
- the occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Should AVROBIO resume development of its product candidates, any inability to successfully complete preclinical and clinical development could result in additional costs to AVROBIO or impair AVROBIO's ability to generate revenues. In addition, if AVROBIO makes changes to AVROBIO's product candidates, or if collaborator-sponsored trials utilize different materials or manufacturing processes from AVROBIO's to generate data, AVROBIO may need to conduct additional studies to compare or bridge AVROBIO's modified product candidates to earlier versions, which could delay AVROBIO's clinical development plan or marketing approval for AVROBIO's product candidates.

Should AVROBIO resume development of its product candidates and, following such resumption, if the results of AVROBIO's clinical studies are inconclusive or if there are safety concerns or adverse events associated with AVROBIO's product candidates, AVROBIO may:

- be delayed in obtaining marketing approval for AVROBIO's product candidates, if 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 changes with the way the product is administered;
- be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to AVROBIO's reputation.

Any of these events could prevent AVROBIO from achieving or maintaining market acceptance of AVROBIO's product candidates and impair AVROBIO's ability to commercialize AVROBIO's products.

Should AVROBIO resume development of its product candidates, even if AVROBIO completes the necessary preclinical and clinical studies, AVROBIO cannot predict whether or when AVROBIO would be able to obtain regulatory approval to commercialize a product candidate, and any approval could be for a narrower indication than anticipated.

AVROBIO cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if AVROBIO resumes development of its product candidates and they are able to demonstrate safety and efficacy in clinical studies to support submitting such programs for marketing approval, the regulatory agencies may not complete their review processes in a timely manner, or AVROBIO may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, AVROBIO may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of AVROBIO's product candidates. If AVROBIO is unable to obtain necessary regulatory approvals or labeling claims, AVROBIO's business, prospects, financial condition and results of operations would be materially and adversely affected.

AVROBIO's commercially-scalable plato platform has been used in only two of AVROBIO's clinical trials and clinical development has been halted.

While AVROBIO has submitted and, should AVROBIO resume development of its product candidates, intends to continue to submit comparability studies to the FDA and other regulatory agencies, as needed, with respect to AVROBIO's implementation of AVROBIO's scalable plato platform, there can be no assurance that the FDA or other regulatory agencies will not in the future require AVROBIO to conduct additional preclinical studies or clinical trials that could result in delays and additional costs in AVROBIO's development or commercialization programs for AVROBIO's product candidates, which could adversely affect AVROBIO's business. Should AVROBIO resume development of its product candidates, AVROBIO intends to continue implementing AVROBIO's scalable plato platform, including heightened vector efficiency, AVROBIO's closed, automated manufacturing system and utilization of a customized conditioning regimen, in connection with each of AVROBIO's investigational product candidates. AVROBIO has developed the plato platform to form the backbone of AVROBIO's commercial programs, with the intent of replacing AVROBIO's original academic platforms with improved solutions for delivering AVROBIO's gene therapy candidates to patients in multiple disease indications. In order to implement this transition, AVROBIO was and would continue to be required to conduct additional studies to bridge AVROBIO's modified product candidates to earlier versions, including any earlier version that may have been utilized in a collaborator-sponsored clinical study, which could delay clinical development or marketing approvals. Clinical trial delays could also shorten any periods during which AVROBIO may have the exclusive right to commercialize AVROBIO's product candidates, if approved, or allow AVROBIO's competitors to bring products to market before AVROBIO does, which could impair AVROBIO's ability to successfully commercialize AVROBIO's product candidates and may harm AVROBIO's business and results of operations.

AVROBIO faces significant competition in AVROBIO's industry and, should AVROBIO resume development of its product candidates, there can be no assurance that AVROBIO's product candidates, if approved, will achieve acceptance in the market over existing established therapies. In addition, AVROBIO's competitors may develop therapies that are more advanced or effective than AVROBIO's, which may adversely affect AVROBIO's ability to successfully market or commercialize any of AVROBIO's product candidates, should AVROBIO resume development of AVROBIO's product candidates.

AVROBIO operates in a highly competitive segment of the biopharmaceutical market. AVROBIO faces competition from many different sources, including larger pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Should AVROBIO resume development of its product candidates, AVROBIO's product candidates, if successfully developed and approved, will compete with established therapies, some of which are being marketed by large and international companies. In addition, should AVROBIO resume development of its product candidates, AVROBIO expects to compete with new treatments that are under development or may be advanced into the clinic by AVROBIO's competitors. There are a variety of product candidates, including gene therapies, in development for the indications that AVROBIO is targeting.

Should AVROBIO resume development of its product candidates, AVROBIO anticipates competing with biotechnology and pharmaceutical companies, many of which may have significantly greater resources than AVROBIO does. For example, for Gaucher disease, Sanofi, Pfizer, and Takeda market existing ERTs that represent the standard of care for Gaucher patients. For Gaucher disease AVROBIO also expects that AVROBIO would compete with oral therapies marketed by Johnson & Johnson and Sanofi. Sanofi also markets an enzyme replacement therapy for Pompe disease. In addition,

AVROBIO may compete with other gene therapy companies in AVROBIO's industry. Moreover, a number of gene therapy companies have announced preclinical or clinical non-viral and adeno-associated viral based gene therapy programs that, if successful in obtaining regulatory approval, could compete with AVROBIO's gene therapies.

Many of AVROBIO's competitors have significantly greater financial, product candidate development, manufacturing and marketing resources than AVROBIO does. Large pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and mergers and acquisitions within these industries may result in even more resources being concentrated among a smaller number of larger competitors. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that AVROBIO develops obsolete. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. AVROBIO's business would be materially and adversely affected if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, have broader market acceptance, are more convenient or are less expensive than any product candidate that AVROBIO may develop.

Even if AVROBIO obtains regulatory approval of AVROBIO's product candidates, the availability and price of AVROBIO's competitors' products could limit the demand and the price AVROBIO is able to charge for AVROBIO's product candidates. AVROBIO may not be able to implement AVROBIO's business plan if the acceptance of AVROBIO's product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to AVROBIO's product candidates, or if physicians switch to other new drug or biologic products or choose to reserve AVROBIO's product candidates for use in limited circumstances.

Should AVROBIO resume development of its product candidates, AVROBIO would expect to seek designations for AVROBIO's product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process or an accelerated regulatory pathway. However, there can be no assurance that AVROBIO could successfully obtain such designations. In addition, even if one or more of AVROBIO's product candidates are granted such designations, AVROBIO may not be able to realize the intended benefits of such designations.

The FDA and comparable foreign regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. However, there can be no assurance that AVROBIO will successfully obtain such designations for any of AVROBIO's product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if AVROBIO obtains such designations for one or more of AVROBIO's product candidates, there can be no assurance that AVROBIO will realize their intended benefits.

AVROBIO may seek a Breakthrough Therapy Designation for some of AVROBIO's product candidates should AVROBIO resume development of its product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA are also eligible for accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if AVROBIO believes one of AVROBIO's product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of AVROBIO's product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification.

Should AVROBIO resume development of its product candidates, AVROBIO may seek an accelerated approval pathway for one or more of AVROBIO's product candidates from the FDA or comparable foreign regulatory authorities. The FDA may grant accelerated approval to a therapeutic candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit, and the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified period after the date of approval. Sponsors

must also update FDA on the status of these studies, and under FDORA, the FDA has increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit.

Should AVROBIO resume development of its product candidates, prior to seeking accelerated approval, AVROBIO would expect to seek feedback from the FDA or comparable foreign regulatory authorities and would otherwise evaluate AVROBIO's ability to seek and receive such accelerated approval. There can be no assurance that after AVROBIO's evaluation of the feedback and other factors AVROBIO would decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA or comparable foreign regulatory authorities, AVROBIO would continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if AVROBIO initially decides to do so. Furthermore, if AVROBIO decides to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require AVROBIO to conduct further studies prior to considering AVROBIO's application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for AVROBIO's product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm AVROBIO's competitive position in the marketplace. Moreover, even if AVROBIO is able to obtain accelerated approval for any of AVROBIO's product candidates, there is no guarantee that post-approval studies will be able to confirm the clinical benefit, which could cause FDA to withdraw AVROBIO's approval.

Should AVROBIO resume development of its product candidates, AVROBIO may also pursue programs or designations from foreign regulatory authorities, such as the UK's Innovative Licensing and Access Pathway, or ILAP, which aims to accelerate the time to market and facilitate patient access to certain types of medicinal products in development which target a life-threatening or seriously debilitating condition, or where there is a significant patient or public health need in the UK. To access the ILAP, an applicant applies for an Innovation Passport designation. Once an Innovation Passport designation is granted, the MHRA and its partner agencies (including The All Wales Therapeutics and Toxicology Centre, National Institute for Health and Care Excellence and the Scottish Medicines Consortium) will work with the Innovation Passport designee to define a Target Development Profile, or TDP. The TDP sets out a unique product-specific roadmap towards patient access in the UK, and provides access to a toolkit to support all stages of the design, development and approvals process, including continuous benefit-risk assessment, increased support for novel development approaches and enhanced patient engagement. However, although the goal of the ILAP is to reduce the time to market and enable earlier patient access, access does not accelerate conduct of clinical trials or mean that the regulatory requirements are less stringent, nor does it ensure that a marketing authorization application will be approved or that any approval will be granted within a particular timeframe or at all.

In addition, should AVROBIO resume development of its product candidates, AVROBIO may seek Fast Track Designation for some of AVROBIO's product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track designation. However, the FDA has broad discretion whether or not to grant Fast Track designation, so even if AVROBIO believes a product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if AVROBIO does receive Fast Track designation, AVROBIO may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from AVROBIO's clinical development program.

In addition, should AVROBIO resume development of AVROBIO's product candidates, AVROBIO may seek a RMAT designation for some of AVROBIO's product candidates. An RMAT is defined as cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Gene therapies, including genetically modified cells that lead to a durable modification of cells or tissues may meet the definition of a regenerative medicine therapy. The RMAT program is intended to facilitate efficient development and expedite review of RMATs, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition. A new drug application or a BLA for an RMAT may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of

clinical evidence, clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. RMAT designation is within the discretion of the FDA. Accordingly, even if AVROBIO believes one of AVROBIO's product candidates meets the criteria for designation as a regenerative medicine advanced therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of AVROBIO's product candidates qualify for RMAT designation, the FDA may later decide that the biological products no longer meet the conditions for qualification.

Should AVROBIO resume development of its product candidates, AVROBIO may be unable to obtain orphan drug designation for AVROBIO's product candidates and, even if AVROBIO obtains such designation, AVROBIO may not be able to realize the benefits of such designation, including potential marketing exclusivity of AVROBIO's product candidates, if approved.

Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the European Commission grants an orphan designation in respect of a product after receiving the opinion of the EMA's Committee for Orphan Medicinal Products on an orphan designation application. Orphan designation in the European Union may be granted to products where the sponsor can establish that such product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union when the application is made. Additionally, orphan designation may be granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the product would generate sufficient returns in the European Union to justify the necessary investment in developing the product. In either case, the applicant must be able to establish that there is no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product would be of a significant benefit to those affected by the condition.

If AVROBIO requests orphan drug designation (or the foreign equivalent) for any other product candidates, there can be no assurances that the FDA or applicable foreign regulatory authorities will grant such designation. Additionally, the designation of any of AVROBIO's product candidates as an orphan product does not mean that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as AVROBIO's product candidates prior to AVROBIO's product candidates receiving exclusive marketing approval.

Generally, if a product candidate with an orphan drug designation 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 foreign regulatory authorities from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before AVROBIO does (regardless of AVROBIO's orphan drug designation), AVROBIO will be precluded from receiving marketing approval for AVROBIO's product for the applicable exclusivity period. The applicable period is seven years in the United States and 10 years in the European Union. The exclusivity period in the European Union can be reduced to six years, if at the end of the fifth year, a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. The European Commission introduced a legislative proposal in April 2023 that, if implemented, could reduce the current ten-year marketing exclusivity period in the European Union for certain orphan medicines. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if AVROBIO obtains orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition in the United States. Even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective

or makes a major contribution to patient care. In the European Union, a marketing authorization may be granted to a similar medicinal product for the same orphan indication at any time if:

- the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.

A marketing application for a product candidate with rare pediatric disease designation, or RPDD, if approved, may not meet the eligibility criteria for a Priority Review Voucher, or PRV, or the RPDD program may sunset before the FDA is able to consider eligibility for a voucher.

Designation of a drug or biologic as a product for a rare pediatric disease does not guarantee that a BLA for such drug or biologic will meet the eligibility criteria for a rare pediatric disease PRV at the time the application is approved. Under the FD&C Act, should AVROBIO resume development of AVROBIO's product candidates, AVROBIO would need to request a rare pediatric disease PRV in AVROBIO's original BLA for any of AVROBIO's product candidates that previously received RPDD. The FDA may determine that any such BLA, if approved, does not meet the eligibility criteria for a PRV, including for the following reasons:

- The disease indication no longer meets the definition of a rare pediatric disease;
- the BLA contains an active ingredient that has been previously approved in a BLA;
- the BLA is not deemed eligible for priority review;
- the BLA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population (that is, if the BLA does not contain sufficient clinical data to allow for adequate labeling for use by the full range of affected pediatric patients); or
- the BLA is approved for a different adult indication than the rare pediatric disease for which the product candidate is designated.

The authority for the FDA to award rare pediatric disease PRVs for drugs that have received rare pediatric disease designation prior to September 30, 2024 currently expires on September 30, 2026. If the BLA for any of AVROBIO's product candidates with RPDD is not approved prior to September 30, 2026 for any reason, regardless of whether it meets the criteria for a rare pediatric disease PRV, it will not be eligible for a PRV. However, it is also possible the authority for FDA to award rare pediatric disease PRVs will be further extended through federal lawmaking.

Should AVROBIO resume development of its product candidates, even if AVROBIO obtains regulatory approval for a product candidate, AVROBIO's products will remain subject to regulatory oversight.

Should AVROBIO resume development of its product candidates, even if AVROBIO obtains any regulatory approval for AVROBIO's product candidates, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that AVROBIO receives for AVROBIO's product candidates also may be subject to a REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. FDA guidance advises that patients treated with gene therapies undergo long-term follow-up observation for potential adverse events for as long as 15 years, unless otherwise agreed by the FDA. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. If AVROBIO, or a regulatory authority, discover previously unknown problems with a product, such as

adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or AVROBIO, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If AVROBIO fails to comply with applicable regulatory requirements following approval of any of AVROBIO's product candidates, a regulatory authority may:

- issue a warning letter asserting that AVROBIO is in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by AVROBIO or AVROBIO's strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of products; or
- refuse to allow AVROBIO to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require AVROBIO to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit AVROBIO's ability to commercialize AVROBIO's product candidates and adversely affect AVROBIO's business, financial condition, results of operations and prospects.

In addition, the FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of AVROBIO's product candidates. AVROBIO cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If AVROBIO is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if AVROBIO is not able to maintain regulatory compliance, AVROBIO may lose any marketing approval that AVROBIO may have obtained and AVROBIO may not achieve or sustain profitability, which would materially and adversely affect AVROBIO's business, financial condition, results of operations and prospects.

Should AVROBIO resume development of its product candidates, AVROBIO's focus on developing such product candidates may not yield any commercially viable products, and AVROBIO's failure to successfully identify and develop additional product candidates could impair AVROBIO's ability to grow.

While AVROBIO initially pursued a growth strategy to identify, develop and market additional product candidates, AVROBIO has halted further development of AVROBIO's programs and, should AVROBIO resume development of its product candidates, AVROBIO does not anticipate actively seeking additional product candidates beyond AVROBIO's existing product candidates. Should AVROBIO resume development of its product candidates, AVROBIO may spend several years completing AVROBIO's development of any particular product candidates, and failure can occur at any stage. The product candidates to which AVROBIO allocates AVROBIO's resources may not end up being successful. Because AVROBIO has limited resources, AVROBIO may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential than AVROBIO's product candidates. AVROBIO's spending on any future research and development programs may not yield any commercially viable product candidates. Should AVROBIO resume development of its product candidates, if AVROBIO does not accurately evaluate the commercial potential for a particular product candidate, AVROBIO may relinquish valuable rights to that product candidate through strategic collaborations, licensing or other arrangements in cases in which it would have been more advantageous for AVROBIO to retain sole development and commercialization rights to such product candidate. If any of these events occur, AVROBIO may be forced to abandon AVROBIO's development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate.

In addition, should AVROBIO resume development of its product candidates, certain of AVROBIO's product candidates may not demonstrate in patients any or all of the pharmacological benefits AVROBIO believes they may possess or compare favorably to existing, approved therapies, such as ERT. AVROBIO has not yet succeeded and may never succeed in demonstrating efficacy and safety of AVROBIO's product candidates in clinical trials or in obtaining marketing approval

thereafter. Accordingly, AVROBIO's focus on treating these diseases may not result in the development of commercially viable products.

Should AVROBIO resume development of its product candidates, if AVROBIO is unsuccessful in AVROBIO's development efforts, AVROBIO may not be able to advance the development of AVROBIO's product candidates, commercialize products, raise capital, expand AVROBIO's business or continue AVROBIO's operations.

Risks Related to Manufacturing

Gene therapies are novel, complex and difficult to manufacture. Should AVROBIO resume development of its product candidates, AVROBIO could experience production problems that result in delays in AVROBIO's development or commercialization programs or otherwise adversely affect AVROBIO's business.

The manufacturing process AVROBIO uses to produce AVROBIO's product candidates is complex, novel and has not been validated for commercial use. Should AVROBIO resume development of its product candidates, several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of AVROBIO's suppliers.

AVROBIO's product candidates require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as AVROBIO's generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, AVROBIO and AVROBIO's manufacturing suppliers employ multiple steps to control the manufacturing process with the goal of ensuring that the product candidate is made strictly and consistently in compliance with the applicable process and specifications. Problems with the manufacturing process, including even minor deviations from the intended process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory. AVROBIO may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA or other applicable regulatory standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA and other foreign regulatory authorities may require AVROBIO to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other foreign regulatory authorities may require that AVROBIO not distribute a lot until the agency authorizes its release. Even slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Should AVROBIO resume development of AVROBIO's product candidates, there is no assurance AVROBIO will not experience lot failures in the future. Lot failures or product recalls could cause AVROBIO to delay clinical trials, or, if approved, commercial product launches, which could be costly to AVROBIO and otherwise harm AVROBIO's business, financial condition, results of operations and prospects. AVROBIO's manufacturing process relies on a platform structure, which AVROBIO refers to as AVROBIO's plato platform, and, if AVROBIO experiences delays, deviations or failures that impact that platform, such delays, deviations or failures could have an adverse impact on AVROBIO's development products or future commercialization programs.

Risks Related to AVROBIO's Reliance on Third Parties

Should AVROBIO resume development of its product candidates, AVROBIO expects to rely on third parties to conduct some or all aspects of AVROBIO's vector production, product manufacturing, protocol development, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

Should AVROBIO resume development of its product candidates, AVROBIO does not expect to independently conduct AVROBIO's vector production, product manufacturing, protocol development, research and preclinical and clinical testing. AVROBIO has historically relied, and, should AVROBIO resume development of its product candidates, expects to continue to rely, on third parties with respect to these items. Any of these third parties may terminate their engagements with AVROBIO or renegotiate the terms of AVROBIO's agreements at any time. If AVROBIO needs to enter into alternative arrangements, it could delay AVROBIO's product development activities. AVROBIO's reliance on these third parties for research and development activities will reduce AVROBIO's control over these activities but will not relieve AVROBIO of AVROBIO's responsibility to ensure compliance with all required regulations and study protocols. For example, for product candidates that AVROBIO develops and commercializes on AVROBIO's own, AVROBIO will remain responsible for ensuring that each of AVROBIO's preclinical and clinical studies are conducted in accordance with the study plan, protocols and regulatory requirements.

Even with relevant experience and expertise, AVROBIO's third-party manufacturers may encounter difficulties in production, such as initial production, managing the transition from early to late-stage clinical and commercial manufacturing, and ensuring that the product meets required specifications. These difficulties may include delays, failure or inability achieving production yields, establishing and maintaining stage-appropriate cGMP quality procedures, operator error, shortages of qualified personnel, and compliance with federal, state and foreign regulations. AVROBIO cannot make any assurances that these difficulties will not occur in the future, or that AVROBIO will be able to resolve or address them in a timely manner or at all as problems arise.

Should AVROBIO resume development of its product candidates, if AVROBIO's contract counterparties do not successfully carry out their contractual duties, meet expected deadlines or conduct AVROBIO's studies in accordance with regulatory requirements or AVROBIO's stated study plans and protocols, AVROBIO will not be able to complete, or may be delayed in completing, the preclinical and clinical studies required to support approval of AVROBIO's product candidates or the FDA or other regulatory agencies may refuse to accept AVROBIO's clinical or preclinical data.

Should AVROBIO resume development of its product candidates, reliance on third-party manufacturers entails risks to which AVROBIO would not be subject if AVROBIO manufactured the product candidates itself, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to AVROBIO; and
- disruptions to the operations of AVROBIO's third-party manufacturers or suppliers caused by conditions unrelated to AVROBIO's business or operations, including the impact of the COVID-19 pandemic or the bankruptcy of the manufacturer or supplier.

Any of these events could lead to delays of AVROBIO's preclinical and clinical studies or failure to obtain regulatory approval, or impact AVROBIO's ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

AVROBIO has historically relied, and, should AVROBIO resume development of its product candidates, expects to continue to rely, on sole source suppliers for AVROBIO's automated, closed cell processing system; vector supply; plasmid supply; cell culture media supply; and drug product manufacturing. In addition, AVROBIO is dependent on a limited number of suppliers for some of AVROBIO's other components and materials used in AVROBIO's product candidates.

AVROBIO has moved AVROBIO's cell processing to an automated, closed system with a sole source supplier. In addition, AVROBIO has historically relied, and, should AVROBIO resume development of its product candidates, expect to continue to rely, on sole source suppliers for vector supply, plasmid supply and cell culture media, as well as drug product manufacturing for AVROBIO-sponsored clinical trials. Should AVROBIO resume development of its product candidates, AVROBIO's sole source suppliers may be unwilling or unable to supply product to AVROBIO reliably, continuously or at the levels AVROBIO anticipates or are required by AVROBIO's clinical trial activities. Such suppliers could still delay, suspend, or terminate supply of product to AVROBIO for a number of reasons, including manufacturing or quality issues, payment disputes with AVROBIO, intellectual property disputes with third parties, bankruptcy or insolvency, earthquakes or other natural disasters or other occurrences.

In addition, AVROBIO depends on a limited number of suppliers for some of the other components necessary for AVROBIO's product candidates. Should AVROBIO resume development of its product candidates, AVROBIO cannot be sure that any of AVROBIO's suppliers will remain in business, or that they will not be purchased by one of AVROBIO's competitors or another company that is not interested in continuing to produce these materials for AVROBIO's intended purpose. AVROBIO's use of a sole source or limited number of suppliers of raw materials, components and finished goods exposes AVROBIO to several risks, including disruptions in supply, price increases, late deliveries and an inability to meet customer demand. There are, in general, relatively few alternative sources of supply for these components and equipment. Any of AVROBIO's vendors may be unable or unwilling to meet AVROBIO's future demands for AVROBIO's clinical trials or commercial sale. Establishing additional or replacement suppliers for these components and materials could take a substantial amount of time and it may be difficult or impossible to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any supplier or manufacturing location could lead to supply delays or interruptions which would damage AVROBIO's business, financial condition, results of operations and prospects.

Should AVROBIO resume development of its product candidates and AVROBIO is required to switch to a replacement supplier or manufacture materials itself, the manufacture and delivery of AVROBIO's product candidates could be interrupted for an extended period, adversely affecting AVROBIO's business. Establishing additional or replacement

suppliers may not be accomplished quickly, and AVROBIO may not be able to enter agreements with replacement suppliers on reasonable terms, if at all. In either scenario, AVROBIO's clinical trials supply could be delayed significantly as AVROBIO establishes alternative supply sources. In some cases, the technical skills required to manufacture AVROBIO's products or product candidates may be unique or proprietary to the original CMO and AVROBIO may have difficulty, or there may be contractual restrictions prohibiting AVROBIO from, transferring such skills to a back-up or alternate supplier, or AVROBIO may be unable to transfer such skills at all. If AVROBIO is able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. For example, the FDA could require additional supplemental bridging data if AVROBIO relies upon a new supplier. AVROBIO may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. If AVROBIO resumes development of its product candidates, AVROBIO would seek to maintain adequate inventory of the components and materials used in AVROBIO's product candidates; however, any interruption or delay in the supply of components or materials, or AVROBIO's inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair AVROBIO's ability to conduct AVROBIO's clinical trials and, if AVROBIO's product candidates are approved, to meet the demand of AVROBIO's customers and cause them to cancel orders.

In addition, as part of the FDA's approval of AVROBIO's product candidates, the FDA must review and approve the individual components of AVROBIO's production process, which includes the manufacturing processes and facilities of AVROBIO's suppliers. AVROBIO's current suppliers have not undergone this process, nor have they had any components included in any product approved by the FDA.
AVROBIO's reliance on suppliers subjects AVROBIO to a number of risks that, should AVROBIO resume development of its product candidates, could materially harm AVROBIO's reputation, business, and financial condition, including, among other things:

- delays in production, supply, shipment or delivery as a result of the COVID-19 pandemic or trade sanctions, embargoes, and heightened export requirements resulting from the war in Ukraine and the evolving conflicts in Israel and the Gaza Strip;
- the interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with AVROBIO's suppliers;
- the inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for AVROBIO's components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- a delay in delivery due to AVROBIO's suppliers prioritizing other customer orders over AVROBIO's;
- damage to AVROBIO's reputation caused by defective components produced by AVROBIO's suppliers;
- increased cost of AVROBIO's warranty program due to product repair or replacement based upon defects in components produced by AVROBIO's suppliers; and
- fluctuation in delivery by AVROBIO's suppliers due to changes in demand from AVROBIO or their other customers.

If any of these risks materialize, AVROBIO's costs could significantly increase and AVROBIO's ability to conduct AVROBIO's clinical trials and, if AVROBIO's product candidates are approved, to meet demand for AVROBIO's products could be impacted.

AVROBIO and AVROBIO's contract manufacturers are subject to significant regulation with respect to manufacturing AVROBIO's products. The manufacturing facilities on which AVROBIO has relied may not continue to meet regulatory requirements and have limited capacity.

In AVROBIO's development activities to date, AVROBIO has relied on sole source suppliers of AVROBIO's automated, closed cell processing system; vector supply; plasmid supply; cell culture media; as well as drug product manufacturing for AVROBIO-sponsored clinical trials. In addition, AVROBIO has depended on a limited number of

suppliers for some of the other components necessary for AVROBIO's product candidates. Each of AVROBIO's suppliers may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain, and AVROBIO may be unable to transfer or sublicense the intellectual property rights AVROBIO may have with respect to such activities.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including AVROBIO's contract manufacturers for AVROBIO's product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of AVROBIO's product candidates that may not be detectable in final product testing. AVROBIO or AVROBIO's contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's GLP and cGMP regulations enforced by the FDA through its facilities inspection program. Some of AVROBIO's contract manufacturers have not produced a commercially-approved product and have never been inspected by the FDA before. AVROBIO's facilities and quality systems and the facilities and quality systems of some or all of AVROBIO's third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of AVROBIO's product candidates or any of AVROBIO's other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of AVROBIO's product candidates or AVROBIO's other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, or if the FDA is unable to conduct such an inspection due to the COVID-19 pandemic or similar public health crisis, the FDA may issue a complete response letter or defer action on AVROBIO's applications, and approval of the products may be delayed or may not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit AVROBIO's manufacturing facilities or those of AVROBIO's third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of AVROBIO's product specifications or applicable regulations occurs independent of such an inspection or audit, AVROBIO or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for AVROBIO or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon AVROBIO or third parties with whom AVROBIO contracts could materially harm AVROBIO's business.

If AVROBIO or any of AVROBIO's third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, AVROBIO's business, financial condition and results of operations may be materially harmed.
Should AVROBIO resume development of its product candidates, these factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of AVROBIO's product candidates, cause AVROBIO to incur higher costs and prevent AVROBIO from commercializing AVROBIO's products successfully. Furthermore, if AVROBIO's suppliers fail to meet contractual requirements, and AVROBIO is unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, AVROBIO's preclinical and clinical studies may be delayed.

AVROBIO's reliance on third parties requires AVROBIO to share AVROBIO's trade secrets, which increases the possibility that a competitor will discover them or that AVROBIO's trade secrets will be misappropriated or disclosed.

Because AVROBIO has relied and, should AVROBIO resume development of its product candidates, would expect to continue to rely on third parties to manufacture AVROBIO's vectors and AVROBIO's product candidates, and because AVROBIO collaborates with various organizations and academic institutions on the advancement of AVROBIO's gene therapy approach, AVROBIO must, at times, share trade secrets with them. AVROBIO seeks to protect AVROBIO's proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with AVROBIO's collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose AVROBIO's confidential information, such as trade secrets.

Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by AVROBIO's competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that AVROBIO's proprietary position is based, in part, on AVROBIO's know-how and trade secrets, a competitor's discovery of

AVROBIO's trade secrets or other unauthorized use or disclosure would impair AVROBIO's competitive position and may have a material adverse effect on AVROBIO's business.

In addition, these agreements typically restrict the ability of AVROBIO's collaborators, advisors, employees and consultants to publish data potentially relating to AVROBIO's trade secrets. AVROBIO's academic collaborators typically have rights to publish data, provided that AVROBIO is notified in advance and may delay publication for a specified time in order to secure AVROBIO's intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by AVROBIO, although in some cases AVROBIO may share these rights with other parties. Despite AVROBIO's efforts to protect AVROBIO's trade secrets, AVROBIO's competitors may discover AVROBIO's trade secrets, either through breach of these agreements, independent development or publication of information including AVROBIO's trade secrets in cases where AVROBIO does not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of AVROBIO's trade secrets would impair AVROBIO's competitive position and have an adverse impact on AVROBIO's business.

Risks Related to Commercialization of AVROBIO's Product Candidates

Should AVROBIO resume development of its product candidates and obtain approval of any of AVROBIO's product candidates, and AVROBIO is unable to establish sales, distribution and marketing capabilities or enter into agreements with third parties to market and sell AVROBIO's product candidates, AVROBIO will be unable to generate any product revenue.

To successfully commercialize any of AVROBIO's product candidates, if approved, AVROBIO will need to develop AVROBIO's commercial capabilities, either on AVROBIO's own or with others, should AVROBIO resume development of its product candidates. The establishment and development of AVROBIO's own commercial team or the establishment of a contract sales force to market any product candidate AVROBIO may develop will be expensive and time-consuming and could delay any product launch. Moreover, AVROBIO cannot be certain that AVROBIO will be able to successfully develop this capability. AVROBIO may enter into collaborations regarding any approved product candidates with other entities to utilize their established marketing and distribution capabilities, but AVROBIO may be unable to enter into such agreements on favorable terms, if at all. If any future collaborators do not commit sufficient resources to commercialize AVROBIO's product candidates, or AVROBIO is unable to develop the necessary capabilities on AVROBIO's own, AVROBIO will be unable to generate sufficient product revenue to sustain AVROBIO's business. AVROBIO competes with many companies that currently have extensive, experienced and well-funded sales, distribution and marketing operations to recruit, hire, train and retain marketing and sales personnel. AVROBIO also faces competition in AVROBIO's search for third parties to assist AVROBIO with the sales and marketing efforts of AVROBIO's product candidates, if approved. Without an internal team or the support of a third-party to perform marketing and sales functions, AVROBIO may be unable to compete successfully against these more established companies.

Should AVROBIO resume development of its product candidates and the market opportunities for AVROBIO's product candidates are smaller than AVROBIO believes they are, AVROBIO's product revenues may be adversely affected and AVROBIO's business may suffer.

AVROBIO has historically focused AVROBIO's research and product development on treatments for serious lysosomal disorders. AVROBIO's understanding of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with AVROBIO's product candidates, are based on estimates. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States and elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment with AVROBIO's products, patients may become increasingly difficult to identify and access, and any approval AVROBIO receives from regulatory agencies may be for a narrower indication and smaller patient population than anticipated, all of which, should AVROBIO resume development of its product candidates, would adversely affect AVROBIO's business, financial condition, results of operations and prospects.

Should AVROBIO resume development of its product candidates, the commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Should AVROBIO resume development of its product candidates, and thereafter if AVROBIO obtains any regulatory approval for AVROBIO's product candidates, the commercial success of AVROBIO's product candidates will depend in part on the medical community, patients, and third-party payors accepting gene therapy products in general, and AVROBIO's product candidates in particular, as effective, safe and cost-effective. Any product that AVROBIO brings to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of

market acceptance of these product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments, including any similar generic treatments;
- the efficacy and safety as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the prevalence and severity of any adverse events or side effects, including any limitations or warnings contained in a product's approved labeling or that are later found to be associated with a product, including in findings from long-term follow-up studies;
- the prevalence and severity of any side effects resulting from the conditioning regimen for the administration of AVROBIO's product candidates;
- the ability to offer the products for sale at competitive prices;
- the clinical indications for which the products are approved by the FDA or comparable regulatory agencies;
- the relative convenience and ease of dosing and administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- restrictions on how the product is distributed;
- the availability of accessible and skilled healthcare centers capable of administering AVROBIO's treatments;
- publicity concerning AVROBIO's products or competing products and treatments; and
- favorable third-party insurance coverage and sufficient reimbursement.

Sales of medical products also depend 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. AVROBIO cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that AVROBIO's product is safe, therapeutically effective and cost effective as compared with competing treatments.

Even if a product candidate displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product, if approved for commercial sale, will not be known until after it is launched. AVROBIO's efforts to educate the medical community and third-party payors on the benefits of AVROBIO's product candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by AVROBIO's competitors. If these products do not achieve an adequate level of acceptance, AVROBIO may not generate significant product revenue and may not become profitable.

Should AVROBIO resume development of its product candidates, if AVROBIO obtains approval to commercialize AVROBIO's product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect AVROBIO's business.

AVROBIO had been conducting clinical trials for AVROBIO's product candidates in the United States, Canada and Australia, and should AVROBIO resume development of its product candidates, AVROBIO would expect to expand AVROBIO's clinical trials to other geographies. If any of AVROBIO's product candidates are approved for commercialization, AVROBIO may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. AVROBIO expects that AVROBIO will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for approval of drugs and biologics in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, fluctuating interest rates, 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 revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

The insurance coverage and reimbursement status of newly-approved products are uncertain. Should AVROBIO resume development of its product candidates, failure to obtain or maintain adequate coverage and reimbursement for any of AVROBIO's product candidates, if approved, could limit AVROBIO's ability to market those products and decrease AVROBIO's ability to generate revenue.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted 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, AVROBIO might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay AVROBIO's or their commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue AVROBIO is able to generate from the sale of the product in that country. Adverse pricing limitations may hinder AVROBIO's ability to recoup AVROBIO's investment in one or more product candidates, even if any product candidates AVROBIO may develop obtain marketing approval. Please see the section titled "*Business – Government Regulation – Coverage and Reimbursement.*"

Should AVROBIO resume development of its product candidates, and obtain regulatory approval for such candidates, AVROBIO's ability to successfully commercialize AVROBIO's product candidates or any other products that AVROBIO may develop also will depend in part on the extent to which 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. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of AVROBIO's product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of AVROBIO's product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. AVROBIO may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement is not available, or is available only at limited levels, AVROBIO may not be able to successfully commercialize AVROBIO's product candidates, if approved. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow AVROBIO to establish or maintain pricing sufficient to realize a sufficient return on AVROBIO's investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS an agency within the HHS as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as AVROBIO's, as there is no body of established practices and precedents for these new products. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs and commercial payors are critical to new product acceptance. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement.

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. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and AVROBIO believes the increasing emphasis on cost-containment initiatives in Europe and certain other major markets where AVROBIO plans to commercialize may put pressure on the pricing and usage

of AVROBIO's product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems, and 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, AVROBIO may be required to conduct a clinical trial that compares the cost effectiveness of AVROBIO's product candidates to other available therapies. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that AVROBIO is able to charge for AVROBIO's product candidates. Accordingly, in markets outside the United States, the reimbursement for AVROBIO's products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, efforts by governmental and other third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for AVROBIO's product candidates. Should AVROBIO resume development of its product candidates, AVROBIO expects to experience pricing pressures in connection with the sale of any of AVROBIO's product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Due to the novel nature of AVROBIO's technology and the potential for AVROBIO's product candidates to offer therapeutic benefit in a single administration, AVROBIO faces uncertainty related to pricing and reimbursement for these product candidates should AVROBIO resume their development.

Should AVROBIO resume development of its product candidates, AVROBIO's target patient populations are relatively small, as a result of which the pricing and reimbursement of AVROBIO's product candidates, if approved, must be adequate to support commercial infrastructure. If AVROBIO is unable to obtain adequate levels of reimbursement, AVROBIO's ability to successfully market and sell AVROBIO's product candidates will be adversely affected. The manner and level at which reimbursement is provided for services related to AVROBIO's product candidates (e.g., for administration of AVROBIO's product to patients) is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect AVROBIO's ability to market or sell AVROBIO's product candidates, if approved. Moreover, if approved for marketing, because AVROBIO's product candidates are designed to provide their intended therapeutic benefit from a single administration, treatment with AVROBIO's product candidates may result in a decrease in the available pool of target patients.

Healthcare legislative reform measures and constraints on national budget social security systems may have a material adverse effect on AVROBIO's business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of AVROBIO's product candidates or any future product candidates, restrict or regulate post-approval activities and affect AVROBIO's ability to profitably sell any product for which AVROBIO obtains marketing approval. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Please see the section titled "*Business – Government Regulation – Healthcare Reform.*"

Should AVROBIO resume development of its product candidates, the continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of AVROBIO's product candidates, if approved;
- the ability to set a price that AVROBIO believes is fair for any of AVROBIO's product candidates, if approved;
- AVROBIO's ability to generate revenues and achieve or maintain profitability;
- the level of taxes that AVROBIO is required to pay; and
- the availability of capital.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. AVROBIO cannot be sure whether additional legislative changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of

such changes on the marketing approvals of AVROBIO's product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject AVROBIO to more stringent product labeling and post-marketing testing and other requirements.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for AVROBIO's product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. It is expected that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that AVROBIO receives for any approved product and could seriously harm AVROBIO's future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Should AVROBIO resume development of its product candidates, the implementation of cost containment measures or other healthcare reforms may prevent AVROBIO from being able to generate revenue, attain profitability or commercialize AVROBIO's product candidates.

Inadequate funding for the FDA and other government agencies 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 AVROBIO's business may rely, which could negatively impact AVROBIO's 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 agency have fluctuated in recent years as a result. In addition, government funding of other agencies on which AVROBIO's operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect AVROBIO's business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. Since March 2020, when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic or any other public health crisis and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process AVROBIO's regulatory submissions, should AVROBIO resume development of its product candidates, which could have a material adverse effect on AVROBIO's business. Further, future shutdowns of other government agencies, such as the SEC, may also impact AVROBIO's business through review of AVROBIO's public filings and AVROBIO's ability to access the public markets.

Should AVROBIO resume development of its product candidates, any contamination in AVROBIO's manufacturing process, shortages of materials or failure of any of AVROBIO's key suppliers to deliver necessary components could result in interruption in the supply of AVROBIO's product candidates and delays in AVROBIO's clinical development or commercialization schedules.

Given the nature of biologics manufacturing, there is a risk of contamination in AVROBIO's manufacturing processes. Should AVROBIO resume development of AVROBIO's product candidates, any contamination could materially adversely affect AVROBIO's ability to produce product candidates on schedule and could, therefore, harm AVROBIO's results of operations and cause reputational damage.

Some of the materials required in AVROBIO's manufacturing process are derived from biologic sources. Such materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of AVROBIO's product candidates could adversely impact or

disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect AVROBIO's development timelines and AVROBIO's business, financial condition, results of operations and prospects.

Risks Related to AVROBIO's Business Operations

AVROBIO's gene therapy approach utilizes lentiviral vectors derived from viruses, which may be perceived as unsafe or may result in unforeseen adverse events. Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of AVROBIO's product candidates or adversely affect AVROBIO's ability to conduct AVROBIO's business or obtain regulatory approvals for AVROBIO's product candidates, should AVROBIO resume their development.

Gene therapy remains a novel technology, with only a limited number of gene therapy products approved to date. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, AVROBIO's success will depend upon physicians specializing in the treatment of those diseases that AVROBIO's product candidates target prescribing treatments that involve the use of AVROBIO's product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on AVROBIO's business or financial condition and may delay or impair the development and commercialization of AVROBIO's product candidates or demand for any products should AVROBIO resume development of its product candidates. For example, earlier gene therapy trials led to several well-publicized adverse events, including cases of leukemia, myelodysplastic syndromes and deaths seen in other trials using other vectors. Adverse events in AVROBIO's clinical studies or discovered in long-term follow-up, even if not ultimately attributable to AVROBIO's product candidates (such as the many adverse events that typically arise from the conditioning process), or adverse events in other gene therapy trials, and the resulting publicity could result in a decline in AVROBIO's stock price, increased governmental regulation, unfavorable public perception and, should AVROBIO resume development of its product candidates, potential regulatory delays in the testing or approval of AVROBIO's potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

AVROBIO's future success depends on AVROBIO's ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

AVROBIO is highly dependent on principal members of AVROBIO's executive team and key employees, the loss of whose services may adversely impact the achievement of AVROBIO's objectives. While AVROBIO has entered into employment agreements with each of AVROBIO's executive officers, any of them could leave AVROBIO's employment at any time, as all of AVROBIO's employees are "at will" employees. Following the resignation of AVROBIO's former President and Chief Executive Officer, Geoff MacKay, on May 1, 2023, AVROBIO appointed its Chief Financial Officer, Erik Ostrowski, to serve in the additional roles of President and Interim Chief Executive Officer, effective on May 1, 2023. In July 2023, in connection with the determination to halt further development of AVROBIO's programs and to conduct a comprehensive exploration of strategic alternatives, AVROBIO paused AVROBIO's search for a permanent Chief Executive Officer. Accordingly, no assurance can be made as to when or whether AVROBIO will hire a permanent Chief Executive Officer. AVROBIO does not maintain "key person" insurance policies on the lives of these individuals or the lives of any of AVROBIO's other employees. The loss of the services of one or more of AVROBIO's current executive or key employees might impede the achievement of AVROBIO's ongoing business commitments and strategic objectives.

Retaining other qualified employees, consultants and advisors for AVROBIO's business, including scientific and technical personnel, remains critical to AVROBIO's success. AVROBIO implemented a reduction in force in January 2022 in connection with the deprioritization of AVROBIO's Fabry disease program, and through the first half of 2022 AVROBIO continued to streamline employee headcount including senior management. In July 2023, in connection with the determination to halt further development of AVROBIO's programs and to conduct a comprehensive exploration of strategic alternatives, AVROBIO implemented a reduction in force by approximately 50% across different areas. AVROBIO's remaining workforce was further reduced by 11 employees in a workforce reduction implemented effective as of October 31, 2023, three employees in a workforce reduction implemented effective as of November 30, 2023, and five employees in a further workforce reduction implemented effective as of December 31, 2023. Reductions in force, management changes and program reprioritizations can have an adverse impact on employee morale. While AVROBIO believes AVROBIO's relations with AVROBIO's continuing employees to be good, there can be no assurance that AVROBIO can avoid retention challenges for skilled personnel as AVROBIO explores potential strategic alternatives. There is currently a shortage of skilled executives and other personnel in AVROBIO's industry, which is likely to continue. As a result, competition for skilled personnel, including in gene therapy research and vector manufacturing, is intense and the turnover rate can be high. AVROBIO may not be able to retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, AVROBIO's ability to retain qualified personnel could be impacted by other factors, such as remote or hybrid working arrangements, which could impact

employees' productivity and morale. In addition, in recent months, the market price of AVROBIO's common stock has experienced significant downward pressure, resulting in "underwater" or "out-of-the-money" stock options for many of AVROBIO's employees, thereby limiting the desired retentive effect that AVROBIO's equity incentive program was intended to achieve. The inability to recruit, if necessary, or the loss of the services of any executive, key employee, skilled personnel, consultant or advisor may impede AVROBIO's business objectives. Furthermore, AVROBIO may not realize, in full or in part, the anticipated benefits, savings and improvements in AVROBIO's cost structure from AVROBIO's workforce reductions and restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If AVROBIO is unable to realize the expected operational efficiencies and cost savings from the restructuring, AVROBIO's operating results and financial condition would be adversely affected. AVROBIO's restructuring plan may also be disruptive to AVROBIO's operations, for example, AVROBIO's reductions in force could yield unanticipated consequences, such as increased difficulties in implementing AVROBIO's pursuit of strategic alternatives, including retention of AVROBIO's remaining employees, attrition beyond AVROBIO's reductions in force and employee litigation related to the reductions in force could be costly and prevent management from fully concentrating on the business.

Should AVROBIO resume development of its product candidates, AVROBIO may need to expand or streamline AVROBIO's operations and AVROBIO may experience difficulties in managing any such changes, which could disrupt AVROBIO's operations.

Should AVROBIO resume development of its product candidates, AVROBIO may need to rapidly expand AVROBIO's full-time employee base and to hire more consultants and contractors. AVROBIO's management may need to divert a disproportionate amount of its attention away from AVROBIO's day-to-day activities and devote a substantial amount of time to managing these growth activities. AVROBIO may not be able to effectively manage the expansion of AVROBIO's operations, which may result in weaknesses in AVROBIO's infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. AVROBIO's expected growth could require significant capital expenditures and may divert financial resources from other projects if AVROBIO's management is unable to effectively manage AVROBIO's growth, AVROBIO's expenses may increase more than expected, AVROBIO's ability to generate and/or grow revenues could be reduced, and AVROBIO may not be able to implement AVROBIO's business strategy. AVROBIO's future financial performance and AVROBIO's ability to commercialize product candidates and compete effectively will depend, in part, on AVROBIO's ability to effectively manage any future growth.

Conversely, headwinds in the overall economy and limited availability of suitable financing to meet AVROBIO's needs could constrain AVROBIO's ability to achieve AVROBIO's growth objectives, and could in turn lead to further reductions in force or scaling back of business operations, that could impact employee morale and adversely impact AVROBIO's ability to manage ongoing operations, should AVROBIO resume development of its product candidates.

Should AVROBIO resume development of its product candidates and AVROBIO is unable to manage expected growth in the scale and complexity of AVROBIO's operations, AVROBIO's performance may suffer.

Should AVROBIO resume development of its product candidates, AVROBIO will need to expand AVROBIO's managerial, operational, financial and other systems and resources to manage AVROBIO's operations, resume AVROBIO's research and development activities and, in the longer term, build a commercial infrastructure to support commercialization of any of AVROBIO's product candidates that are approved for sale. Future growth would impose significant added responsibilities on members of management. It is likely that AVROBIO's management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. AVROBIO's need to effectively manage AVROBIO's operations, growth and product candidates requires that AVROBIO continues to develop more robust business processes and improve AVROBIO's systems and procedures in each of these areas and to attract and retain sufficient numbers of talented employees. AVROBIO may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve AVROBIO's research, development and growth goals.

AVROBIO's employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

AVROBIO is exposed to the risk of fraud or other misconduct by AVROBIO's employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA or of other foreign regulatory authorities, provide accurate information to the FDA and other foreign regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to AVROBIO. In particular, sales, marketing and business conduct in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of healthcare professional interactions, drug pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to

AVROBIO's reputation. AVROBIO has adopted a code of conduct applicable to all of AVROBIO's employees, but it is not always possible to identify and deter employee misconduct, and the precautions AVROBIO takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting AVROBIO from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against AVROBIO, and AVROBIO is not successful in defending itself or asserting AVROBIO's rights, those actions could have a significant impact on AVROBIO's business, including the imposition of significant fines or other sanctions.

AVROBIO is subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. AVROBIO can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. AVROBIO has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. AVROBIO also expects, should AVROBIO resume development of its product candidates, that AVROBIO's non-U.S. activities would increase in time. Should AVROBIO resume development of its product candidates, AVROBIO would also expect to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and AVROBIO can be held liable for the corrupt or other illegal activities of AVROBIO's personnel, agents, or partners, even if AVROBIO does not explicitly authorize or have prior knowledge of such activities. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the United States Foreign Corrupt Practices Act's accounting provisions.

AVROBIO is subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws health information privacy and security laws, and other health care laws and regulations. If AVROBIO is unable to comply, or have not fully complied, with such laws, AVROBIO could face substantial penalties.

AVROBIO is subject, and may be increasingly subject if AVROBIO obtains FDA approval for any of AVROBIO's product candidates, to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal FCA and Physician Payments Sunshine Act and regulations. Please see the section titled "*Business – Government Regulation – Other Healthcare Laws and Compliance Requirements.*"

These laws will impact, among other things, AVROBIO's clinical trial programs, healthcare professional interactions, grant making activities, and AVROBIO's anticipated sales, marketing and medical educational programs. In addition, AVROBIO may be subject to patient privacy laws by both the federal government and the states in which AVROBIO conducts AVROBIO's business.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in federal and state funded healthcare programs (such as Medicare and Medicaid), contractual damages and the curtailment or restructuring of AVROBIO's operations, as well as additional reporting obligations and oversight if AVROBIO becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. If any of the physicians or other healthcare providers or entities with whom AVROBIO expects to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on personnel, sales or withdrawal of future marketed products could materially affect business in an adverse way.

Efforts to ensure that AVROBIO's business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that AVROBIO's business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against AVROBIO, and AVROBIO is not successful in defending itself or asserting AVROBIO's rights, those actions could have a significant impact on AVROBIO's business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of AVROBIO's operations, any of which could adversely affect AVROBIO's ability to operate AVROBIO's business and AVROBIO's results of operations. In addition, the approval and commercialization of any of AVROBIO's candidates outside the United States will also likely subject AVROBIO to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect AVROBIO's operating results and business.

AVROBIO and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to AVROBIO's operations or the operations of AVROBIO's collaborators. In addition, AVROBIO may obtain health information from third parties (including research institutions from which AVROBIO obtains clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, AVROBIO could be subject to civil, criminal, and administrative penalties if AVROBIO knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with U.S. and international data protection laws and regulations could require AVROBIO to take on more onerous obligations in AVROBIO's contracts, restrict AVROBIO's ability to collect, use and disclose data, or in some cases, impact AVROBIO's ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect AVROBIO's operating results and business. Moreover, clinical trial patients, employees and other individuals about whom AVROBIO or AVROBIO's potential collaborators obtain personal information, as well as the providers who share this information with AVROBIO, may limit AVROBIO's ability to collect, use and disclose the information. Claims that AVROBIO has violated individuals' privacy rights, failed to comply with data protection laws, or breached AVROBIO's contractual obligations, even if AVROBIO is not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm AVROBIO's business.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

Should AVROBIO resume development of its product candidates, AVROBIO would expect to conduct clinical trials in the EEA, and the UK and as a result would be subject to additional privacy restrictions. The collection, use, disclosure, transfer or other processing of personal health data in the EU and the UK is governed by the provisions of the GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to ensuring a legal basis or condition applies to the processing of personal data, stricter requirements relating to the processing of sensitive data (such as health data), providing information to individuals regarding data processing activities, where necessary obtaining consent from individuals to whom the data processing relates, responding to additional data subject requests, imposing notification of personal data breaches to the competent national data protection authorities, implementing safeguards in connection with the security and confidentiality of the personal data, accountability requirements and taking certain measures when engaging third-party processors. The GDPR informs AVROBIO's obligations with respect to any clinical trials conducted in the EEA or the UK. Its definition of personal data includes coded data, requires changes to informed consent practices and detailed notices for clinical trial subjects and investigators. In addition, the GDPR imposes strict rules on the transfer of personal data out of the EEA or the UK, including to the United States (see below). The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal data and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros (£ 17.5 million for the UK), 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 EEA member states or the UK may

make their own further laws and regulations limiting the processing of personal data, including genetic, biometric, or health data.

The GDPR prohibits cross-border data transfers of personal data to countries outside the EEA or the UK that are not considered by the European Commission and UK government as providing "adequate" protection to personal data, or third countries, including the United States in certain circumstances, unless a valid GDPR transfer mechanism (for example, the European Commission approved the SCCs and the UK IDTA) has been put in place. Where relying on the SCCs/UK IDTA for data transfers, AVROBIO may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. Further, the EU and United States have adopted its adequacy decision for the Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost, and may result in AVROBIO needing to make strategic considerations around where EEA and UK personal data is located and which service providers AVROBIO can utilize for the processing of EEA and UK personal data.

AVROBIO has yet to adopt and implement comprehensive processes, systems and other relevant measures within AVROBIO's organization, and/or with AVROBIO's relevant collaborators, service providers, contractors or consultants, which are appropriate to address relevant requirements relating to international transfers of personal data from Europe, and to minimize the potential impacts and risks resulting from those requirements, across AVROBIO's organization. Failure to implement valid mechanisms for personal data transfers from Europe may result in AVROBIO's facing increased exposure to regulatory actions, substantial fines and injunctions against processing personal data from Europe. Inability to export personal data may also: restrict AVROBIO's activities outside Europe; limit AVROBIO's ability to collaborate with partners as well as other service providers, contractors and other companies outside of Europe; and/or require AVROBIO to increase AVROBIO's processing capabilities within Europe at significant expense or otherwise cause AVROBIO to change the geographical location or segregation of AVROBIO's relevant systems and operations – any or all of which could adversely affect AVROBIO's operations or financial results. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering AVROBIO's services and operating AVROBIO's business. The type of challenges AVROBIO faces in Europe will likely also arise in other jurisdictions that adopt laws similar in construction to the GDPR or regulatory frameworks of equivalent complexity.

Although the UK is regarded as a third country under the EU GDPR, the European Commission has issued an adequacy decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EU remain free flowing. The UK Government has also now introduced a Data Protection and Digital Information Bill, or the UK Bill, into the UK legislative process. The aim of the UK Bill is to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime and threaten the UK adequacy decision from the European Commission. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to AVROBIO's handling of personal data and AVROBIO's privacy and data security compliance programs and could require AVROBIO to implement different compliance measures for the UK and the EEA.

Given the breadth and depth of its obligations, complying with the GDPR's requirements is rigorous and time intensive and requires significant resources and assessment of AVROBIO's 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 EEA or the UK. Compliance with the GDPR will be a rigorous and time-intensive process that may increase AVROBIO's cost of doing business and require AVROBIO to change AVROBIO's business practices, and despite those efforts, there is a risk that AVROBIO may be subject to fines and penalties, litigation, and reputational harm in connection with European activities.

AVROBIO faces potential product liability, and, if successful claims are brought against AVROBIO, AVROBIO may incur substantial liability and costs. If the use of AVROBIO's product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to AVROBIO's product candidates, AVROBIO's regulatory approvals could be revoked or otherwise negatively impacted and AVROBIO could be subject to costly and damaging product liability claims.

The use of AVROBIO's product candidates including in clinical studies and, should AVROBIO resume the development of its product candidates, the future sale of any products for which AVROBIO may obtain marketing approval, exposes AVROBIO to the risk of product liability claims. Product liability claims might be brought against AVROBIO by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with AVROBIO's products. There is a risk that AVROBIO's product candidates may induce adverse events. If AVROBIO cannot successfully defend against product liability claims, AVROBIO could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the impairment of AVROBIO's business reputation;
- the withdrawal of clinical study participants;
- costs due to related litigation;
- the distraction of management's attention from AVROBIO's primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize AVROBIO's product candidates; and
- decreased demand for AVROBIO's product candidates, if approved for commercial sale.

AVROBIO carries master product liability insurance of $5.0 million per occurrence and $5.0 million in the aggregate in the United States. For studies conducted in certain countries outside the United States, AVROBIO maintains local admitted policies with varying limits. AVROBIO believes AVROBIO's product liability insurance coverage is sufficient in light of AVROBIO's current clinical programs; however, AVROBIO may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect AVROBIO against losses due to liability. If AVROBIO resume development of its product candidates and thereafter obtain marketing approval for product candidates, AVROBIO expects that AVROBIO would expand AVROBIO's insurance coverage to include the sale of commercial products; however, AVROBIO may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against AVROBIO could cause AVROBIO's stock price to decline and, if judgments exceed AVROBIO's insurance coverage, could adversely affect AVROBIO's results of operations and business.

Patients with the diseases targeted by certain of AVROBIO's product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to AVROBIO's product candidates. Such events could subject AVROBIO to costly litigation, require AVROBIO to pay substantial amounts of money to injured patients, delay, negatively impact or end AVROBIO's opportunity to receive or maintain regulatory approval to market AVROBIO's products, or require AVROBIO to suspend or abandon AVROBIO's commercialization efforts. Even in a circumstance in which AVROBIO does not believe that an adverse event is related to AVROBIO's products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt AVROBIO's sales efforts, delay AVROBIO's regulatory approval process in other countries, or impact and limit the type of regulatory approvals AVROBIO's product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on AVROBIO's business, financial condition or results of operations.

If AVROBIO fails to comply with environmental, health and safety laws and regulations, AVROBIO could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of AVROBIO's business.

AVROBIO is 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. AVROBIO's operations involve the use of hazardous and flammable materials, including chemicals and biological materials. AVROBIO's operations also produce hazardous waste products. AVROBIO generally contracts with third parties for the disposal of these materials and wastes. AVROBIO cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from AVROBIO's use of hazardous materials, AVROBIO could be held liable for any resulting damages, and any liability could exceed AVROBIO's resources. AVROBIO also could incur significant costs associated with civil or criminal fines and penalties. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. AVROBIO cannot predict the impact of such changes and cannot be certain of AVROBIO's future compliance. In addition, AVROBIO 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 AVROBIO's research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although AVROBIO maintains workers' compensation insurance to cover AVROBIO for costs and expenses AVROBIO may incur due to injuries to AVROBIO's employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, AVROBIO 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 AVROBIO's research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect AVROBIO's business, financial condition, results of operations and prospects.

AVROBIO might not be able to utilize a significant portion of AVROBIO's net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2023 and 2022, AVROBIO had federal and state net operating loss carryforwards of $575.9 million and $657.0 million, respectively, and federal research and development tax credit carryforwards of approximately $6.4 million and $6.8 million, respectively. If not utilized, the net operating loss carryforwards and research and development credits will generally expire at various dates through 2041 (other than federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017, which are not subject to expiration and generally may not be carried back to prior taxable years except that net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years). These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code, or Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. AVROBIO may have experienced ownership changes in the past. AVROBIO may also experience ownership changes in the future as a result of subsequent shifts in AVROBIO's stock ownership, some of which may be outside of AVROBIO's control. In addition, the merger, if consummated, may also constitute an ownership change (within the meaning of Section 382 of the Code) which could eliminate or otherwise substantially limit AVROBIO's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes.

If an ownership change occurred or occurs and AVROBIO's ability to use AVROBIO's historical net operating loss and tax credit carryforwards is materially limited (or entirely eliminated), or if AVROBIO's research and development carryforwards are adjusted, it would harm AVROBIO's future operating results by effectively increasing AVROBIO's future tax obligations. For taxable years beginning after December 31, 2020, deductions for federal net operating losses arising in taxable years beginning after December 31, 2017 may only offset 80% of taxable income.

Risks Related to AVROBIO's Intellectual Property

Should AVROBIO resume development of its product candidates, third-party claims of intellectual property infringement may prevent or delay AVROBIO's development and commercialization efforts.

AVROBIO's commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter parties reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which AVROBIO is pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that AVROBIO's product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that AVROBIO or AVROBIO's licensors are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of AVROBIO's product candidates. In particular, AVROBIO is aware of issued patents in the United States that cover the lentiviral vectors used in the manufacture of AVROBIO's product candidates. While AVROBIO believes that AVROBIO has reasonable defenses against a claim of infringement, potentially including that certain of these patents are expected to expire prior to commercializing AVROBIO's product candidates, if approved, in the United States, there can be no assurance that AVROBIO will prevail in any such action by the holder of these patents. In the event that the holder of these patents seeks to enforce its patent rights and AVROBIO's defenses against a claim of infringement are unsuccessful, AVROBIO may not be able to commercialize AVROBIO's product candidates in the United States, if approved, without first obtaining a license to some or all of these patents, which may not be available on commercially reasonable terms or at all. In addition, the defense of any claim of

infringement, even if successful, is time-consuming, expensive and diverts the attention of AVROBIO's management from AVROBIO's ongoing business operations.

Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that AVROBIO's product candidates may infringe or be alleged to infringe. In addition, third parties may obtain patents in the future and claim that use of AVROBIO's or AVROBIO's licensors' technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of AVROBIO's product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block AVROBIO's ability to commercialize such product candidate unless AVROBIO obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of AVROBIO's formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block AVROBIO's ability to develop and commercialize the applicable product candidate unless AVROBIO obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against AVROBIO may obtain injunctive or other equitable relief, which could effectively block AVROBIO's ability to further develop and commercialize one or more of AVROBIO's product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from AVROBIO's business. In the event of a successful claim of infringement against AVROBIO, AVROBIO may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign AVROBIO's infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Even in the absence of a finding of infringement, AVROBIO may choose to obtain a license, if such a license is available. A successful claim of patent or other intellectual property infringement against AVROBIO could materially adversely affect AVROBIO's business, results of operations and financial condition.

AVROBIO's rights to develop and commercialize its product candidates, should AVROBIO resume development of its product candidates, are subject, in part, to the terms and conditions of licenses granted to AVROBIO by others.

AVROBIO depends upon the intellectual property rights granted to AVROBIO under licenses from third parties that are important or necessary to the development of AVROBIO's technology and products, including technology related to AVROBIO's manufacturing process and AVROBIO's gene therapy product candidates. In particular, AVROBIO had in-licensed certain intellectual property rights and know-how from the University Health Network, or UHN (relevant to AVR-RD-01 and AVROBIO's Fabry program, which AVROBIO deprioritized in January 2022) and affiliates of Lund University (relevant to AVR-RD-02 and AVROBIO's Gaucher type 1 and type 3 programs). The Fabry license agreement with UHN was terminated as of January 4, 2024. In addition, AVROBIO has in-licensed patents and patent applications from BioMarin (relevant to AVR-RD-03 and AVROBIO's Pompe program) directed to compositions and methods related to the manufacture and use of AVR-RD-03. AVROBIO also previously had in place in-licensed patent applications from The University of Manchester relevant to AVR-RD-05 and AVROBIO's Hunter program, which license agreement was terminated as of September 8, 2023. Any termination of AVROBIO's remaining licenses could result in the loss of significant rights and could harm or prevent AVROBIO's ability to commercialize AVROBIO's product candidates, should AVROBIO resume development of such product candidates.

Each of AVROBIO's existing licenses with affiliates of Lund University and BioMarin are exclusive but are limited to particular fields, such as Gaucher disease type 1, or Pompe disease, and are subject to certain retained rights. Absent an amendment or additional agreement, AVROBIO may not have the right to use intellectual property in-licensed for one of AVROBIO's programs for another program. In addition, licenses that AVROBIO may enter into in the future may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which AVROBIO may wish to develop or commercialize AVROBIO's technology and products in the future. As a result, AVROBIO may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of AVROBIO's licenses. Licenses to additional third-party technology that may be required for AVROBIO's development programs may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on AVROBIO's business and financial condition.

In some circumstances, AVROBIO may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that AVROBIO licenses from third parties. For example, pursuant to each of AVROBIO's intellectual property licenses with BioMarin, the rights holders associated with Lund University, AVROBIO's licensors retain control of such activities. Therefore, AVROBIO cannot be certain that these patents and applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of AVROBIO's business. If AVROBIO's licensors fail to maintain such patents, or lose rights to those patents or patent applications, the

rights AVROBIO has licensed may be reduced or eliminated and AVROBIO's right to develop and commercialize any of AVROBIO's products that are the subject of such licensed rights could be adversely affected.

AVROBIO's current license agreements impose, and AVROBIO expects that future license agreements that AVROBIO may enter into will impose, various obligations, including diligence and certain payment obligations. If AVROBIO fails to satisfy AVROBIO's obligations, the licensor may have the right to terminate the agreement. Disputes may arise between AVROBIO and any of AVROBIO's licensors regarding intellectual property subject to such agreements and other issues. Such disputes over intellectual property that AVROBIO has licensed or the terms of AVROBIO's license agreements may prevent or impair AVROBIO's ability to maintain AVROBIO's current arrangements on acceptable terms, or at all, or may impair the value of the arrangement to AVROBIO. Any such dispute could have a material adverse effect on AVROBIO's business. If AVROBIO cannot maintain a necessary license agreement or if the agreement is terminated, AVROBIO may be unable to successfully develop and commercialize the affected product candidates.

If AVROBIO is unable to obtain and maintain patent protection for AVROBIO's product candidates, or if the scope of the patent protection obtained is not sufficiently broad, AVROBIO's competitors could develop and commercialize products similar or identical to AVROBIO's, and AVROBIO's ability to successfully commercialize AVROBIO's product candidates may be adversely affected.

Should AVROBIO resume development of its product candidates, AVROBIO's ability to compete effectively will depend, in part, on AVROBIO's ability to maintain the proprietary nature of AVROBIO's technology and manufacturing processes. AVROBIO relies on manufacturing and other know-how, patents, trade secrets, trademarks, license agreements and contractual provisions to establish AVROBIO's intellectual property rights and protect AVROBIO's products. These legal means, however, afford only limited protection and may not adequately protect AVROBIO's rights. The failure to obtain, maintain, enforce or defend such intellectual property rights, for any reason, could allow third parties to make competing products or impact AVROBIO's ability to develop, manufacture and market AVROBIO's products, if approved, on a commercially viable basis, or at all, which could have a material adverse effect on AVROBIO's financial condition and results of operations.

In particular, AVROBIO relies primarily on trade secrets, know-how and other unpatented technology, which are difficult to protect. Although AVROBIO seeks such protection in part by entering into confidentiality agreements with AVROBIO's vendors, employees, consultants and others who may have access to proprietary information, AVROBIO cannot be certain that these agreements will not be breached, adequate remedies for any breach would be available or AVROBIO's trade secrets, know-how and other unpatented proprietary technology will not otherwise become known to or be independently developed by AVROBIO's competitors. Should AVROBIO resume development of its product candidates and AVROBIO is unsuccessful in protecting AVROBIO's intellectual property rights, sales of AVROBIO's products may suffer and AVROBIO's ability to generate revenue could be severely impacted.

AVROBIO's licensors and AVROBIO has sought, and AVROBIO intends to continue to seek to protect AVROBIO's proprietary position by filing patent applications in the United States and, in at least some cases, one or more countries outside the United States related to product candidates that are important to AVROBIO's business. However, AVROBIO cannot predict whether the patent applications AVROBIO and AVROBIO's licensors are currently pursuing will issue as patents, whether the claims of any issued patents will provide AVROBIO with a competitive advantage, or whether AVROBIO will be able to successfully pursue patent applications in the future related to AVROBIO's product candidates, should AVROBIO resume development of its product candidates. While AVROBIO has in-licensed patents and patent applications relevant to AVR-RD-03, AVROBIO currently has no owned or in-licensed patents or patent applications covering AVR-RD-01 or AVR-RD-02. Some of AVROBIO's product candidates are in-licensed from third parties. Accordingly, in some cases, the availability and scope of potential patent protection is limited based on prior decisions by AVROBIO's licensors or the inventors, such as decisions on when to file patent applications or whether to file patent applications at all.

Should AVROBIO resume development of its product candidates, AVROBIO may not be able to protect AVROBIO's intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and AVROBIO's intellectual property rights in some countries outside the United States could be less extensive than those in the United States. Although AVROBIO's license agreements grant AVROBIO worldwide rights, and AVROBIO's currently in-licensed U.S. patent rights have certain corresponding foreign patents or patent applications, there can be no assurance that AVROBIO will obtain or maintain such corresponding patents or patent applications with respect to any future license agreements. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States even in jurisdictions where AVROBIO and AVROBIO's licensors pursue patent protection. Consequently, AVROBIO and AVROBIO's licensors may not be able to prevent third parties from practicing AVROBIO's inventions in all countries outside the United States, even in jurisdictions

where AVROBIO and AVROBIO's licensors pursue patent protection, or from selling or importing products made using AVROBIO's inventions in and into the United States or other jurisdictions. Competitors may use AVROBIO's technologies in jurisdictions where AVROBIO and AVROBIO's licensors have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where AVROBIO has patent protection, but enforcement is not as strong as that in the United States. These products may compete with AVROBIO's product candidates and AVROBIO's 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 foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for AVROBIO to stop the infringement of AVROBIO's patents or marketing of competing products in violation of AVROBIO's proprietary rights generally. Proceedings to enforce AVROBIO's patent rights, even if obtained, in foreign jurisdictions could result in substantial costs and divert AVROBIO's efforts and attention from other aspects of AVROBIO's business, could put AVROBIO's patents at risk of being invalidated or interpreted narrowly and AVROBIO's patent applications at risk of not issuing and could provoke third parties to assert claims against AVROBIO. AVROBIO may not prevail in any lawsuits that AVROBIO initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, AVROBIO's efforts to enforce AVROBIO's intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that AVROBIO develops or licenses.

Issued patents covering AVROBIO's product candidates could be found invalid or unenforceable if challenged in court. AVROBIO may not be able to protect AVROBIO's trade secrets in court.

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

In addition to the protection afforded by patents, AVROBIO relies on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that AVROBIO elects not to patent, processes for which patents are difficult to enforce and any other elements of AVROBIO's product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. AVROBIO seeks to protect AVROBIO's proprietary technology and processes, in part, by entering into confidentiality agreements with AVROBIO's employees, consultants, scientific advisors and contractors. AVROBIO cannot guarantee that AVROBIO has entered into such agreements with each party that may have or have had access to AVROBIO's trade secrets or proprietary technology and processes. AVROBIO also seeks to preserve the integrity and confidentiality of AVROBIO's data and trade secrets by maintaining physical security of AVROBIO's premises and physical and electronic security of AVROBIO's information technology systems. While AVROBIO has confidence in these individuals, organizations and systems, agreements or security measures may be breached, and AVROBIO may not have adequate remedies for any breach. In addition, AVROBIO's trade secrets may otherwise become known or be independently discovered by competitors.

AVROBIO may be subject to claims asserting that AVROBIO's employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what AVROBIO regards as AVROBIO's own intellectual property.

Certain of AVROBIO's employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including AVROBIO's competitors or potential competitors. Although AVROBIO tries to ensure that AVROBIO's employees, consultants and advisors do not use the proprietary information or know-how of others in their work for AVROBIO, AVROBIO may be subject to claims that these individuals or AVROBIO has 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. If AVROBIO fails in defending any such claims, in addition to paying monetary damages, AVROBIO may lose valuable intellectual property rights or personnel. Even if AVROBIO is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. AVROBIO's licensors may face similar risks, which could have an adverse impact on intellectual property that is licensed to AVROBIO.

In addition, while it is AVROBIO's policy to require AVROBIO's employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to AVROBIO, AVROBIO may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that AVROBIO regards as AVROBIO's own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and AVROBIO may be forced to bring claims against third parties, or defend claims that they may bring against AVROBIO, to determine the ownership of what AVROBIO regards as AVROBIO's intellectual property.

AVROBIO may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that AVROBIO owns or licenses.

AVROBIO or AVROBIO's licensors may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that AVROBIO owns or licenses or that AVROBIO may own or license in the future. While it is AVROBIO's policy to require AVROBIO's employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to AVROBIO, AVROBIO may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that AVROBIO regards as AVROBIO's own; AVROBIO's licensors may face similar obstacles. AVROBIO could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing AVROBIO's product candidates. Litigation may be necessary to defend against any claims challenging inventorship or ownership. If AVROBIO or AVROBIO's licensors fail in defending any such claims, AVROBIO may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact AVROBIO's business, results of operations and financial condition.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing AVROBIO's ability to protect AVROBIO's product candidates.

Changes in either the patent laws or the interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes several significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of AVROBIO's business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of AVROBIO's patent applications and the enforcement or defense of AVROBIO's issued patents, all of which could have a material adverse effect on AVROBIO's business, financial condition, results of operations and prospects.

The patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Two cases involving diagnostic method claims and "gene patents" were decided this year by the Supreme Court of the United States, or Supreme Court. On March 20, 2012, the Supreme Court issued a

decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc., or Prometheus, a case involving patent claims directed to a process of measuring a metabolic product in a patient to optimize a drug dosage for the patient. According to the Supreme Court, the addition of well-understood, routine or conventional activity such as "administering" or "determining" steps was not enough to transform an otherwise patent-ineligible natural phenomenon into patent-eligible subject matter. On July 3, 2012, the USPTO issued a guidance memo to patent examiners indicating that process claims directed to a law of nature, a natural phenomenon or a naturally occurring relation or correlation that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to not patent-eligible subject matter. On June 13, 2013, the Supreme Court issued its decision in Association for Molecular Pathology v. Myriad Genetics, Inc., or Myriad, a case involving patent claims held by Myriad relating to the breast cancer susceptibility genes BRCA1 and BRCA2. Myriad held that an isolated segment of naturally occurring DNA, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patent-eligible subject matter, but that complementary DNA, which is an artificial construct that may be created from RNA transcripts of genes, may be patent-eligible. On March 4, 2014, the USPTO issued a guidance memorandum to patent examiners entitled 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products. These guidelines instruct USPTO examiners on the ramifications of the Prometheus and Myriad rulings and apply the Myriad ruling to natural products and principles including all naturally occurring nucleic acids.

Certain claims of AVROBIO's licensed patents and patent applications contain, and any future patents AVROBIO may obtain may contain, claims that relate to specific recombinant DNA sequences that are naturally occurring at least in part and, therefore, could be the subject of future challenges made by third parties. In addition, the 2014 USPTO guidance could impact AVROBIO's ability to pursue similar patent claims in patent applications AVROBIO may prosecute in the future.

AVROBIO cannot assure you that AVROBIO's efforts to seek patent protection for AVROBIO's product candidates will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO. AVROBIO cannot fully predict what impact the Supreme Court's decisions in Prometheus and Myriad may have on the ability of life science companies to obtain or enforce patents relating to their products in the future. These decisions, the guidance issued by the USPTO and rulings in other cases or changes in USPTO guidance or procedures could have a material adverse effect on AVROBIO's existing patent rights and AVROBIO's ability to protect and enforce AVROBIO's intellectual property in the future.

Moreover, although the Supreme Court has held in Myriad that isolated segments of naturally occurring DNA are not patent-eligible subject matter, certain third parties could allege that activities that AVROBIO may undertake infringe other gene-related patent claims, and AVROBIO may deem it necessary to defend itself against these claims by asserting non-infringement and/or invalidity positions, or paying to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if AVROBIO is unsuccessful in defending against claims of patent infringement, AVROBIO could be forced to pay damages or be subjected to an injunction that would prevent AVROBIO from utilizing the patented subject matter. Such outcomes could harm AVROBIO's business, financial condition, results of operations or prospects.

Should AVROBIO resume development of its product candidates and AVROBIO does not obtain patent term extension and data exclusivity for AVROBIO's product candidates, AVROBIO's business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of AVROBIO's product candidates, one or more U.S. patents that AVROBIO licenses or may own or license in the future, if any, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. A patent may only be extended once and only based on a single approved product. However, AVROBIO may not be granted an extension 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 applicable time period or the scope of patent protection afforded could be less than AVROBIO requests. If AVROBIO is unable to obtain patent term extension or the term of any such extension is less than AVROBIO requests, AVROBIO's competitors may obtain approval of competing products following AVROBIO's patent expiration, and AVROBIO's revenue could be reduced, possibly materially. In addition, AVROBIO does not control the efforts of AVROBIO's licensors to obtain a patent term extension, and there can be no assurance that they will pursue or obtain such extensions to the patents that AVROBIO licenses from them.

If AVROBIO's trademarks and trade names are not adequately protected, then AVROBIO may not be able to build name recognition in AVROBIO's markets of interest and AVROBIO's business may be adversely affected.

AVROBIO has registered the marks "AVROBIO" and "plato" with the USPTO and in certain other countries, but AVROBIO does not have trademarks or trademark applications with the USPTO for the marks "AVRO" or the AVROBIO logo. In the future, even if AVROBIO applies for registration of these marks, there can be no assurance that such registration will be approved. Once registered, AVROBIO's trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. AVROBIO may not be able to protect AVROBIO's rights to these trademarks and trade names, which AVROBIO needs to build name recognition among potential partners or customers in AVROBIO's markets of interest. At times, competitors may adopt trade names or trademarks similar to AVROBIO's, thereby impeding AVROBIO's ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of AVROBIO's registered or unregistered trademarks or trade names. Over the long term, if AVROBIO is unable to establish name recognition based on AVROBIO's trademarks and trade names, then AVROBIO may not be able to compete effectively and AVROBIO's business may be adversely affected. AVROBIO's efforts to enforce or protect AVROBIO's proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact AVROBIO's financial condition or results of operations.

Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats.

The degree of future protection afforded by AVROBIO's intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect AVROBIO's business or permit AVROBIO to maintain AVROBIO's competitive advantage, should AVROBIO resume development of its product candidates. For example:

- others may be able to make gene therapy products that are similar to AVROBIO's product candidates but that are not covered by the claims of the patents that AVROBIO licenses or may own or license in the future;
- AVROBIO, AVROBIO's license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patents or pending patent applications that AVROBIO licenses or may own or license in the future;
- AVROBIO, AVROBIO's license partners or current or future collaborators, might not have been the first to file patent applications covering certain of AVROBIO's or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of AVROBIO's technologies without infringing AVROBIO's owned or licensed intellectual property rights;
- it is possible that AVROBIO's pending licensed patent applications or those that AVROBIO may own or license in the future will not lead to issued patents;
- issued patents that AVROBIO holds rights to or may hold rights to in the future may be held invalid or unenforceable, including as a result of legal challenges by AVROBIO's competitors;
- one or more of AVROBIO's product candidates may never be protected by patents;
- AVROBIO's competitors might conduct research and development activities in countries where AVROBIO does not have patent rights and then use the information learned from such activities to develop competitive products for sale in AVROBIO's major commercial markets;
- AVROBIO may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on AVROBIO's business; and
- AVROBIO may choose not to file a patent application for certain trade secrets or know-how, and a third party may subsequently file a patent application or obtain a patent covering such intellectual property.

Should any of these events occur, they could significantly harm AVROBIO's business, financial condition, results of operations and prospects.

Risks Related to Ownership of AVROBIO Common Stock

The market price of AVROBIO common stock may be highly volatile, and you may not be able to resell your shares at or above the price at which you purchased AVROBIO's shares.

AVROBIO's stock price is likely to be volatile. Since AVROBIO's IPO in June 2018, through March 7, 2024, the trading price of AVROBIO common stock has ranged from $53.70 to $0.56. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which you purchased shares. The market price for AVROBIO common stock may be influenced by many factors, including:

- the outcome of AVROBIO's exploration of strategic alternatives;
- adverse results or delays in preclinical studies or clinical trials;
- reports of adverse events in other gene therapy products or clinical studies of such products;
- an inability to obtain additional funding;
- failure by AVROBIO to successfully develop and commercialize AVROBIO's product candidates;
- failure by AVROBIO to maintain AVROBIO's existing strategic collaborations or enter into new collaborations;
- failure by AVROBIO or AVROBIO's licensors and strategic partners to prosecute, maintain or enforce AVROBIO's intellectual property rights;
- changes in laws or regulations applicable to AVROBIO's product candidates;
- an inability to obtain adequate product supply for AVROBIO's product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- the introduction of new products, services or technologies by AVROBIO's competitors;
- failure by AVROBIO to meet or exceed financial projections AVROBIO may provide to the public;
- failure by AVROBIO to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by AVROBIO, AVROBIO's strategic partners or AVROBIO's competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and AVROBIO's ability to obtain patent protection for AVROBIO's technologies;
- additions or departures of key scientific or management personnel, or other skilled personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of AVROBIO's common stock by AVROBIO or AVROBIO stockholders in the future; and
- the trading volume of AVROBIO common stock.

In addition, companies trading in the stock market in general, and Nasdaq in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of AVROBIO common stock, regardless of AVROBIO's actual operating performance.

AVROBIO could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for AVROBIO because pharmaceutical companies have experienced significant stock price volatility in recent years. If AVROBIO faces such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm AVROBIO's business.

An active trading market for AVROBIO's common stock may not be sustained.

Prior to AVROBIO's IPO in June 2018, there had been no public market for AVROBIO common stock. Although AVROBIO common stock is listed on Nasdaq, an active trading market for AVROBIO's shares may never be sustained. If an active market for AVROBIO common stock is not sustained, it may be difficult for you to sell shares you purchased without depressing the market price for the shares, or at all.

An inactive trading market may also impair AVROBIO's ability to raise capital to continue to fund operations by selling additional shares and may impair AVROBIO's ability to acquire other companies or technologies by using AVROBIO's shares as consideration.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about AVROBIO's business, AVROBIO's share price and trading volume could decline.

The trading market for AVROBIO common stock will likely depend in part on the research and reports that securities or industry analysts publish about AVROBIO or AVROBIO's business. AVROBIO does not have any control over these analysts. Although AVROBIO has obtained research coverage from certain analysts, there can be no assurance, including during such time period that AVROBIO pursues potential strategic alternatives, that analysts will continue to cover AVROBIO or provide favorable coverage. If one or more analysts downgrade AVROBIO's stock or change their opinion of AVROBIO's stock, AVROBIO's share price would likely decline. In addition, if one or more analysts cease coverage of AVROBIO's company or fail to regularly publish reports on AVROBIO, AVROBIO could lose visibility in the financial markets, which could cause AVROBIO's share price or trading volume to decline.

Concentration of ownership of AVROBIO common stock among AVROBIO's existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based on shares outstanding as of March 7, 2024, AVROBIO's executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 37.8% of AVROBIO's voting stock. As a result, if these stockholders were to act together, they would be able to significantly influence all matters submitted to AVROBIO stockholders for approval, as well as AVROBIO's management and affairs. For example, these stockholders, acting together, may be able to influence elections of directors, amendments of AVROBIO's organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for AVROBIO common stock that you may believe are in your best interest as one of AVROBIO stockholders. Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current trading price of AVROBIO's stock and have held their shares for a longer period, they may be more interested in selling AVROBIO's company to an acquirer than other investors or they may want AVROBIO to pursue strategies that deviate from the interests of other stockholders. Additionally, from time to time, any of AVROBIO's non-affiliated stockholders may accumulate or acquire significant positions in AVROBIO common stock and may similarly be able to influence AVROBIO's business or matters submitted to AVROBIO stockholders for approval.

AVROBIO is a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make AVROBIO common shares less attractive to investors.

AVROBIO is a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements in its Annual Report on Form 10-K, and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. To the extent AVROBIO takes advantage of such reduced disclosure obligations, it may also make comparison of its financial statements with other public companies difficult or impossible. AVROBIO will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of its common shares held by non-affiliates exceeds $250 million as of the end of that year's second fiscal quarter, or (ii) its annual revenues exceeded $100 million during such completed fiscal year and the market value of its common shares held by non-affiliates exceeds $700 million as of the end of that year's second fiscal quarter.

Investors may find AVROBIO common stock less attractive to the extent AVROBIO will rely on these exemptions. If some investors find AVROBIO common stock less attractive as a result, there may be a less active trading market for AVROBIO common stock and its stock price may be more volatile.

AVROBIO expects to continue to incur increased costs as a result of operating as a public company, and AVROBIO's management is required to devote substantial time to new compliance initiatives.

As a public company, and particularly because AVROBIO is no longer an "emerging growth company" as defined in Regulation S-K, AVROBIO will incur significant legal, accounting and other expenses that AVROBIO did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure

and financial controls and corporate governance practices. AVROBIO's management and other personnel will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased AVROBIO's legal and financial compliance costs and will continue to make some activities more time-consuming and costly. For example, AVROBIO expects that these rules and regulations may make it more difficult and increasingly more expensive for AVROBIO to obtain and maintain director and officer liability insurance.

Pursuant to Section 404, AVROBIO is required to furnish a report by AVROBIO's management on AVROBIO's internal control over financial reporting, and, once AVROBIO is no longer a smaller reporting company, AVROBIO will be required to furnish an attestation report on internal control over financial reporting issued by AVROBIO's independent registered public accounting firm. To achieve compliance with Section 404, AVROBIO continues to be engaged in a process to document and evaluate AVROBIO's internal control over financial reporting, which is both costly and challenging. In this regard, AVROBIO will need to continue to dedicate internal resources, potentially continue to 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 AVROBIO's efforts, there is a risk that AVROBIO will not be able to conclude that AVROBIO's internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of AVROBIO's financial statements.

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

Effective internal control over financial reporting is necessary for AVROBIO 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 AVROBIO to fail to meet AVROBIO's reporting obligations. In addition, any testing by AVROBIO conducted in connection with Section 404, or any subsequent testing by AVROBIO's independent registered public accounting firm, may reveal deficiencies in AVROBIO's internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to AVROBIO's financial statements, or may identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in AVROBIO's reported financial information, which could have a negative effect on the trading price of AVROBIO's stock.

AVROBIO is required to disclose changes made in AVROBIO's internal controls and procedures on a quarterly basis and AVROBIO's management is required to assess the effectiveness of these controls annually. However, for as long as AVROBIO is a smaller reporting company, AVROBIO's independent registered public accounting firm will not be required to attest to the effectiveness of AVROBIO's internal control over financial reporting pursuant to Section 404. AVROBIO will qualify as a smaller reporting company if the market value of AVROBIO's common stock held by non-affiliates is below $250 million (or $700 million if AVROBIO's annual revenue is less than $100 million) as of June 30 in any given year. An independent assessment of the effectiveness of AVROBIO's internal control over financial reporting could detect problems that AVROBIO's management's assessment might not. Undetected material weaknesses in AVROBIO's internal control over financial reporting could lead to financial statement restatements and require AVROBIO to incur the expense of remediation.

If AVROBIO experiences material weaknesses or deficiencies in the future, or otherwise fails to establish and maintain effective internal controls, AVROBIO may be unable to produce timely and accurate financial statements, and AVROBIO may conclude that its internal control over financial reporting is not effective, which could adversely impact AVROBIO's investors' confidence and AVROBIO's stock price.

AVROBIO expects to continue AVROBIO's efforts to improve AVROBIO's control processes, though there can be no assurance that AVROBIO's efforts will ultimately be successful or avoid potential material weaknesses, and AVROBIO expects to continue incurring additional costs as a result of these efforts. If AVROBIO is unable to successfully remediate any material weaknesses in AVROBIO's internal control over financial reporting, the accuracy and timing of AVROBIO's financial reporting may be adversely affected, AVROBIO may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in AVROBIO's financial reporting, and AVROBIO's stock price may decline as a result. AVROBIO also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities.

AVROBIO's disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

AVROBIO's disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by AVROBIO in reports AVROBIO files or submits 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. AVROBIO believes 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 AVROBIO's control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

AVROBIO does not intend to pay dividends on AVROBIO common stock, so any returns will be limited to the value of AVROBIO's stock.

AVROBIO has never declared or paid any cash dividends on AVROBIO common stock. AVROBIO currently anticipates that AVROBIO will retain future earnings for the development, operation and expansion of AVROBIO's business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in AVROBIO's charter and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire AVROBIO or increase the cost of acquiring AVROBIO, even if doing so would benefit AVROBIO stockholders or remove AVROBIO's current management.

AVROBIO's charter and bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of AVROBIO or changes in AVROBIO's management. AVROBIO's charter and bylaws, include provisions that:

- authorize "blank check" preferred stock, which could be issued by the AVROBIO Board without stockholder approval and may contain voting, liquidation, dividend and other rights superior to AVROBIO common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of AVROBIO stockholders can be called only by the AVROBIO Board, the chairperson of the AVROBIO Board, AVROBIO's Chief Executive Officer or AVROBIO's President;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of AVROBIO stockholders, including proposed nominations of persons for election to the AVROBIO Board;
- provide that AVROBIO's directors may be removed only for cause;
- provide that vacancies on the AVROBIO Board may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize the AVROBIO Board to modify, alter or repeal AVROBIO's amended and restated by-laws; and
- require supermajority votes of the holders of AVROBIO common stock to amend specified provisions of AVROBIO's charter and bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in AVROBIO's management.

In addition, because AVROBIO is incorporated in Delaware, AVROBIO is governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which limits the ability of stockholders owning in excess of 15% of AVROBIO's outstanding voting stock to merge or combine with AVROBIO.

Any provision of AVROBIO's amended and restated certificate of incorporation or amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for AVROBIO stockholders to receive a premium for their shares of AVROBIO common stock, and could also affect the price that some investors are willing to pay for AVROBIO common stock.

AVROBIO's bylaws contain exclusive forum provisions, which may limit a stockholder's ability to bring a claim in a judicial forum it finds favorable and may discourage lawsuits with respect to such claims.

AVROBIO's amended and restated bylaws provide that, unless AVROBIO consents in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (1) any derivative action or proceeding brought on AVROBIO's behalf; (2) any action asserting a claim of breach of or based on a fiduciary duty owed by any of AVROBIO's current or former directors, officers or other employees to AVROBIO or AVROBIO stockholders; (3) any action asserting a claim against AVROBIO or any of AVROBIO's current or former directors, officers, employees or stockholders arising pursuant to any provision of the DGCL, AVROBIO's amended and restated certificate of incorporation or AVROBIO's amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. AVROBIO's amended and restated bylaws further provide that, unless AVROBIO consents in writing to an alternative forum, the United States District Court for the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, as AVROBIO's principal executive offices are located in Cambridge, Massachusetts. In addition, AVROBIO's amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of AVROBIO's capital stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived AVROBIO's compliance with the U.S. federal securities laws and the rules and regulations thereunder.

AVROBIO recognizes that the Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, these forum selection clauses in AVROBIO's amended and restated bylaws may limit AVROBIO stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with AVROBIO or AVROBIO's directors, officers or employees, which may discourage such lawsuits against AVROBIO and AVROBIO's directors, officers and employees even though an action, if successful, might benefit AVROBIO stockholders. Section 22 of the Securities Act creates a concurrent jurisdiction for state and federal courts over all suits brought concerning a duty or liability created by the securities laws, rules and regulations thereunder. While the Delaware Supreme Court and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce AVROBIO's Federal Forum Provision. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert the provision is unenforceable, and if the Federal Forum Provision is found to be unenforceable, AVROBIO may incur additional costs with resolving such matters. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to AVROBIO than AVROBIO stockholders.

AVROBIO's failure to meet Nasdaq's continued listing requirements could result in a delisting of AVROBIO common stock.

If AVROBIO fails to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the requirement to maintain a minimum bid price of $1.00 per share pursuant to Nasdaq Listing Rule 5450(a)(1), or the Minimum Bid Price Requirement, Nasdaq may take steps to delist AVROBIO common stock.

On October 4, 2022, AVROBIO received a written notice from the staff, or the Staff, of Nasdaq's Listing Qualifications Department, notifying AVROBIO that, for the 30 consecutive business day period between August 22, 2022 through October 3, 2022, AVROBIO common stock had not complied with the Minimum Bid Price Requirement. On February 23, 2023, AVROBIO received a written notice from the Staff notifying AVROBIO that for 10 consecutive business days, from February 8, 2023 to February 22, 2023, the closing bid price of AVROBIO common stock was at $1.00 per share or greater, and accordingly, the Staff advised AVROBIO that AVROBIO had regained compliance with the Minimum Bid Price Requirement.

On May 11, 2023, AVROBIO received a written notice from the Staff notifying AVROBIO that, for the 30 consecutive business day period between March 29, 2023 through May 10, 2023, AVROBIO common stock had not complied with the Minimum Bid Price Requirement. On June 12, 2023, AVROBIO received a written notice from the Staff notifying AVROBIO that for 14 consecutive business days, from May 22, 2023 to June 9, 2023, the closing bid price of AVROBIO common stock was at $1.00 per share or greater, and accordingly, the Staff advised AVROBIO that AVROBIO had regained compliance with the Minimum Bid Price Requirement.

While AVROBIO has regained compliance with the Minimum Bid Price Requirement as of the date hereof, AVROBIO can provide no assurance that AVROBIO will continue to remain in compliance with the Minimum Bid Price Requirement. If AVROBIO is unable to maintain compliance with any of Nasdaq's continued listing requirements in the

future, AVROBIO may be subject to delisting. At that time, AVROBIO may appeal the Staff's delisting determination to a Nasdaq Hearing Panel. There can be no assurance that, if AVROBIO receives a delisting notice and appeal the delisting determination by the Staff to the Nasdaq Hearing Panel, such appeal would be successful.

Such a delisting would likely have a negative effect on the price of AVROBIO common stock and would impair your ability to sell or purchase AVROBIO common stock when you wish to do so. Any such delisting could also adversely impact AVROBIO's ability to raise additional capital or enter into strategic transactions. Additionally, if AVROBIO common stock is not listed on, or becomes delisted from, Nasdaq for any reason, trading AVROBIO common stock could be conducted only in the over-the-counter, or OTC, market or on an electronic bulletin board established for unlisted securities such as the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, and the liquidity and price of AVROBIO common stock may be more limited than if AVROBIO was quoted or listed on Nasdaq or another national securities exchange. In such circumstances, you may be unable to sell your common stock unless a market can be established or sustained.

General Risk Factors

Unfavorable global economic conditions could adversely affect AVROBIO's business, financial condition or results of operations.

AVROBIO's results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the COVID-19 pandemic has caused extreme volatility and disruptions in the capital and credit markets. In addition, Russia's invasion of Ukraine and the evolving events in Israel and the Gaza Strip may lead to a prolonged, adverse impact on global economic, social and market conditions. A severe or prolonged economic downturn could result in a variety of risks to AVROBIO's business, including weakened demand for AVROBIO's product candidates and AVROBIO's ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain AVROBIO's suppliers, possibly resulting in supply disruption, or cause delays in payments for AVROBIO's services by third-party payors or AVROBIO's collaborators. For example, while AVROBIO does not have any current operations in Ukraine, Russia, Israel or the Gaza Strip, AVROBIO does not know the extent to which continuing and evolving conflicts in such regions could impact any of AVROBIO's current suppliers and their ability to provide AVROBIO with supplies and services. Any of the foregoing could harm AVROBIO's business and AVROBIO cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact AVROBIO's business, financial condition, results of operations and prospects.

AVROBIO or the third parties upon whom AVROBIO depends may be adversely affected by earthquakes or other natural disasters and AVROBIO's business continuity and disaster recovery plans may not adequately protect AVROBIO from a serious disaster.

Earthquakes or other natural disasters could severely disrupt AVROBIO's operations, and have a material adverse effect on AVROBIO's business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented AVROBIO from using all or a significant portion of AVROBIO's headquarters, that damaged critical infrastructure, such as the manufacturing facilities of AVROBIO's third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for AVROBIO to continue its business for a substantial period of time. The disaster recovery and business continuity plans AVROBIO has in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. AVROBIO may incur substantial expenses as a result of the limited nature of its disaster recovery and business continuity plans, which, particularly when taken together with AVROBIO's lack of earthquake insurance, could have a material adverse effect on AVROBIO's business, financial condition, results of operations and prospects.

AVROBIO's internal computer systems, or those of AVROBIO's collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of AVROBIO's business operations or, if AVROBIO resumes development of its product candidates, AVROBIO's product development programs.

Despite AVROBIO's security measures, AVROBIO's internal computer systems and those of its current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. For example, in 2017 AVROBIO was subjected to a cyberattack by a third party, which led to the theft of a portion of AVROBIO's funds. AVROBIO implemented remedial measures promptly following this breach and does not believe that this breach had a material adverse effect on its business. In addition, in February 2019, one of AVROBIO's vendors was subject to a cyberattack by a third party, which resulted in the payment by AVROBIO of a fraudulent invoice. AVROBIO has implemented remedial measures following this breach and does not believe that this breach had a material effect on its business. However, if any cyberattack or data breach were to occur in the future and cause interruptions in AVROBIO's or its collaborators', contractors' or consultants' operations, it could result in a material disruption of AVROBIO's business operations or, if AVROBIO resumes development

of its product candidates, its product development programs, whether due to a loss of AVROBIO's business data, 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 AVROBIO's regulatory approval efforts and significantly increase AVROBIO's costs to recover or reproduce the data. Should AVROBIO resume development of its product candidates. To the extent that any disruption or security breach were to result in a loss of, or damage to, AVROBIO's data or applications, or inappropriate disclosure of confidential or proprietary information, AVROBIO could incur liability, its competitive position could be harmed and the development and commercialization of AVROBIO's product candidates, should AVROBIO resume their development, could be delayed.

Changes in tax law could adversely affect AVROBIO's business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect AVROBIO or holders of AVROBIO common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on AVROBIO's business, cash flow, financial condition or results of operations. AVROBIO urges investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in AVROBIO common stock.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We, under the oversight of our Audit Committee, have implemented and maintain an enterprise risk management program that encompasses cybersecurity risk management and is designed to identify, assess and mitigate critical risks from cybersecurity threats. Our cybersecurity risk management program is informed by, and incorporates elements of, recognized industry standards and frameworks, including elements of the National Institute of Standards and Technology Cybersecurity Framework. Our program includes controls and procedures designed to identify, classify and escalate certain cybersecurity incidents to provide management visibility and obtain direction from management as to the public disclosure and reporting of material incidents, if any, in a timely manner.

As part of our cybersecurity risk management program, we implement technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls. Additionally, we have established and maintain processes related to incident response and have been developing processes related to business continuity and disaster recovery designed to address our response to a cybersecurity incident. We leverage third parties and cybersecurity consultants as appropriate, including a virtual Chief Information Security Officer, or vCISO, to develop strategies to assess, address and align cybersecurity efforts with our business objectives and operational requirements. Further, we have a risk-based process to assess the cybersecurity practices of certain third parties prior to onboarding, including vendors, service providers and other external users of our systems.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, like other companies in our industry, we and our third-party vendors may, from time to time, experience threats and security incidents relating to our and our third-party vendors' information systems. See Item 1A "Risk Factors" in this Annual Report on Form 10-K for more information.

Governance

Our information technology representative, in consultation with our vCISO, is responsible for the day-to-day administration of our cybersecurity policies, processes and practices. The information technology representative and our vCISO meet regularly to review any outstanding cybersecurity risks and to discuss any recommended hardening or remediation measures. The information technology representative reports and provides periodic updates regarding the cybersecurity risk management program to our Chief Financial Officer. The individual currently operating as our information technology representative has 19 years of experience in information technology and information security, including at another public company.

The AVROBIO Board has delegated oversight of the Company's cybersecurity risk management program to our Audit Committee, which generally oversees our enterprise risk management program. Our Audit Committee receives periodic updates on the cybersecurity risk management program, including our risk management practices, from our information technology representative. Our Audit Committee reports on cybersecurity risks and risk management to the full AVROBIO Board as appropriate.

Item 2. Properties

Our corporate headquarters are located in Cambridge, Massachusetts, and encompasses a total of approximately 26,114 square feet of leased office space and laboratory facilities, pursuant to a sub-sublease. We initially entered into the sub-sublease for 13,643 square feet of laboratory space, or the Lab Sublease, in August 2018. The Lab Sublease was set to expire in April 2022. In January 2022, we amended the Lab Sublease to increase the premises to a total of 26,114 square feet and extend the term through April 30, 2023, and we have thereafter agreed to extend the Lab Sublease through April 30, 2024. In June 2020, we entered into a lease agreement for 3,885 square feet of office space located in Toronto, Ontario, Canada, which provided for expiration in June 2025. In October 2022, we subleased the entirety of the Toronto leased office space to a third party for a term extending through June 2025. In October 2023 we agreed with the landlord and subtenant to terminate each of the lease and sublease for the Toronto leased office space effective as of October 31, 2023. We believe that we have office and/or laboratory space sufficient to meet our current needs and that suitable additional space or alternative space will be available to the extent needed on commercially reasonable terms.

Item 3. Legal Proceedings

From time to time, we are subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this Annual Report on Form 10-K, we are not presently subject to any pending or threatened litigation that we believe, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "AVRO". Trading of our common stock commenced on June 21, 2018, following the completion of our IPO. Prior to that time, there was no established public trading market for our common stock.

Holders of Common Stock

As of February 29, 2024, the number of holders of record of our common stock was five. The number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to dividend policy will be made at the discretion of the AVROBIO Board and will depend on, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Offerings

We did not sell any unregistered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. [Reserved]

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

Our management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements included in this Annual Report on Form 10-K, which have been prepared by us in accordance with United States generally accepted accounting principles, or GAAP, and with Regulation S-X promulgated under the Exchange Act. This discussion and analysis should be read in conjunction with the consolidated financial statements and the notes thereto included 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, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part I, Item 1A. Risk Factors of this 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.

Overview

We are a gene therapy company with a purpose to free people from a lifetime of genetic disease. Our company has been focused on developing potentially curative HSC gene therapies to treat patients with rare diseases following a single dose treatment regimen. The gene therapies we had been developing employ HSCs that are harvested from the patient and then modified with a lentiviral vector to insert the equivalent of a functional copy of the gene that is mutated in the target disease. We believe that our approach, which is designed to transform stem cells from patients into therapeutic products, has the potential to provide curative benefit for a range of diseases. Our development focus has been on a group of rare genetic diseases referred to as lysosomal disorders, some of which today are primarily managed with enzyme replacement therapies, or ERTs.

On July 12, 2023, following a comprehensive review of our business by the AVROBIO Board, we announced our intention to halt development of our programs and explore strategic alternatives focused on maximizing stockholder value, which may include, but are not limited to, an acquisition, a merger, business combination or divestiture.

Subsequently, in connection with ongoing cost reduction efforts related to our ongoing review of potential strategic alternatives, we have terminated all Company-sponsored treatment-related and Company-sponsored long-term follow-up clinical studies relating to our AVR-RD-02, or Gaucher disease type 1, program, and Company-sponsored long term follow-up studies relating to our AVR-RD-01, or Fabry disease, program (which we previously deprioritized). In addition, in September 2023, we terminated our agreements with the University of Manchester for the license and development of a gene therapy for MPSII and discontinued our AVR-RD-05, or Hunter syndrome gene therapy program. Previously, in June 2023, we sold our cystinosis gene therapy program to Novartis. As of the date of the filing of this Annual Report, we currently have a total of three gene therapy product candidates, none of which are currently in active clinical development, including AVR-RD-02 for the treatment of Gaucher disease type 1 and type 3, AVR-RD-03 for the treatment of Pompe disease and AVR-RD-01 for the treatment of Fabry disease.

After a comprehensive review of strategic alternatives, including identifying and reviewing potential candidates for a strategic transaction, on January 30, 2024, AVROBIO entered into the Merger Agreement, with Merger Sub and Tectonic, pursuant to which Merger Sub will merge with and into Tectonic, with Tectonic surviving as AVROBIO's wholly-owned subsidiary. The merger was unanimously approved by the AVROBIO Board, and the AVROBIO Board resolved to recommend approval of the Merger Agreement to AVROBIO stockholders. In connection with the merger, certain investors have agreed to purchase shares of Tectonic common stock at a purchase price of $12.39908 per share, subject to and immediately prior to the closing of the merger, pursuant to the terms of the Subscription Agreement, and certain investors have consummated or will consummate certain additional purchases of Tectonic common stock pursuant to the Tectonic SAFEs for an aggregate purchase price among the transactions contemplated by the Subscription Agreement and such Tectonic SAFEs of approximately $130.7 million. At the effective time of the merger, each share of then-outstanding Tectonic common stock will be converted into the right to receive a number of shares of AVROBIO common stock, equal to the exchange ratio as set forth in the Merger Agreement. Concurrently with the closing of the merger, and assuming approval by AVROBIO stockholders, AVROBIO anticipates effecting a reverse stock split at a ratio in the range between 1:3 to 1:30, inclusive. Additionally, at or prior to the effective time of the merger, AVROBIO and a rights agent will enter into a CVR Agreement, pursuant to which AVROBIO stockholders of record as of immediately prior to such effective time (including holders of AVROBIO common stock issued upon settlement of the AVROBIO RSUs) will receive one non-transferable CVR for each outstanding share of AVROBIO common stock held by such stockholder on such date.

The closing of the merger is subject to approval by AVROBIO stockholders and Tectonic stockholders, as well as other customary closing conditions, including the effectiveness of a registration statement on Form S-4 filed with the SEC in connection with the transaction and Nasdaq's approval of the listing of the shares of the AVROBIO common stock to be issued in connection with the proposed merger. The closings of the private financings are conditioned upon the satisfaction or

waiver of the conditions to the closing of the merger as well as certain other conditions. If the transactions are completed, the business of Tectonic will continue as the business of the combined company.

AVROBIO's future operations are highly dependent on the success of the merger and there can be no assurances that the merger will be successfully consummated. There can be no assurance that the strategic review process or any transaction relating to a specific asset, including the merger and any AVROBIO asset sale (as defined below), will result in AVROBIO pursuing such a transaction(s), or that any transaction(s), if pursued, will be completed on terms favorable to AVROBIO and its stockholders in the existing AVROBIO entity or any possible entity that results from a combination of entities. If the strategic review process is unsuccessful, and if the merger is not consummated, the AVROBIO Board may decide to pursue a dissolution and liquidation of AVROBIO.

Since our inception in 2015, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring or discovering product candidates and securing related intellectual property rights, conducting discovery, research and development activities for our programs and planning for potential commercialization. To date, we have not generated any product revenue and have financed our operations primarily through the private placement of our securities and through public offerings of our common stock. Through December 31, 2023, we had received gross cash proceeds of $87.5 million from sales of our preferred stock; gross cash proceeds, before deducting underwriting discounts and commissions and expenses, of $428.1 million from sales of our common stock through our IPO and follow-on offerings; gross cash proceeds, before deducting commissions and expenses, of $23.5 million from sales of our common stock under our prior ATM facility; $15.0 million drawn in term loans under our Term Loan Agreement, which was repaid in full and terminated on June 9, 2023; and gross proceeds, before deducting transaction costs, of $87.5 million from the sale of our cystinosis gene therapy program.

Additionally, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates and programs. Our net income (losses) were $12.2 million and $(105.9) million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $477.3 million. Should we resume development of our product candidates, we would expect to continue to incur significant expenses for at least the next several years as we advance our product candidates from preclinical development and clinical trials and seek regulatory approval of our product candidates. Should we resume development of our product candidates, we would expect to expend significant resources to advance these candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

Should we resume development of our product candidates, we would need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we would expect to finance our operations with proceeds from outside sources, with a majority of such proceeds expected to be derived from sales of equity. We may also pursue additional funding from outside sources, including borrowing arrangements and entry into potential future collaboration agreements for one or more of our programs. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability, should we resume development of our product candidates. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Components of Our Consolidated Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses consist of costs incurred in connection with the development of our product candidates, including:

- license maintenance fees and milestone fees incurred in connection with various license agreements;
- expenses incurred under agreements with CROs, CMOs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;

- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- costs of purchasing lab supplies and non-capital equipment used in our preclinical activities;
- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements; and
- allocated facilities costs, depreciation and other expenses, which include rent and utilities.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs, and central laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under license agreements. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee the research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

The table below summarizes our research and development expenses related to our product candidates (in thousands):

	Year Ended December 31,	
	2023	2022
Gaucher	$ 10,859	$ 8,662
Hunter	6,599	4,968
Fabry	2,775	9,644
Cystinosis	439	4,615
Pompe	(58)	830
Other research activities	189	105
Unallocated research and development expenses	26,897	43,362
Total research and development expenses	$ 47,700	$ 72,186

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Should we resume development of our product candidates, we would expect our research and development expenses to increase substantially over the next several years, particularly as we increase personnel costs, including stock-based compensation, contractor costs and facilities costs, and advance the development of our product candidates. Should we resume development of our product candidates, we would also expect to incur additional expenses related to milestone and royalty payments payable to third parties with whom we have entered into license agreements to acquire the rights to our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates should we resume their development, or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety profile with IND-enabling studies;
- successful patient enrollment in, and the design, initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;

- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- maintaining a continued acceptable safety profile of the product candidates following approval; and
- the risks disclosed in the section entitled "*Risk Factors*" of this Annual Report on Form 10-K.

Should we resume development of our product candidates, we may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA, or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate. 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 marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, travel and stock-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, consulting, accounting and audit services.

Should we resume development of our product candidates, we would anticipate that our general and administrative expenses would increase as we increase our headcount to support research activities and development of our product candidates. We also anticipate that we would incur increased accounting, audit, legal, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company. We anticipate the additional costs for these services would substantially increase our general and administrative expenses. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other commercialization-related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidate.

Other Income (Expense), Net

Other (expense) income, net primarily consists of interest income earned on our cash and cash equivalents, changes in foreign currency, and interest expense related to our prior Term Loan Agreement.

Consolidated Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our consolidated results of operations (in thousands):

	Year Ended December 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 47,700	$ 72,186	$ (24,486)
General and administrative	23,967	33,248	(9,281)
Total operating expenses	71,667	105,434	(33,767)
Gain on asset sale	83,736	—	83,736
Loss on impairment	(1,877)	—	(1,877)
Income (loss) from operations	10,192	(105,434)	115,626
Other income (expense):			
Interest income (expense), net	2,420	(299)	2,719
Other expense, net	(78)	(157)	79
Total other income (expense), net	2,342	(456)	2,798
Income (loss) before income taxes	12,534	(105,890)	118,424
Provision for income tax expense	377	—	377
Net income (loss)	$ 12,157	$ (105,890)	$ 118,047

Research and Development Expenses

Research and development expenses decreased by $24.5 million to $47.7 million for the year ended December 31, 2023, from approximately $72.2 million for the year ended December 31, 2022. This decrease was driven by a $12.3 million decrease in personnel-related and consulting costs, including non-cash stock-based compensation, a $7.8 million decrease in manufacturing costs, a $2.5 million decrease in preclinical costs, a $1.5 million decrease in allocated facility expense, and a $0.3 million decrease in development costs, which includes a payment made in connection with the termination of the MPSII License Agreement.

General and Administrative Expenses

General and administrative expenses decreased by $9.3 million to $24.0 million for the year ended December 31, 2023, from $33.2 million for the year ended December 31, 2022. This decrease was driven by a $10.8 million decrease in personnel-related and consulting costs, including non-cash stock-based compensation and a $0.9 million decrease in information technology-related costs which was partially offset by a $2.4 million increase in legal expenses.

Gain on Asset Sale

For the year ended December 31, 2023 we recognized $83.7 million as a gain on asset sale, net of $3.8 million in transaction costs. We completed the Asset Sale on June 9, 2023.

Loss on Impairment

For the year ended December 31, 2023 we recognized a $1.9 million loss on impairment. Of this amount, $0.9 million is related to the loss on impairment of property, plant, and equipment as a result of the reclassification of these assets to held for sale. In addition, $0.9 million is related to the loss on impairment of the right of use asset for the subleased lab space located in Cambridge, Massachusetts, which is no longer in use.

Other Income (Expense), Net

Other income (expense), net was $2.3 million for the year ended December 31, 2023, compared to $(0.5) million of other income (expense), net for the year ended December 31, 2022. The increase in income was driven by a $2.8 million increase in interest income earned on short-term money market funds. Interest expense is relatively consistent period over

period. The Term Loan Agreement was terminated in the second quarter of 2023 which resulted in an increase in interest expense from the loss on the extinguishment of debt due to the write-off of the debt discount balance.

Provision for Income Tax Expense

For the year ended December 31, 2023 we recognized $0.4 million as a provision for income tax expense as a result of income recognized from the Asset Sale.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from the sale of preferred stock and our common stock through our IPO, and we have raised additional capital through subsequent follow-on offerings and our prior ATM facility. Through December 31, 2023, we had received gross cash proceeds of $87.5 million from sales of our preferred stock; gross cash proceeds, before deducting underwriting discounts and commissions and expenses, of $428.1 million from sales of our common stock through our IPO and follow-on offerings; gross cash proceeds, before deducting commissions and expenses, of $23.5 million from sales of our common stock under our prior ATM facility; $15.0 million drawn in term loans under our Term Loan Agreement, which was repaid in full and terminated on June 9, 2023; and gross proceeds, before deducting transaction costs, of $87.5 million from the sale of our cystinosis gene therapy program.

On July 1, 2019, we filed a shelf registration statement on Form S-3 with the SEC, or the July 2019 Shelf, which covers the offering, issuance and sale by us of up to an aggregate of $200.0 million of our common stock, preferred stock, debt securities, warrants and/or units. We simultaneously entered into a Sales Agreement with Cowen and Company, LLC, as sales agent, to provide for the offering, issuance and sale by us of up to $50.0 million of our common stock from time to time in ATM offerings under the July 2019 Shelf. The July 2019 Shelf was declared effective by the SEC on July 10, 2019.

On December 20, 2019, we filed a shelf registration statement on Form S-3 with the SEC, or the December 2019 Shelf, which covers the offering, issuance and sale by us of up to an aggregate of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units. The December 2019 Shelf was declared effective by the SEC on January 14, 2020.

In July 2019, we closed an underwritten public offering, or the July 2019 Follow-On Offering, under the July 2019 Shelf of 7,475,000 shares of our common stock at a public offering price of $18.50 per share, which included 975,000 shares of our common stock resulting from the full exercise of the underwriters' option to purchase additional shares at the public offering price. The net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were $129.5 million.

In February 2020, we closed an underwritten public offering, or the February 2020 Follow-On Offering, under the December 2019 Shelf of 4,350,000 shares of our common stock at a public offering price of $23.00 per share. The net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were $93.6 million.

In June 2020, we sold an aggregate of 384,140 shares of common stock under the prior ATM facility for net proceeds, after deducting commissions and other offering expenses payable by us, of $8.1 million.

In November 2020, we closed an underwritten public offering, or the November 2020 Follow-On Offering, of 5,000,000 shares of our common stock at a public offering price of $15.00 per share. The net proceeds to us from the November 2020 Follow-On Offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were $70.2 million.

In May 2021, we sold an aggregate of 1,829,268 shares of common stock under the prior ATM facility for net proceeds, after deducting commissions and other offering expenses payable by us, of $14.5 million. As of September 30, 2023, approximately $26.5 million of common stock remained available for future issuance under the prior ATM facility.

On November 2, 2021, or the Closing Date, we entered into the Term Loan Agreement. The Term Loan Agreement provided for (i) on the Closing Date, $30.0 million aggregate principal amount of term loans available through October 31, 2023; (ii) an additional $20.0 million in term loan facilities available through October 31, 2023 upon the achievement of certain regulatory or clinical milestones prior to the time of draw, or the Milestone Funding; and (iii) an additional

discretionary $15.0 million term loan facility available upon our request and approval by the Agent and the Lenders, or, collectively, the Term Loans. We drew $15.0 million in term loans on the Closing Date. On June 9, 2023, upon the closing of the Asset Sale, all outstanding amounts due and owed, including principal, interest, and other charges, under the Term Loan Agreement, dated as of November 2, 2021, by and among the Company, Silicon Valley Bank, a division of First-Citizens Bank & Trust and the other parties thereto, were repaid in full and the Term Loan Facility was terminated. Upon repayment, the obligations of the Company under the Term Loan Facility were satisfied in full, the Term Loan Facility and all related loan documents were terminated and all liens and security interests granted thereunder were released and terminated (excluding certain indemnification obligations that expressly survive termination of the Term Loan Facility).

In July 2022, the July 2019 Shelf expired, and on November 8, 2022, we filed a shelf registration statement on Form S-3 with the SEC, or the November 2022 Shelf, which covered the offering, issuance and sale by us of up to an aggregate of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units. The December 2019 Shelf expired in December 2022, and the November 2022 Shelf carried forward unsold securities previously covered by the December 2019 Shelf, thus registering an aggregate total of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units. In connection with the November 2022 Shelf, we simultaneously entered into a new Sales Agreement with Cowen and Company, LLC, as sales agent, to provide for the offering, issuance and sale by us of up to $50.0 million of our common stock from time to time in "at-the-market" offerings under the November 2022 Shelf, or the 2022 ATM Facility. As of the date of this report, we have not made any sales under the 2022 ATM Facility. On November 3, 2023, we withdrew the November 2022 Shelf. We will not make any potential sales under the 2022 ATM Facility unless a new shelf registration statement on Form S-3 is filed and declared effective.

As of December 31, 2023, we had cash and cash equivalents of $98.0 million. Cash in excess of immediate requirements is invested primarily with a view to liquidity and capital preservation.

Our material cash requirements include contractual obligations with third parties. We have non-cancelable operating leases for office and laboratory space, which are located in Cambridge, Massachusetts and will expire in April 2024. As of December 31, 2023, we expect our future minimum lease payments under this commitment to total approximately $0.9 million in 2024. These minimum lease payments do not include any related common area maintenance charges or real estate taxes.

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included above as the amount and timing of such payments are not known.

In addition, pursuant to our current or former license agreements with UHN, BioMarin, The University of Manchester, Papillon and the Lund University rights holders, we are or were required to make certain milestone and royalty payments to our licensors. See "*Business—License Agreements*" for additional details regarding our payment obligations to these licensors.

Cash Flows

The following table summarizes our cash flows for each of the periods presented (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (63,190)	$ (97,208)
Net cash provided by (used in) investing activities	85,076	(267)
Net cash (used in) provided by financing activities	(16,029)	262
Net increase (decrease) increase in cash, cash equivalents and restricted cash	$ 5,857	$ (97,213)

Operating Activities

During the year ended December 31, 2023, operating activities used $63.2 million of cash and cash equivalents, resulting from our net income of $12.2 million, including gain on asset sale of $83.7 million, which was offset by the gain on asset sale that is classified as investing activities, net non-cash charges of $12.7 million and changes in our operating assets

and liabilities of $4.3 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2023 was primarily due to a $6.7 million decrease in accrued expenses and other current liabilities and a $2.5 million decrease in current and non-current operating lease liabilities, partially offset by a $5.2 million decrease in prepaids and other current assets. The non-cash charges included $6.9 million of stock-based compensation expense, $1.9 million in non-cash asset impairment charges, $1.1 million in non-cash interest expense, $1.9 million in non-cash lease expense, and $0.6 million in depreciation and amortization expense.

During the year ended December 31, 2022, operating activities used $97.2 million of cash and cash equivalents, resulting from our net loss of $(105.9) million and cash used by changes in our operating assets and liabilities of $7.4 million which was offset by non-cash charges of $16.1 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2022 consists primarily of a $2.5 million decrease in prepaid expenses and other current assets, a $3.9 million decrease in accrued expenses and other current liabilities, a $3.1 million decrease in accounts payable, and a $2.9 million decrease in current and non-current operating lease liabilities. The increase in accrued expenses and other current liabilities was primarily due to an increase in accrued compensation and benefit costs.

Investing Activities

Net cash provided by (used in) investing activities was $85.1 million for the year ended December 31, 2023 compared to $(0.3) million for the year ended December 31, 2022. The increase in cash provided by investing activities is related to the net proceeds received for the sale of the cystinosis program in the second quarter of 2023 for proceeds net of transaction costs of $83.7 million, and $1.4 million in proceeds from the sale of property, plant, and equipment.

Financing Activities

Net cash used by financing activities was $16.0 million for the year ended December 31, 2023 compared to net cash provided by financing activities of $0.3 million for the year ended December 31, 2022. The change is related to the repayment of the Term Loan Agreement in the second quarter of 2023.

Funding Requirements

Should we resume development of our product candidates, we would expect our expenses to increase substantially in connection with such activities, particularly with respect to preclinical activities and clinical trials of our product candidates. Our expenses would also increase should we:

- continue our development of our product candidates, including enrollment and dosing of patients in clinical trials;
- initiate clinical trials and preclinical studies for product candidates;
- seek to identify and develop or in-license or acquire additional product candidates and technologies;
- seek to industrialize our HSC gene therapy approach into a robust, scalable and, if approved, commercially viable process;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- hire and retain additional personnel, such as clinical, quality control, and scientific personnel;
- expand our infrastructure, office space and facilities to accommodate our employee base, including adding equipment and physical infrastructure to support our research and development; and
- continue to incur additional public company-related costs.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaboration agreements, government and other third-party funding, strategic alliances, licensing arrangements or marketing and distribution arrangements. 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, making capital expenditures or declaring dividends. If we raise additional funds through government and other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, 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, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with GAAP principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 *"Summary of Significant Accounting Policies"* to our consolidated financial statements appearing elsewhere in this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. 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 actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including central laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical and clinical studies; and
- CMOs in connection with drug substance and drug product formulation of preclinical and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials 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 expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. 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 the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in

any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure stock options and other stock-based awards granted to employees and members of our board of directors for their services as directors based on the fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We have issued stock options, restricted stock and RSUs with service-based vesting conditions.

Modifications to stock-based awards are treated as an exchange of the original award for a new award with total compensation equal to the grant-date fair value of the original award plus any incremental value of the modification. The incremental value is based on the excess of the fair value of the modified award over the fair value of the original award immediately before the modification.

Prior to the adoption of Accounting Standards Update (ASU) No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting (ASU 2018-07)*, as discussed in Note 2 *"Summary of Significant Accounting Policies"* to our consolidated financial statements appearing elsewhere in this Annual Report, the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. After the adoption of ASU 2018-07, the measurement date for non-employee awards is the later of the adoption date of ASU 2018-07, or the date of grant, without change in the fair value of the award.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the estimated fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

We determined the assumptions for the Black-Scholes option-pricing model as discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

- *Determination of the Fair Value of Common Stock.* The fair value of our common stock is determined based on the quoted market price of our common stock. Prior to our IPO, there was no public market for our common stock, and consequently, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering third-party valuations of our common stock as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Following the closing of our IPO, it was no longer necessary for our board of directors to estimate the fair market value of our common stock in connection with our accounting for granted equity awards.
- *Expected Term.* The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term of stock options granted has been determined using the simplified method, which uses the midpoint between the vesting date and the contractual term.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the stock-based award's expected term.
- *Expected Volatility.* Because we do not have long-term trading history of our common stock, the expected volatility was derived from the average historical stock volatilities of several public companies within our industry that we consider to be comparable to our business over a period equivalent to the expected term of the stock-based awards.
- *Dividend Rate.* The expected dividend is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.

If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation for future awards may differ materially compared with the awards granted previously.

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 *"Summary of Significant Accounting Policies"* to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

As of December 31, 2023, we had cash and cash equivalents of $98.0 million, which consisted of cash and money market funds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material impact on our cash and cash equivalents, debt-related obligations, financial position or results of operations.

Foreign Currency Exchange Risk

We are exposed to foreign exchange rate risk. Our headquarters are located in the United States, where the majority of our general and administrative expenses and research and development costs are incurred in U.S. dollars. A portion of our research and development costs are incurred by our subsidiaries in Australia and Canada, whose functional currencies are the U.S. dollar but engage in transactions in Australian dollars and Canadian dollars, respectively. During each of the years ended December 31, 2023 and 2022, we recognized immaterial foreign currency transaction losses. These losses primarily related to unrealized and realized foreign currency gains and losses as a result of transactions entered into by our Australian and Canadian subsidiaries in currencies other than the U.S. dollar. These foreign currency transaction gains and losses were recorded in other expense, net in our consolidated statements of operations. We believe that a 10% change in the exchange rate between the U.S. dollar, Australian dollar and Canadian dollar would not have a material impact on our financial position or results of operations.

Our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk.

Item 8. Financial Statements and Supplementary Data.

All financial statements and supplementary data required to be filed hereunder are filed as listed under Item 15(a) of this Annual Report on Form 10-K and are incorporated herein by this reference.

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 Interim Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under 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, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and 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, 2023, our Interim Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of the end of the period covered by this Annual Report on Form 10-K.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the Company. Our internal control over financial reporting is designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with U.S. GAAP and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate.

Our management, with the participation of its Interim Chief Executive Officer and Chief Financial Officer, assessed our internal control over financial reporting as of December 31, 2023. Management based its assessment on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and concluded that our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2023.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting because we are not an "accelerated filer" or "large accelerated filer."

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

During the three months ended December 31, 2023, none of our directors or officers adopted, materially modified or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangement.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following are AVROBIO's directors and executive officers and their respective ages and positions as of the date of this Annual Report on Form 10-K:

Name	Position Held with AVROBIO	Age
Gail Farfel, Ph.D.	Director	60
Christopher Paige, Ph.D.	Director	71
Philip J. Vickers, Ph.D.	Director	64
Ian Clark	Director	63
Annalisa Jenkins, M.B.B.S., F.R.C.P.	Director	58
Bruce Booth, D. Phil.	Director	49
Phillip B. Donenberg	Director	63
Erik Ostrowski	President, Interim Chief Executive Officer, Chief Financial Officer and Treasurer	51
Steven Avruch	Chief Legal Officer and Secretary	63
Azadeh Golipour, Ph.D.	Chief Technology Officer	45
Essra Ridha, M.D., MRCP, FFPM	Chief Medical Officer	41

Directors

Gail M. Farfel, Ph.D. has served as a member of the AVROBIO Board since October 2020. Dr. Farfel served as the chief executive officer of ProMIS Neurosciences, Inc., a biopharmaceutical company, from September 2022 to December 2023. From June 2015 to September 2022, Dr. Farfel was executive vice president and chief development officer of Zogenix Inc., a biopharmaceutical company. Previously, Dr. Farfel was chief clinical and regulatory officer of Marinus Pharmaceuticals (Nasdaq: MRNS), establishing and overseeing clinical, medical and regulatory strategies for adult and pediatric seizure disorders, including a pediatric epileptic orphan disease. She also previously served as vice president, therapeutic area head for neuroscience clinical development and medical affairs at Novartis Pharmaceuticals Corporation, where she oversaw a portfolio of products for multiple sclerosis, Alzheimer's disease and Parkinson's disease. Dr. Farfel serves on the board of directors of Durect Corporation (Nasdaq: DRRX). She previously served on the board of directors of Zogenix International Ltd., a wholly owned subsidiary of Zogenix, Inc. (Nasdaq: ZGNX). Dr. Farfel holds a Ph.D. in neuropsychopharmacology from the University of Chicago, where she received the Ginsburg Prize for Dissertation Excellence and is a director on the Medical and Biological Sciences Alumni Board. She also holds a B.S in biochemistry from the University of Virginia. AVROBIO believes that Dr. Farfel is qualified to serve on the AVROBIO Board because of her scientific, executive, and industry experience in the field in which AVROBIO operates.

Christopher Paige, Ph.D. has served as a member of the AVROBIO Board since January 2016. Dr. Paige is a professor in the departments of medical biophysics and immunology at the University of Toronto and has served in that role since 1987. He also holds the position of Emeritus Senior Scientist at UHN after having served as a senior scientist at UHN from 1987 to 2021. From 1997 to October 2016, he served as the vice president, research of UHN. In 1990, Dr. Paige became the founding director of the Arthritis and Autoimmunity Research Centre as well as director of research at The Wellesley Hospital. He became a member of the Basel Institute for Immunology in Switzerland in 1980 where he worked until joining the Ontario Cancer Institute as a senior scientist in 1987. Dr. Paige also has experience serving on the board of directors of privately held companies. Dr. Paige earned a B.S. in biology at the University of Notre Dame in 1974 and a Ph.D. in immunology at the Sloan-Kettering Division of Cornell University Graduate School of Medical Sciences in 1979. AVROBIO believes Dr. Paige is qualified to serve on the AVROBIO Board because of his scientific and industry experience in the field in which AVROBIO operates.

Philip J. Vickers, Ph.D. has served as a member of the AVROBIO Board since January 2019. Dr. Vickers is president and chief executive officer of Solu Therapeutics, a biotechnology company, and has served in this role since September 2023. Dr. Vickers was the chief executive officer of Faze Medicines, a biotechnology company from January 2021 to November 2022. From November 2017 until December 2020, Dr. Vickers served as the president and chief executive officer and a member of the board of directors of Northern Biologics Inc., a biotechnology company. From June 2013 until June 2017, Dr. Vickers served as global head of research and development and a member of the executive committee of Shire plc, a biotechnology company focused on the development of therapies for the treatment of rare and specialty conditions. From October 2010 to September 2013, Dr. Vickers served as the senior vice president, head of research and development, human genetic therapies at Shire. Prior to Shire, Dr. Vickers held positions of increasing responsibility in research and development at Merck & Co., Inc., Pfizer Inc., Boehringer-Ingelheim International GmbH and Resolvyx Pharmaceuticals, Inc. Dr. Vickers

previously served on the board of directors of Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company, from February 2015 until May 2023. Dr. Vickers also serves as a scientific advisor to the PTEN Research Foundation. Dr. Vickers obtained his Ph.D. in biochemistry from the University of Toronto, which was followed by postdoctoral research in mechanisms of multidrug resistance in breast cancer at the National Cancer Institute in Bethesda, Maryland. AVROBIO believes that Dr. Vickers is qualified to serve on the AVROBIO Board because of his scientific, executive, and industry experience in the field in which AVROBIO operates.

Ian Clark has served as a member of the AVROBIO Board since January 2018. From 2010 to 2016, Mr. Clark served as the chief executive officer and head of North American commercial operations and was a member of the board of directors for Genentech, a member of the Roche Group. He joined Genentech in 2003 as senior vice president and general manager, BioOncology. In August 2005, he became senior vice president, commercial operations of Genentech. In January 2006, Mr. Clark became executive vice president, commercial operations of Genentech and became a member of its executive committee. Mr. Clark was named head of global product strategy and chief marketing officer of Roche in April 2009. Prior to joining Genentech, Mr. Clark held various positions of increasing responsibility at Novartis, Sanofi, Ivax and Searle, working in the USA, UK, Canada, Eastern Europe and France. Mr. Clark currently serves on the board of directors of Corvus Pharmaceuticals, Inc. (Nasdaq: CRVS), Takeda Pharmaceutical Company Limited (NYSE: TAK), Olema Pharmaceuticals, Inc. (Nasdaq: OLMA), where he serves as chairman of the board of directors, Kyverna Therapeutics, Inc. (Nasdaq: KYTX), where he serves as chairman of the board of directors, and Guardant Health, Inc. (Nasdaq: GH), where he also serves as the lead independent director. Mr. Clark serves as an advisor to KKR. Mr. Clark previously served on the board of directors of Agios Pharmaceuticals, Forty Seven, Inc., Shire plc, Kite Pharma, and TerraVia (formerly Solazyme). He also previously served on the board of directors of the Biotechnology Industry Organization (BIO), as a member of the economic advisory council of the Federal Reserve Bank of San Francisco, as an operating partner of Blackstone Life Sciences, a private investment firm focusing on the life sciences sector and an operating unit within The Blackstone Group L.P., and as a member of the strategic priorities board of BioFulcrum, an initiative within the Gladstone Institutes. Mr. Clark received a B.S. and honorary doctorate in biological sciences from Southampton University in the United Kingdom. AVROBIO believes Mr. Clark is qualified to serve on the AVROBIO Board because of his industry experience in the field in which AVROBIO operates and his executive experience with companies in AVROBIO's industry.

Annalisa Jenkins, M.B.B.S., F.R.C.P. has served as a member of the AVROBIO Board since April 2018. From November 2017 until April 2019, Dr. Jenkins served as the chief executive officer of PlaqueTec Ltd., a biotechnology company focusing on coronary artery disease treatment and prevention. Previously, Dr. Jenkins served as the president and chief executive officer and a member of the board of directors of Dimension Therapeutics, Inc., a biotechnology company focused on rare and metabolic diseases associated with the liver, from September 2014 until its sale to Ultragenyx Pharmaceutical Inc. in November 2017. From October 2013 to March 2014, Dr. Jenkins served as executive vice president, head of global research and development for Merck Serono Pharmaceuticals, a biopharmaceutical company. Previously, from September 2011 to October 2013, she served as Merck Serono's executive vice president, global development and medical, and was a member of Merck Serono's executive committee. Prior to that, Dr. Jenkins pursued a 15-year career at Bristol-Myers Squibb Company, a biopharmaceutical company, where, from July 2009 to June 2011, she was a senior vice president and head of global medical affairs. Dr. Jenkins currently serves on the board of Genomics England, a UK government entity dedicated to advancing the 100,000 Genomes Project. Dr. Jenkins also serves on the board of directors of Affimed N.V. (Nasdaq: AFMD), Compass Pathways (Nasdaq: CMPS), Mereo Biopharma Group plc (Nasdaq: MREO), and a number of privately held biotechnology and life science companies, and serves as a trustee to a number of non-profit organizations. Dr. Jenkins previously served on the board of numerous biotechnology and life science companies, including AgeX Therapeutics, Inc. (NYSE American: AGE), Silence Therapeutics, Ardelyx, Inc., Oncimmune Holdings plc (LSE: ONC), OncoSec Medical Incorporated, and Sensyne Health plc., and she served as a committee member of the science board to the FDA, which advised leadership on complex scientific and technical issues. Dr. Jenkins graduated with a degree in medicine from St. Bartholomew's Hospital in the University of London and subsequently trained in cardiovascular medicine in the UK National Health Service. Earlier in her career, Dr. Jenkins served as a medical officer in the British Royal Navy. AVROBIO believes Dr. Jenkins is qualified to serve on the AVROBIO Board based on her industry experience in the field in which AVROBIO operates and her executive experience with companies in AVROBIO's industry.

Bruce Booth, D.Phil. has served as the Chairperson of the AVROBIO Board since February 2016. Dr. Booth joined Atlas Venture in 2005, and currently serves as general partner. Previously, from 2004 to 2005, Dr. Booth was a principal at Caxton Health Holdings L.L.C., a healthcare-focused investment firm, where he focused on the firm's venture capital activities. Prior to Caxton, from 1999 to 2004, he was an associate principal at McKinsey & Company, a global strategic management consulting firm, where he advised clients on research and development productivity, corporate strategy and business development issues across the biopharmaceutical sector. Dr. Booth is chairman of the board of directors and co-founder of Kymera Therapeutics, Inc. (Nasdaq: KYMR) and chairman of the board of directors of Vigil Neuroscience (Nasdaq: VIGL), which are biotechnology companies. He also serves on the board of several privately held companies. From February 2018 until July 2020, Dr. Booth served as chairperson of the board of directors of Unum Therapeutics Inc. (Nasdaq:

UMRX), now called Cogent Biosciences (Nasdaq: COGT); from February 2017 until December 2018, Dr. Booth served as independent chairperson of the board of directors of miRagen Therapeutics, Inc. (Nasdaq: MGEN), now called Viridian Therapeutics, Inc (Nasdaq: VRDN); from August 2006 until June 2018, Dr. Booth served on the board of directors of Zafgen, Inc. (Nasdaq: ZFGN), now called Larimar Therapeutics, Inc. (Nasdaq: LRMR); and from February 2016 until September 2023, Dr. Booth served on the board of directors of Magenta Therapeutics, Inc. (Nasdaq: MGTA), now called Dianthus Therapeutics, Inc. (Nasdaq: DNTH). As a British Marshall Scholar, Dr. Booth holds a D.Phil. in molecular immunology from Oxford University's Nuffield Department of Medicine and a B.S. in biochemistry, summa cum laude, from Pennsylvania State University. AVROBIO believes Dr. Booth's extensive leadership, executive, managerial and business experience with life sciences companies, including experience in the formation, development and business strategy of multiple start-up companies in the life sciences sector, qualifies him to serve on the AVROBIO Board.

Phillip B. Donenberg has served as a member of the AVROBIO Board and Audit Committee chair since June 2018. Mr. Donenberg served as senior vice president and chief financial officer of Jaguar Gene Therapy, LLC, a privately held early-stage gene therapy company from February 2020 to March 2023. From July 2018 to November 2018, Mr. Donenberg served as the chief financial officer and senior vice president of Assertio Therapeutics, Inc. (Nasdaq: ASRT), a pharmaceutical company. Previously, Mr. Donenberg served at AveXis, Inc. (now a Novartis company), a gene therapy company, as senior vice president and chief financial officer from October 2017 to June 2018 and as vice president, corporate controller from September 2016 to October 2017. He was the chief financial officer of RestorGenex Corporation from May 2014 to January 2016, when RestorGenex merged with Diffusion Pharmaceuticals LLC, a pharmaceutical company, and served as the merged company's consultant chief financial officer until September 2016, and the chief financial officer of 7wire Ventures LLC, an early-stage healthcare venture fund, from September 2013 to May 2014. Prior to that time, Mr. Donenberg served as the chief financial officer of BioSante Pharmaceuticals, Inc. from July 1998 to June 2013, when BioSante merged with ANIP Pharmaceuticals, Inc. Mr. Donenberg currently serves on the board of directors and as audit committee chair of Taysha Gene Therapies, Inc. (Nasdaq: TSHA), a gene therapy company, and also has experience serving on the boards of directors of privately held companies. Mr. Donenberg holds a B.S. in accountancy from the University of Illinois Champaign-Urbana College of Business and is a Certified Public Accountant. AVROBIO believes Mr. Donenberg is qualified to serve on the AVROBIO Board because of his financial expertise and his experience as an executive of companies in the industry in which AVROBIO operates.

Executive Officers

Erik Ostrowski has been AVROBIO's Chief Financial Officer and Treasurer since January 2019 and has also served as AVROBIO's President and Interim Chief Executive Officer since May 1, 2023. From June 2014 to December 2018, Mr. Ostrowski served as the chief financial officer of Summit Therapeutics plc., a biotechnology company. Prior to that, he served as vice president of finance at Organogenesis Inc., a biotechnology company, from July 2010 to June 2014, and previously worked in investment banking, most recently as a director with Leerink Partners LLC. Mr. Ostrowski began his career as an accountant with Coopers & Lybrand (now PricewaterhouseCoopers). Mr. Ostrowski has served on the board of directors of Faron Pharmaceuticals Oy (AIM: FARN, First North: FARON) since April 2022. He received a B.S. in accounting and economics from Babson College and a M.B.A. from the University of Chicago Booth School of Business.

Steven Avruch has been AVROBIO's Chief Legal Officer and Secretary since March 2020 and previously served as AVROBIO's Vice President, General Counsel and Secretary from January 2019 to March 2020. Prior to joining AVROBIO, from May 2018 to December 2018, Mr. Avruch was an independent legal consultant to biotechnology and other companies. Prior to that, Mr. Avruch served at Biogen Inc., a biotechnology company, as chief corporation counsel and assistant secretary from January 2015 to December 2017, and as associate general counsel from March 2013 to December 2014. Mr. Avruch graduated with an A.B. in Russian Studies from Dartmouth College, and later earned his J.D. from Boston College Law School.

Azadeh Golipour, Ph.D. has been AVROBIO's Chief Technology Officer since January 2022. Prior to that she was SVP, Portfolio Planning and Program Management from October 2021 to January 2022. From July 2016 through October 2021 Dr. Golipour held positions of increasing responsibility at AVROBIO, including: SVP, CMC Strategy & Manufacturing; VP, Manufacturing Operations; Senior Director, Manufacturing Operations; and Director, Manufacturing Operations. Dr. Golipour received a Ph.D. in molecular genetics from University of Toronto (Canada) and has published multiple articles, including two first-author articles in the journal Cell, Stem Cell and one article in the journal Nature. Dr. Golipour's articles on reprogramming stem cells have been cited more than 1,000 times.

Essra Ridha, M.D., M.R.C.P., F.F.P.M. has been AVROBIO's Chief Medical Officer since October 2021, and from April 2021 to July 2021, she was AVROBIO's Vice President, Clinical Development. Prior to joining AVROBIO, from June 2019 to February 2021, Dr. Ridha was senior medical director at Sangamo Therapeutics, a biotechnology company, and before that, from March 2016 to December 2018, she served as clinical development director at GlaxoSmithKline, a pharmaceutical company. From June 2014 to March 2016, Dr. Ridha worked as a medical expert at Bristol Myers Squibb

Pharmaceuticals advising on late-stage clinical development, medical affairs, real-world evidence and health economics and outcomes research in cardiovascular medicine. Dr. Ridha is a member of the Royal College of Physicians of London, as well as a Fellow of the Faculty of Pharmaceutical Medicine. She was an expert panel member at the World Health Organization Expert Advisory Committee to develop Global Standards for the Governance and Oversight of Human Genome Editing. She earned her medical degrees from the Royal Free & University College London Medical School and earned her Bachelor of Science Neuroscience with Basic Medical Sciences, with honors, from University College London.

Family Relationships

There are no family relationships between or among any of AVROBIO's directors or executive officers. The principal occupation and employment during the past five years of each of AVROBIO's directors and executive officers was carried on, in each case except as specifically identified above, with a corporation or organization that is not a parent, subsidiary or other affiliate of AVROBIO. Other than as described in this Annual Report on Form 10-K, there is no arrangement or understanding between any of AVROBIO's directors or executive officers and any other person or persons pursuant to which he or she was or is to be selected as a director or an executive officer, as applicable.

Involvement in Certain Legal Proceedings

There are no material legal proceedings to which any of AVROBIO's executive officers is a party adverse to AVROBIO or AVROBIO's subsidiaries or in which any such person has a material interest adverse to AVROBIO or AVROBIO's subsidiaries.

Code of Business Conduct and Ethics

AVROBIO has adopted a written code of business conduct and ethics that applies to AVROBIO's directors, officers and employees, including AVROBIO's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is posted on the Investors & Media – Corporate Governance section of AVROBIO's website, which is located at www.avrobio.com. If AVROBIO makes any substantive amendments to, or grants any waivers from, the code of business conduct and ethics for any officer or director, AVROBIO will disclose the nature of such amendment or waiver on AVROBIO's website or in a Current Report on Form 8-K.

Corporate Governance

Number and Terms of Officers and Directors

The AVROBIO Board consists of seven members. In accordance with the terms of AVROBIO's charter and bylaws, the AVROBIO Board is divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires. The directors are divided among the three classes as follows:

- the Class I directors are Gail Farfel, Ph.D., Christopher Paige, Ph.D. and Philip Vickers, Ph.D., and their terms will expire at AVROBIO's annual meeting of stockholders to be held in 2025;
- the Class II directors are Ian Clark and Annalisa Jenkins, M.B.B.S., F.R.C.P., and their terms will expire at AVROBIO's annual meeting of stockholders to be held in 2026; and
- the Class III directors are Bruce Booth, D.Phil. and Phillip Donenberg, and their terms will expire at the annual meeting of stockholders to be held in 2024.

AVROBIO expects that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of the AVROBIO Board into three classes with staggered three-year terms may delay or prevent a change of AVROBIO's management or a change in control.

Director Nomination Process

AVROBIO's Nominating and Corporate Governance Committee is responsible for identifying individuals qualified to serve as directors, consistent with criteria approved by the AVROBIO Board, and recommending such persons to be nominated for election as directors, except where AVROBIO is legally required by contract, law or otherwise to provide third parties with the right to nominate.

The process followed by the Nominating and Corporate Governance Committee to identify and evaluate director candidates includes requests to board members and others for recommendations, meetings from time to time to evaluate biographical information and background material relating to potential candidates, and interviews of selected candidates by management, recruiters, members of the committee and the AVROBIO Board. The minimum qualifications, qualities and skills that the Nominating and Corporate Governance Committee believes must be met by a committee-recommended nominee for a position on the AVROBIO Board are as follows:

- The nominee shall have experience at a strategic or policymaking level in a business, government, non-profit or academic organization of high standing.
- The nominee shall be highly accomplished in his or her respective field, with superior credentials and recognition.
- The nominee shall be well regarded in the community and shall have a long-term reputation for the high ethical and moral standards.
- The nominee shall have sufficient time and availability to devote to the affairs of AVROBIO, particularly in light of the number of boards of directors on which such nominee may serve.
- To the extent such nominee serves or has previously served on other boards, the nominee shall have a demonstrated history of actively contributing at board meetings.

In addition to the foregoing, the Nominating and Corporate Governance Committee will consider other facts and circumstances that it deems appropriate or advisable, as outlined in AVROBIO's Corporate Governance Guidelines.

Stockholders may recommend individuals to the Nominating and Corporate Governance Committee for consideration as potential director candidates. Any such proposals should be submitted to AVROBIO's Corporate Secretary at AVROBIO's principal executive offices no later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the one-year anniversary of the date of the preceding year's annual meeting and should include appropriate biographical and background material to allow the Nominating and Corporate Governance Committee to properly evaluate the potential director candidate and the number of shares of AVROBIO common stock beneficially owned by the stockholder proposing the candidate. Stockholder proposals should be addressed to AVROBIO, Inc., 100 Technology Square, 6th Floor, Cambridge, Massachusetts 02139, Attention: Corporate Secretary. AVROBIO encourages any such proposal to also be submitted via email to CorporateSecretary@AVROBIO.com. Assuming that biographical and background material has been provided on a timely basis in accordance with AVROBIO's bylaws, any recommendations received from stockholders will be evaluated in the same manner as potential nominees proposed by the Nominating and Corporate Governance Committee. If the AVROBIO Board determines to nominate a stockholder-recommended candidate and recommends his or her election, then his or her name will be included on AVROBIO's proxy card for the next annual meeting of stockholders.

Committees of the Board of Directors

The AVROBIO Board has established an Audit Committee, a Compensation Committee, a Nominating and Corporate Governance Committee and a Science & Technology Committee. Each of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee operates under a charter that satisfies the applicable standards of the SEC and Nasdaq, and the Science & Technology Committee, while not subject to specific SEC or Nasdaq rules, also operates under a charter. Each such committee reviews its respective charter at least annually. A current copy of the charter for each of the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee, and Science & Technology Committee is posted on the Investors & Media – Corporate Governance section of AVROBIO's website, www.avrobio.com. The AVROBIO Board may from time to time establish other special or standing committees to facilitate the management of AVROBIO or to discharge specific duties delegated by the full AVROBIO Board. Members will serve on these committees until their resignation or until otherwise determined by the AVROBIO Board.

Audit Committee

Phillip Donenberg, Annalisa Jenkins and Christopher Paige serve on the Audit Committee, which is chaired by Mr. Donenberg. The AVROBIO Board has determined that each member of the Audit Committee is "independent" for Audit Committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and each has sufficient knowledge in financial and auditing matters to serve on the Audit Committee. The AVROBIO Board has designated Mr. Donenberg as an "audit committee financial expert," as defined under the applicable rules of the SEC. The Audit Committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of AVROBIO's independent registered public accounting firm;

- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by AVROBIO's independent registered public accounting firm;
- reviewing the overall audit plan with AVROBIO's independent registered public accounting firm and members of management responsible for preparing AVROBIO's financial statements;
- reviewing and discussing with management and AVROBIO's independent registered public accounting firm AVROBIO's annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by AVROBIO;
- coordinating the oversight and reviewing the adequacy of AVROBIO's internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the Audit Committee's review and discussions with management and AVROBIO's independent registered public accounting firm whether AVROBIO's audited financial statements shall be included in this Annual Report on Form 10-K;
- monitoring the integrity of AVROBIO's financial statements and AVROBIO's compliance with legal and regulatory requirements as they relate to AVROBIO's financial statements and accounting matters;
- preparing the Audit Committee report required by SEC rules to be included in AVROBIO's annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing and discussing quarterly earnings releases.

Compensation Committee

Ian Clark, Bruce Booth and Philip Vickers serve on the Compensation Committee, which is chaired by Mr. Clark. The AVROBIO Board has determined that each member of the Compensation Committee is "independent" as defined in the applicable Nasdaq rules. The Compensation Committee's responsibilities include:

- annually reviewing and approving corporate goals and objectives relevant to the compensation of AVROBIO's Chief Executive Officer;
- evaluating the performance of AVROBIO's Chief Executive Officer in light of such corporate goals and objectives, and based on such evaluation, reviewing and approving the proposed compensation for AVROBIO's Chief Executive Officer, including (i) the cash compensation of AVROBIO's Chief Executive Officer, (ii) grants and awards to AVROBIO's Chief Executive Officer under equity-based plans, (iii) amendments to or extensions of AVROBIO's Chief Executive Officer's employment agreement or other similar arrangements, (iv) any severance or change in control arrangement, (v) any supplemental or retirement benefits, and (vi) any other compensation matters as may be directed by the Compensation Committee or the AVROBIO Board;
- annually evaluating the performance of, or reviewing AVROBIO's Chief Executive Officer's assessment of, AVROBIO's other executive officers in light of the corporate goals and objectives relevant to their compensation;
- reviewing and approving the cash compensation of AVROBIO's other executive officers;
- establishing and periodically reviewing any policies and programs concerning perquisite benefits and non-cash or other benefits for AVROBIO's executive officers;
- reviewing and establishing AVROBIO's overall management compensation, philosophy, and policy;
- reviewing AVROBIO's overall compensation policies and practices, and assessing whether any risks arising from such policies and practices are reasonably likely to have a material adverse effect on AVROBIO;
- overseeing and administering AVROBIO's compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- reviewing and approving AVROBIO's policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the AVROBIO Board the compensation of AVROBIO's directors;

- preparing the Compensation Committee report if and when required by SEC rules;
- reviewing and discussing with the AVROBIO Board corporate succession plans for AVROBIO's Chief Executive Officer and AVROBIO's other key officers;
- reviewing and discussing annually with management AVROBIO's "Compensation Discussion and Analysis," if and when required, to be included in AVROBIO's annual proxy statement;
- reviewing and discussing with the AVROBIO Board management proposals to AVROBIO stockholders as well as proposals received from AVROBIO stockholders that relate to executive compensation matters;
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters; and
- retaining and approving the compensation of any compensation advisors.

Nominating and Corporate Governance Committee

Annalisa Jenkins, Phillip Donenberg and Christopher Paige serve on the Nominating and Corporate Governance Committee, which is chaired by Dr. Jenkins. The AVROBIO Board has determined that each member of the Nominating and Corporate Governance Committee is "independent" as defined in the applicable Nasdaq rules. The Nominating and Corporate Governance Committee's responsibilities include:

- developing and recommending to the AVROBIO Board criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the size and composition of the AVROBIO Board to ensure that it is composed of members containing the appropriate skills and expertise to advise AVROBIO;
- identifying individuals qualified to become members of the AVROBIO Board;
- recommending to the AVROBIO Board the persons to be nominated for election as directors and to each of the AVROBIO Board's committees;
- developing and recommending to the AVROBIO Board a set of corporate governance guidelines; and
- overseeing the evaluation of the AVROBIO Board.

The Nominating and Corporate Governance Committee considers candidates for board of director membership suggested by its members and AVROBIO's Chief Executive Officer. Additionally, in selecting nominees for directors, the Nominating and Corporate Governance Committee will review candidates recommended by stockholders in the same manner and using the same general criteria as candidates recruited by the committee and/or recommended by the AVROBIO Board.

Identifying and Evaluating Director Nominees. The AVROBIO Board is responsible for filling vacancies on the AVROBIO Board and for nominating candidates for election by AVROBIO's stockholders each year in the class of directors whose term expires at the relevant annual meeting. The AVROBIO Board delegates the selection and nomination process to the Nominating and Corporate Governance Committee, with the expectation that other members of the AVROBIO Board, and of management, will be requested to take part in the process as appropriate.

Generally, the Nominating and Corporate Governance Committee identifies candidates for director nominees in consultation with management, through the use of search firms or other advisors, through the recommendations submitted by stockholders or through such other methods as the Nominating and Corporate Governance Committee deems to be helpful to identify candidates. Once candidates have been identified, the Nominating and Corporate Governance Committee confirms that the candidates meet all of the minimum qualifications for director nominees established by the Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee may gather information about the candidates through interviews, detailed questionnaires, comprehensive background checks or any other means that the Nominating and Corporate Governance Committee deems to be appropriate in the evaluation process. The Nominating and Corporate Governance Committee then meets as a group to discuss and evaluate the qualities and skills of each candidate, both on an individual basis and taking into account the overall composition and needs of the AVROBIO Board. Based on the results of the evaluation process, the Nominating and Corporate Governance Committee recommends candidates for the AVROBIO Board's approval to fill a vacancy or as director nominees for election to the AVROBIO Board by AVROBIO's stockholders each year in the class of directors whose term expires at the relevant annual meeting.

Science & Technology Committee

Philip Vickers, Bruce Booth, Gail Farfel, Annalisa Jenkins and Christopher Paige serve on the Science & Technology Committee, which is chaired by Dr. Vickers. The Science & Technology Committee's responsibilities include:

- reviewing and advising the AVROBIO Board on AVROBIO's research and development programs and progress in achieving research and development goals and objectives;
- advising the AVROBIO Board on the scientific and research and development aspects of licensing, collaboration and acquisition transactions that require approval by the AVROBIO Board;
- overseeing management's exercise of its responsibility to assess and manage risks associated with AVROBIO's research and development activities, clinical development and intellectual property; and
- making any recommendations to the AVROBIO Board that the Science & Technology Committee deems appropriate on any areas within its responsibility, including where action or improvement is needed.

Board and Committee Evaluations

The Nominating and Corporate Governance Committee oversees and establishes a periodic board and committee evaluation process. Generally, the AVROBIO Board and each committee conduct self-evaluations by means of written questionnaires completed by each director and committee member. The anonymous responses are summarized and provided to the AVROBIO Board and each committee at their next meetings in order to facilitate an examination and discussion by the AVROBIO Board and each committee of the effectiveness of the AVROBIO Board and committees, AVROBIO Board and committee structure and dynamics, and areas for possible improvement. The Nominating and Corporate Governance Committee establishes the board and committee evaluation process, typically on an annual basis, and may determine to use an independent third party evaluation process from time to time in the future. For example, in 2020 AVROBIO engaged an independent third-party consultant to interview AVROBIO Board members on board performance and then provided feedback to the Nominating and Corporate Governance Committee for review and consideration.

Board and Committee Meetings Attendance

The full AVROBIO Board met ten (10) times during 2023. During 2023, each member of the AVROBIO Board, with the exception of Ian Clark, attended in person or participated in 75% or more of the aggregate of (i) the total number of meetings of the AVROBIO Board` (held during the period for which such person has been a director) and (ii) the total number of meetings held by all committees of the AVROBIO Board on which such person served (during the periods that such person served).

Director Attendance at Annual Meeting of Stockholders

AVROBIO does not have a policy with regard to the AVROBIO Board members' attendance at AVROBIO's annual meetings of stockholders, but all of AVROBIO's directors attended the 2023 annual meeting of stockholders which was held on June 6, 2023.

Board Leadership Structure and Board's Role in Risk Oversight

Currently, the role of Chairperson of the AVROBIO Board is separated from the role of Chief Executive Officer. AVROBIO believes that separating these positions allows AVROBIO's Chief Executive Officer to focus on the day-to-day business, while allowing the Chairperson of the AVROBIO Board to lead the AVROBIO Board in its fundamental role of providing advice to, and independent oversight, of management. The AVROBIO Board recognizes the time, effort, and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required by as AVROBIO's Chairperson, particularly as the AVROBIO Board's oversight responsibilities continue to grow. While AVROBIO's bylaws and corporate governance guidelines do not require that AVROBIO's Chairperson and Chief Executive Officer positions be separate, the AVROBIO Board believes that having separate positions is the appropriate leadership structure for AVROBIO at this time and demonstrates commitment to good corporate governance.

Risk is inherent to every business, and how well a business manages risk can ultimately determine its success. AVROBIO faces a number of risks, including risks relating to AVROBIO's financial condition, operations, strategic direction, and intellectual property. Management is responsible for the day-to-day management of risks AVROBIO faces, while the AVROBIO Board, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, the AVROBIO Board has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

Generally, the role of the AVROBIO Board in overseeing the management of AVROBIO's risks is conducted primarily through committees of the AVROBIO Board, as disclosed in the descriptions of each of the committees above and in the charters of each of the committees. However, at least annually management provides to the full AVROBIO Board an overview of potential risks to AVROBIO, which is then updated and presented to the Audit Committee on a periodic (currently quarterly) basis. The full AVROBIO Board (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management AVROBIO's major risk exposures, their potential impact on AVROBIO, and the steps AVROBIO takes to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full AVROBIO Board during the committee reports portion of the next board meeting. This enables the AVROBIO Board and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Policy on Trading, Pledging and Hedging of Company Stock

Certain transactions in AVROBIO's securities (such as purchases and sales of publicly traded put and call options, and short sales) create a heightened compliance risk or could create the appearance of misalignment between management and stockholders. In addition, securities held in a margin account or pledged as collateral may be sold without consent if the owner fails to meet a margin call or defaults on the loan, thus creating the risk that a sale may occur at a time when an officer or director is aware of material, non-public information or otherwise is not permitted to trade in Company securities. AVROBIO's insider trading policy expressly prohibits AVROBIO's executive officers, directors and designated employees and consultants from engaging in certain prohibited transactions, including short sales, purchases or sales of derivative securities or hedging transactions, the use of AVROBIO's securities as collateral in a margin account, and pledging of AVROBIO's securities.

Item 11. Executive Compensation.

AVROBIO has opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies," as such term is defined in the rules promulgated under the Securities Act. This section provides an overview of the compensation awarded to, earned by, or paid to AVROBIO's principal executive officer and AVROBIO's next two most highly compensated executive officers in respect of their service to AVROBIO for the fiscal year ended December 31, 2023 and up to two additional individuals for whom disclosure would have been provided but for the fact that the individual was not serving as an executive officer as of December 31, 2023, or the 2023 named executive officers. The 2023 named executive officers are:

- Erik Ostrowski, President, Interim Chief Executive Officer, Chief Financial Officer and Treasurer;
- Geoff MacKay, former Chief Executive Officer and President;
- Azadeh Golipour, Chief Technology Officer; and
- Essra Ridha, Chief Medical Officer.

AVROBIO's executive compensation program is based on a pay for performance philosophy. Compensation for AVROBIO's executive officers is composed primarily of the following main components: base salary; bonus; and equity incentives in the form of options. AVROBIO's executive officers, like all full-time employees, are eligible to participate in AVROBIO's health and welfare benefit plans.

2023 Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by, or paid to each of the 2023 named executive officers for services rendered to AVROBIO in all capacities during the fiscal year ended December 31, 2023. The following table also presents information regarding the compensation awarded to, and earned by, and paid to each such individual during the fiscal year ended December 31, 2022, to the extent such individual was a named executive officer for such year.

Name	Year	Salary ($)	Bonus ($)[1]	Stock awards ($)[2]	Option awards ($)[3]	Non-Equity Incentive Plan Compensation ($)[4]	All other compensation ($)		Total ($)
Erik Ostrowski									
	2023	504,400	732,179	339,878	—	—	14,435	(5)	1,590,892
President, Interim Chief Executive Officer, Chief Financial Officer and Treasurer	2022	460,000	299,000	—	404,806	174,800	13,487	(5)	1,352,093
Geoff MacKay									
	2023	203,284	—	508,127	5,720	—	9,636	(6)	726,767
Former President and Chief Executive Officer	2022	580,000	431,000	—	710,700	303,050	12,542	(6)	2,037,292
Azadeh Golipour									
	2023	450,000	526,498	252,373	—	—	37,302	(7)	1,266,173
Chief Technology Officer									
	2022	353,000	141,000 (8)	—	302,231	124,688	109,519	(9)	1,030,438
Essra Ridha[10]									
	2023	498,020	589,493	221,953	—	—	33,448	(11)	1,342,914
Chief Medical Officer									

(1) Except as otherwise provided, the 2022 amounts reflect discretionary retention bonuses granted in January 2022 and paid in two equal installments in June 2022 and December 2022. In addition, the 2023 amounts reflect a discretionary retention bonus granted to Mr. Ostrowski, Dr. Golipour and Dr. Ridha in June 2023 in the amount of $582,179, $426,498, and $489,493, respectively, and paid in January 2024. Further, for Mr. Ostrowski, Dr. Golipour and Dr. Ridha, the 2023 amounts reflect a transaction bonus granted to Mr. Ostrowski, Dr. Golipour and Dr. Ridha in the amount of $150,000, $100,000, and $100,000, respectively.

(2) Amounts reflect the grant date fair value of the RSUs granted in 2023 in accordance with Financial Accounting Standards Board's Accounting Standards Codification Topic 718, or ASC 718. Such grant date fair value does not take into account any estimated forfeitures. See Note 9 of *"Notes to Consolidated Financial Statements"* included elsewhere in this Annual Report on Form 10-K for a discussion of assumptions made by AVROBIO in determining the aggregate grant date fair value of such RSUs. These amounts do not correspond to the actual value that may be received by the 2023 named executive officers upon vesting and settlement of the shares of RSUs or any sale of the shares.

(3) Amounts reflect the grant date fair value of stock options granted in 2023 and 2022 in accordance with ASC 718. Such grant date fair value does not take into account any estimated forfeitures related to service-vesting conditions. See Note 9 of *"Notes to Consolidated Financial Statements"* included elsewhere in this Annual Report on Form 10-K for a discussion of assumptions made by AVROBIO in determining the aggregate grant date fair value of such stock options. These amounts do not correspond to the actual value that may be recognized by the 2023 named executive officers upon vesting of applicable awards. Additionally, the 2023 amount for Mr. MacKay includes the incremental fair value related to the extension of the post-termination exercise period of certain stock options (determined as of such extension date in accordance with ASC 718).

(4) Amounts reflect bonuses paid with respect to performance during the 2023 fiscal year pursuant to the Senior Executive Cash Incentive Bonus Plan. Such annual bonuses were based on achievement of AVROBIO's goals related to achievement of clinical program objectives and milestones, regulatory objectives, and manufacturing development objectives.

(5) Amount reflects the dollar value of 401(k) contributions and life insurance premiums paid by AVROBIO on behalf of Mr. Ostrowski.

(6) Amount reflects the dollar value of 401(k) contributions and life insurance premiums paid by AVROBIO on behalf of Mr. MacKay.

(7) Amount reflects the dollar value of life insurance premiums and relocation benefits paid by AVROBIO on behalf of Dr. Golipour.

(8) Amount includes a $10,000 lump sum payment, paid in accordance with Dr. Golipour's employment agreement.

(9) Amount reflects the dollar value of life insurance premiums, $90,571 in relocation benefits paid by AVROBIO on behalf of Dr. Golipour pursuant to her employment agreement, and a tax gross-up on such relocation benefits.

(10) Amounts in the Salary, Bonus, and All Other Compensation columns were originally denominated in GBP when paid to Dr. Ridha and have been converted to USD using the average exchange rate for 2023 (1 GBP = 1.2439 USD).

(11) Amount reflects the dollar value of benefits allowance and pension contributions paid by AVROBIO on behalf of Dr. Ridha.

Narrative to Summary Compensation Table

The AVROBIO Board and Compensation Committee review compensation annually for all employees, including AVROBIO's executives. In setting executive base salaries and bonuses and granting equity incentive awards, AVROBIO considers compensation for comparable positions in the market, the historical compensation levels of AVROBIO's executives, individual performance as compared to AVROBIO's expectations and objectives, AVROBIO's desire to motivate AVROBIO's employees to achieve short- and long-term results that are in the best interests of AVROBIO stockholders, and a long-term commitment to AVROBIO. AVROBIO targets a generally competitive position, based on independent third-party benchmark analytics to inform the mix of compensation of base salary, bonus or long-term incentives.

The Compensation Committee reviews and approves the compensation to be paid to AVROBIO's Chief Executive Officer and AVROBIO's other executive officers. The Compensation Committee typically reviews and discusses management's proposed compensation with the Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, taking into account the factors noted above, the Compensation Committee then approves the compensation of AVROBIO's Chief Executive Officer and other executive officers without the Chief Executive Officer or other members of management present. Frederic W. Cook & Co., Inc., or FW Cook, advised the AVROBIO Board and the Compensation Committee on certain compensation matters and decisions during fiscal year 2023. FW Cook served at the discretion of the Compensation Committee and did not provide any other services to AVROBIO during fiscal year 2023 other than those for which they were engaged by the Compensation Committee. The Compensation Committee requires that its compensation consultants be independent of AVROBIO management and performs an annual assessment of the compensation consultants' independence to determine whether the consultants are independent. The Compensation Committee has determined that FW Cook is independent and that its respective work has not raised any conflicts of interest.

Annual Base Salary

AVROBIO uses base salaries to recognize the experience, skills, knowledge and responsibilities required of all AVROBIO's employees, including the 2023 named executive officers. Base salaries for AVROBIO's named executive officers are reviewed annually by the Compensation Committee, typically in connection with AVROBIO's annual performance review process, and adjusted from time to time, based on the recommendation of the Compensation Committee, to realign salaries with market levels after taking into account individual responsibilities, performance and experience. AVROBIO increased Mr. Ostrowski's base salary to $535,000 from $473,800, effective July 1, 2023. None of the 2023 named executive officers are currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary. During 2023 the annual base salaries for each of Mr. Ostrowski, Mr. MacKay, Dr. Golipour, and Dr. Ridha were $535,000, $603,000, $450,000, and $498,020, respectively.

Annual Bonus

AVROBIO currently has a Senior Executive Cash Incentive Bonus Plan, which is intended to reward AVROBIO's executive officers, including the 2023 named executive officers, for meeting objective and/or subjective performance goals for a fiscal year. From time to time, the AVROBIO Board or Compensation Committee may approve annual bonuses for AVROBIO's executive officers, including the 2023 named executive officers, based on individual performance, company performance or as otherwise determined appropriate.

Performance goals for each new fiscal year are reviewed by the Compensation Committee and then reviewed and approved by the AVROBIO Board. The Compensation Committee thereafter reviews and determines AVROBIO's performance and level of attainment of such goals following the completion of the applicable fiscal year. For 2023, the Compensation Committee reviewed and drafted 2023 goals based on achievement of clinical program objectives and milestones, regulatory objectives, manufacturing development objectives and business development and financing objectives. Following the Board's decision in July 2023 to halt development of AVROBIO's clinical programs and pursue potential strategic alternatives, the Board opted to forgo annual bonuses based on earlier corporate objectives with respect to fiscal 2023, taking into account previously awarded retention and transaction bonuses for each of the remaining 2023 named executive officers with respect to such year. Accordingly, no annual bonus was paid to the 2023 named executive officers based on performance objectives in 2023.

Retention Bonuses

On January 4, 2022, the Compensation Committee approved one-time cash retention payments to all employees remaining with AVROBIO following AVROBIO's workforce reduction, including AVROBIO's executive officers. Each retention bonus was payable in two equal installments in June 2022 and December 2022, provided that the employee had not resigned or provided notice of intention to resign and AVROBIO had not terminated such employee's employment for cause or provided notice of intent to terminate such employee's employment for cause. The aggregate retention bonuses granted to each of Mr. Ostrowski, Mr. MacKay and Dr. Golipour were $299,000, $431,000 and $131,000, respectively.

On June 9, 2023, the Compensation Committee approved cash retention bonuses for each of Mr. Ostrowski, Dr. Golipour and Dr. Ridha. The retention bonuses were payable to each of Mr. Ostrowski, Dr. Golipour and Dr. Ridha, subject to each executive continuing to be employed by AVROBIO as of December 31, 2023. The amount of the retention bonuses payable to each of Mr. Ostrowski, Dr. Golipour and Dr. Ridha equaled (i) 125% of each executive's base salary for calendar year 2023 as in effect on June 9, 2023 (except that, in the case of Mr. Ostrowski, such calculation was based on his base salary in effect as of July 1, 2023), plus (ii) 125% of each executive's target 2023 annual bonus as in effect on June 9, 2023 (except that, in the case of Mr. Ostrowski, such calculation was based on his target 2023 annual bonus in effect for the six month period commencing July 1, 2023), in each case pro-rated for the period of time from June 9, 2023 to December 31, 2023. The retention bonus for each of Mr. Ostrowski, Dr. Golipour and Dr. Ridha is reported in the Bonus column in the 2023 Summary Compensation Table, above.

Transaction Bonuses

In connection with the closing of the sale of AVROBIO's cystinosis program, each of Mr. Ostrowski, Dr. Golipour and Dr. Ridha received a transaction bonus in the amount of $150,000, $100,000, and $100,000, respectively, which was payable in three installments in July, August, and September 2023, subject to the executive's continued employment on the date of each payment.

Equity Compensation

Although AVROBIO does not have a formal policy with respect to the grant of equity incentive awards to AVROBIO's executive officers, or any formal equity ownership guidelines applicable to them, AVROBIO believes that equity grants provide AVROBIO's executives with a strong link to AVROBIO's long-term performance, create an ownership culture and help to align the interests of AVROBIO's executives and AVROBIO stockholders. In addition, AVROBIO believes that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes AVROBIO's executive officers to remain in AVROBIO's employment during the vesting period. Accordingly, the AVROBIO Board periodically reviews the equity incentive compensation of the 2023 named executive officers and from time to time may grant equity incentive awards to them in the form of stock options or RSUs.

AVROBIO typically grants stock option awards to each of AVROBIO's executives in connection with their start of employment. Such stock option awards are typically granted on the first trading day of the month after the employees' start date. AVROBIO sets the option exercise price and grant date fair value based on the value of AVROBIO common stock on the date of grant. For grants in connection with initial employment, vesting begins on the initial date of employment.

401(k) Plan

AVROBIO maintains a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax-advantaged basis. All participants' interests in their contributions are 100% vested when contributed. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The retirement plan is intended to qualify under Section 401(a) of the Code. Matching contributions to the plan are made at the discretion of the AVROBIO Board.

Outstanding Equity Awards at 2023 Fiscal Year End

The following table sets forth information concerning outstanding equity awards held by the 2023 named executive officers as of December 31, 2023. All equity awards set forth in the table below were granted under either AVROBIO's

Amended and Restated 2015 Stock Option and Grant Plan, or the 2015 Plan, or AVROBIO's 2018 Stock Option and Incentive Plan, as amended, or the 2018 Plan.

	Option Awards				Stock Awards		
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested (#)		Market Value of Shares or Units that Have Not Vested ($)[1]
Erik Ostrowski	186,000	—	15.65	1/1/2029	—		—
	94,594	6,306 (2)	21.44	3/3/2030	—		—
	84,363	34,737 (3)	16.02	2/3/2031	—		—
	62,500	62,500 (4)	9.63	6/9/2031	—		—
	144,375	170,625 (5)	1.84	2/1/2032	—		—
	110,500	110,500 (6)	0.79	12/7/2032	—		—
	—	—	—	—	160,333	(7)	218,053
	—	—	—	—	70,000	(8)	95,200
Geoff MacKay	213,938	— (5)	1.84	4/30/2024	—		—
Azadeh Golipour	353	—	1.20	10/24/2026	—		—
	736	—	0.91	6/12/2027	—		—
	5,908	—	5.00	3/15/2028	—		—
	20,000	—	16.98	2/24/2029	—		—
	29,531	1,969 (9)	20.98	3/1/2030	—		—
	18,229	6,771 (10)	14.57	1/3/2031	—		—
	32,583	13,417 (3)	16.02	2/3/2031	—		—
	105,416	124,584 (5)	1.84	2/1/2032	—		—
	82,500	82,500 (6)	0.79	12/7/3032	—		—
	—	—	—	—	18,172	(11)	24,714
	—	—	—	—	149,333	(12)	203,093
Essra Ridha	65,000	55,000 (13)	5.67	10/31/2023	—		—
	71,042	83,958 (14)	1.84	2/1/2032	—		—
	91,500	91,500 (15)	0.79	12/7/2032	—		—
	—	—	—	—	131,333	(16)	178,613

(1) This column is based on the fair market value of AVROBIO common stock as of December 29, 2023, the last trading day of 2023, which was $1.36 per share.

(2) The shares underlying this stock option were scheduled to vest as follows: 25% of the shares vested on March 4, 2021 and the remainder vest in equal monthly installments until the option is fully vested on March 4, 2024, subject to the continued employment of the executive officer through each such vesting date.

(3) The shares underlying this stock option were scheduled to vest as follows: 25% of the shares vested on February 4, 2022 and the remainder vest in equal monthly installments until the option is fully vested on February 4, 2025, subject to the continued employment of the executive officer through each such vesting date.

(4) The shares underlying this stock option were scheduled to vest as follows: 50% of the shares vested on June 10, 2023 and the remainder will vest on June 10, 2024, subject to the continued employment of the executive officer through each such vesting date.

(5) The shares underlying this stock option were scheduled to vest as follows: 25% of the shares vested on February 2, 2023 and the remainder vest in equal monthly installments until the option is fully vested on February 2, 2026, subject to the continued employment of the executive officer through each such vesting date.

(6) The shares underlying this stock option were scheduled to vest as follows: 50% of the shares vested on December 8, 2023 and the remainder vest in equal monthly installments until the option is fully vested on December 8, 2024, subject to the continued employment of the executive officer through each such vesting date.

(7) Represents an RSU award for 160,333 shares, which vests in four equal annual installments commencing on the first anniversary of February 1, 2023, subject to the continued employment of the executive officer through each such vesting date.

(8) Represents an RSU award for 70,000 shares, which vests in four equal annual installments commencing on the first anniversary of July 1, 2023, subject to the continued employment of the executive officer through each such vesting date.

(9) The shares underlying this stock option vest as follows: 25% of the shares vested on March 2, 2021 and the remainder vest in equal monthly installments until the option is fully vested on March 2, 2024, subject to the continued employment of the executive officer through each such vesting date.
(10) The shares underlying this stock option vest as follows: 25% of the shares vested on January 4, 2022 and the remainder vest in equal monthly installments until the option is fully vested on January 4, 2025, subject to the continued employment of the executive officer through each such vesting date.
(11) Represents an RSU award for 36,344 shares, which vests as follows: 50% of the shares vested on June 10, 2023 and the remaining 50% vest on June 10, 2024, subject to the continued employment of the executive officer through each such vesting date.
(12) Represents an RSU award for 149,333 shares, which vests in four equal annual installments commencing on the first anniversary of February 1, 2023, subject to the continued employment of the executive officer through each such vesting date.
(13) The shares underlying this stock option vest as follows: 25% of the shares vested on October 19, 2023 and the remainder vest in equal monthly installments until the option is fully vested on October 19, 2026, subject to the continued employment of the executive officer through each such vesting date.
(14) The shares underlying this stock option vest as follows: 25% of the shares vested on February 2, 2024 and the remainder vest in equal monthly installments until the option is fully vested on February 2, 2027, subject to the continued employment of the executive officer through each such vesting date.
(15) The shares underlying this stock option vest as follows: 50% of the shares will vest on December 8, 2024 and the remainder will vest in 12 equal monthly installments until the option is fully vested on December 8, 2025, subject to the continued employment of the executive officer through each such vesting date.
(16) Represents an RSU award for 131,333 shares, which vests in four equal annual installments commencing on the first anniversary of February 1, 2023, subject to the continued employment of the executive officer through each such vesting date.

Employment Arrangements with AVROBIO's Named Executive Officers

AVROBIO entered into employment agreements with each of Erik Ostrowski, Geoff MacKay, Azadeh Golipour and Essra Ridha which set forth the initial terms and conditions of each executive's employment with AVROBIO, including base salary, target annual bonus opportunity and standard employee benefit plan participation. These employment agreements provide for "at will" employment. The material terms of the employment agreements with the 2023 named executive officers are described below. The terms "change of control," "cause" and "good reason" referred to below are defined in the applicable agreement.

Employment Agreement with Erik Ostrowski

On December 17, 2018, AVROBIO entered into an employment agreement with Erik Ostrowski for the position of chief financial officer. Under the terms of the employment agreement, Mr. Ostrowski is entitled to receive an annual base salary of $412,000, subject to annual review by the AVROBIO Board or Compensation Committee. In addition, Mr. Ostrowski is eligible to receive cash incentive compensation as determined by the AVROBIO Board or Compensation Committee from time to time, with an initial target annual bonus of 40% of his annual base salary. Mr. Ostrowski also received a signing bonus in the form of (i) a one-time cash bonus of $170,000 and (ii) an RSU for 2,300 shares of AVROBIO common stock, or the Signing Bonus Award. In addition, pursuant to the terms of the employment agreement, Mr. Ostrowski was granted an option to purchase 186,000 shares of AVROBIO common stock, or the New Hire Award. Each of the Signing Bonus Award and the New Hire Award will vest over four years, with 25% of the shares vesting on the one-year anniversary of Mr. Ostrowski's start date and the remaining shares vesting in thirty-six equal monthly installments thereafter, subject to Mr. Ostrowski's continued service to AVROBIO through the applicable vesting date. Mr. Ostrowski also entered into an Employee Confidentiality, Assignment and Noncompetition Agreement with AVROBIO, the terms of which are incorporated into his employment agreement.

Mr. Ostrowski's employment agreement provides that, in the event that his employment is terminated by AVROBIO without "cause" or by Mr. Ostrowski with "good reason" (as each term is defined in his employment agreement), subject to the execution and effectiveness of a separation agreement and release, he will be entitled to receive (i) an amount equal to 75% of his base salary less any amount paid to Mr. Ostrowski in the same calendar year under the Employee Confidentiality, Assignment and Noncompetition Agreement, provided that Mr. Ostrowski has not breached any of the confidentiality, noncompetition or cooperation provisions set forth in, or incorporated into, the employment agreement, payable in equal installments over nine months in accordance with AVROBIO's normal payroll cycle, (ii) if Mr. Ostrowski was participating in AVROBIO's group health plan and elects COBRA health continuation, a monthly cash payment equal to the monthly employer contribution that AVROBIO would have made to provide health insurance to Mr. Ostrowski had he remained employed with AVROBIO for up to nine months, and (iii) acceleration of vesting of all stock options and other stock based

awards held by Mr. Ostrowski that would have vested if he had remained employed by AVROBIO for an additional nine months following the date of termination.

Under the employment agreement, in the event of a "change in control" (as defined in his employment agreement) all time-based stock options and other stock-based awards granted to Mr. Ostrowski at least 12 months prior to the effective date of the employment agreement shall accelerate and become fully exercisable or non-forfeitable immediately prior to the change in control. In addition, in the event that Mr. Ostrowski's employment is terminated by AVROBIO without "cause" or by Mr. Ostrowski for "good reason," in each case, within three months prior to or 18 months after a "change in control," subject to the execution and effectiveness of a separation agreement and release, he will be entitled to receive (i) a lump sum amount equal to 100% of the sum of his current base salary (or his base salary in effect immediately prior to the change in control if higher) plus his target bonus for that year, less any amount paid to Mr. Ostrowski in the same calendar year under the Employee Confidentiality, Assignment and Noncompetition Agreement, (ii) if Mr. Ostrowski was participating in AVROBIO's group health plan and elects COBRA health continuation, a monthly cash payment equal to the monthly employer contribution that AVROBIO would have made to provide health insurance to Mr. Ostrowski had he remained employed with AVROBIO for up to 12 months, and (iii) full acceleration of vesting of all time-based stock options and other time-based stock-based awards held by Mr. Ostrowski.

Employment Agreement with Geoff MacKay

Prior to his resignation effective on May 1, 2023, Geoff MacKay, AVROBIO's former President and Chief Executive Officer, was party to an employment agreement with AVROBIO. Effective upon the closing of AVROBIO's IPO in June 2018, AVROBIO entered into an amended employment agreement with Mr. MacKay. Under the terms of the employment agreement, Mr. MacKay was entitled to receive an annual base salary of $500,000, subject to annual review by the Board or Compensation Committee. In addition, Mr. MacKay was eligible to receive cash incentive compensation as determined by the AVROBIO Board or Compensation Committee from time to time, with an initial target annual bonus of 50% of his annual base salary. Mr. MacKay also previously entered into a Confidentiality and IP Assignment Agreement with AVROBIO, the terms of which were incorporated into his employment agreement.

Mr. MacKay's employment agreement provided that, in the event that his employment is terminated by AVROBIO without "cause" or by Mr. MacKay with "good reason" (as each term is defined in his employment agreement), subject to the execution and effectiveness of a separation agreement and release, he would have been entitled to receive (i) an amount equal to 100% of his base salary, provided that Mr. MacKay hadn't breached any of the confidentiality, noncompetition or cooperation provisions set forth in, or incorporated into, the new employment agreement, payable in equal installments over 12 months in accordance with AVROBIO's normal payroll cycle, and (ii) if Mr. MacKay was participating in AVROBIO's group health plan and elects COBRA health continuation, a monthly cash payment equal to the monthly employer contribution that AVROBIO would have made to provide health insurance to Mr. MacKay had he remained employed with AVROBIO for up to 12 months, and (iii) acceleration of vesting of all stock options and other stock based awards held by Mr. MacKay that would have vested if he had remained employed by AVROBIO for an additional 12 months following the date of termination.

Under the employment agreement, in the event of a "change in control" (as defined in his employment agreement) all time-based stock options and other stock-based awards granted to Mr. MacKay at least 12 months prior to the effective date of the employment agreement would have accelerated and become fully exercisable or non-forfeitable immediately prior to the change in control. In addition, in the event that Mr. MacKay's employment was terminated by AVROBIO without "cause" or by Mr. MacKay for "good reason," in each case, within three months prior to or 18 months after a "change in control," subject to the execution and effectiveness of a separation agreement and release, he would have been entitled to receive (i) a lump sum amount equal to 150% of the sum of his current base salary (or his base salary in effect immediately prior to the change in control if higher) plus his target bonus for that year, (ii) if Mr. MacKay was participating in AVROBIO's group health plan and elects COBRA health continuation, a monthly cash payment equal to the monthly employer contribution that AVROBIO would have made to provide health insurance to Mr. MacKay had he remained employed with AVROBIO for up to 18 months, and (iii) full acceleration of vesting of all time-based stock options and other time-based stock-based awards held by Mr. MacKay.

Employment Agreement with Azadeh Golipour

Azadeh Golipour was previously employed by AVROBIO pursuant to an offer letter dated December 22, 2021. On January 26, 2022, AVROBIO entered into an employment agreement with Dr. Golipour which sets forth the terms of her employment as AVROBIO's Chief Technology Officer and supersedes her previous offer letter in the entirety. Under the terms of the employment agreement, Dr. Golipour is entitled to receive an annual base salary of $342,000, subject to annual review by the AVROBIO Board or Compensation Committee. In addition, Dr. Golipour is eligible to receive cash incentive compensation as determined by the AVROBIO Board or Compensation Committee from time to time, with an initial target annual bonus of 35% of her annual base salary. In addition, Dr. Golipour is eligible to receive a reimbursement of relocation

costs associated with relocating from Toronto, Ontario to Cambridge, Massachusetts (and tax gross-up on such reimbursements) and additional $10,000 lump sum payment. Until Dr. Golipour is no longer treated as a Canadian tax resident, Dr. Golipour is also eligible to receive a $25,000 annual travel allowance, a $5,000 per month housing allowance for 2022, up to $2,500 per year for tax advice and preparation, and tax gross-up on such payments and benefits. Dr. Golipour also entered into an Employee Confidentiality, Assignment and Noncompetition Agreement with AVROBIO, dated January 24, 2022.

Dr. Golipour's employment agreement provides that, in the event that her employment is terminated by AVROBIO without "cause" or by Dr. Golipour with "good reason" (as each term is defined in her employment agreement), subject to the execution and effectiveness of a separation agreement and release, she will be entitled to receive (i) an amount equal to 75% of her base salary less any garden leave pay paid to Dr. Golipour in the same calendar year under the Employee Confidentiality, Assignment and Noncompetition Agreement, provided that Dr. Golipour has not breached any of the confidentiality, noncompetition or cooperation provisions set forth in, or incorporated into, the employment agreement, payable in equal installments over nine months in accordance with AVROBIO's normal payroll cycle, (ii) if Dr. Golipour was participating in AVROBIO's group health plan and elects COBRA health continuation, a monthly cash payment equal to the monthly employer contribution that AVROBIO would have made to provide health insurance to Dr. Golipour had she remained employed with AVROBIO for up to nine months, and (iii) acceleration of vesting of all stock options and other stock based awards held by Dr. Golipour that would have vested if she had remained employed by AVROBIO for an additional nine months following the date of termination.

In addition, in the event that Dr. Golipour's employment is terminated by AVROBIO without "cause" or by Dr. Golipour for "good reason," in each case, within three months prior to or 18 months after a "change in control" (as defined in her employment agreement), subject to the execution and effectiveness of a separation agreement and release, she will be entitled to receive (i) a lump sum amount equal to 100% of the sum of her current base salary (or her base salary in effect immediately prior to the change in control if higher) plus her target bonus for that year, less any amount paid to Dr. Golipour in the same calendar year under the Employee Confidentiality, Assignment and Noncompetition Agreement, (ii) if Dr. Golipour was participating in AVROBIO's group health plan and elects COBRA health continuation, a monthly cash payment equal to the monthly employer contribution that AVROBIO would have made to provide health insurance to Dr. Golipour had she remained employed with AVROBIO for up to 12 months, and (iii) full acceleration of vesting of all time-based stock options and other time-based stock-based awards held by Dr. Golipour.

Employment Agreement with Essra Ridha

In October 2021, AVROBIO entered into an employment agreement with Essra Ridha for the position of Chief Medical Officer. Under the terms of the employment agreement, Dr. Ridha is entitled to receive an annual base salary of £310,000. In addition, Dr. Ridha is eligible to receive cash incentive compensation as determined by the AVROBIO Board or Compensation Committee from time to time, with an initial target annual bonus of 40% of her annual base salary. Dr. Ridha also received a signing bonus in the form of a one-time signing bonus of £52,000 and was eligible to receive a one-time discretionary bonus of £60,000 based on the successful completion within the first six (6) months of her employment of key objectives defined by the Chief Executive Officer. In addition, pursuant to the terms of the employment agreement, Dr. Ridha was granted an option to purchase 120,000 shares of AVROBIO common stock, which will vest over four years, with 25% of the shares vesting on the one-year anniversary of Dr. Ridha start date and the remaining shares vesting in thirty-six equal monthly installments thereafter, subject to Dr. Ridha's continued service to AVROBIO through the applicable vesting date. Dr. Ridha is subject to confidentiality, non-solicitation and noncompetition provisions provided in her employment agreement with AVROBIO.

Dr. Ridha's employment agreement provides that, in the event that her employment is terminated by AVROBIO without "cause" or by Dr. Ridha with "good reason" (as each term is defined in her employment agreement), subject to the execution and effectiveness of a separation agreement and release, she will be entitled to receive (i) an amount equal to 75% of her base salary, (ii) nine (9) months of benefits allowance, which would include medical, dental, vision, and leisure travel insurance benefits, and (iii) acceleration of vesting of all stock options and other stock based awards held by Dr. Ridha that would have vested if she had remained employed by AVROBIO for an additional nine months following the date of termination.

In addition, in the event that Dr. Ridha's employment is terminated by AVROBIO without "cause" or by Dr. Ridha for "good reason," in each case, within three months prior to or 18 months after a "change in control" (as defined in her employment agreement), subject to the execution and effectiveness of a separation agreement and release, she will be entitled to receive (i) a lump sum amount equal to 100% of the sum of her current base salary (or her base salary in effect immediately prior to the change in control if higher) plus her target bonus for that year, (ii) 12 months of benefits allowance, which would include medical, dental, vision, and leisure travel insurance benefits, and (iii) full acceleration of vesting of all time-based stock options and other time-based stock-based awards held by Dr. Ridha.

Compensation Risk Assessment

AVROBIO believes that although a portion of the compensation provided to its executive officers and other employees is performance-based, its executive compensation program does not encourage excessive or unnecessary risk taking. AVROBIO's compensation programs are designed to encourage its executive officers and other employees to remain focused on both short-term and long-term strategic goals, in particular in connection with its pay-for-performance compensation philosophy. As a result, AVROBIO does not believe that AVROBIO's compensation programs are reasonably likely to have a material adverse effect on AVROBIO.

Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of the AVROBIO Board and received compensation for such service during the fiscal year ended December 31, 2023. Other than as set forth in the table and described more fully below, AVROBIO did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of the AVROBIO Board in 2023. AVROBIO reimburses non-employee members of the AVROBIO Board for reasonable travel expenses. Mr. MacKay, AVROBIO's former President and Chief Executive Officer, did not receive any compensation for his service as a member of the AVROBIO Board in 2023. Mr. MacKay's compensation for service as an employee for fiscal year 2023 is presented in the section titled *"—Executive Compensation—2023 Summary Compensation Table"* included elsewhere in this Annual Report on Form 10-K .

NAME	FEES EARNED OR PAID IN CASH ($)	OPTION AWARDS ($)[1]	TOTAL ($)
Bruce Booth, D.Phil.[2]	85,000	13,968	98,968
Ian Clark[3]	50,000	13,968	63,968
Phillip Donenberg[4]	59,000	13,968	72,968
Gail Farfel[5]	47,500	13,968	61,468
Annalisa Jenkins, M.B.B.S., F.R.C.P.[6]	63,000	13,968	76,968
Christopher Paige, Ph.D.[7]	59,000	13,968	72,968
Philip Vickers, Ph.D.[8]	60,000	13,968	73,968

(1) Amounts reflect the grant date fair value of option awards granted or modified in 2023 in accordance with ASC 718. Such grant date fair value does not take into account any estimated forfeitures related to service-vesting conditions. See Note 9 of *"Notes to Consolidated Financial Statements"* included elsewhere in this Annual Report on Form 10-K for a discussion of assumptions made by AVROBIO in determining the aggregate grant date fair value of such option awards. These amounts do not correspond to the actual value that may be recognized by the director upon vesting of applicable awards.

(2) As of December 31, 2023, Dr. Booth held options to purchase a total of 93,712 shares of AVROBIO common stock, of which 76,069 shares were vested as of such date.

(3) As of December 31, 2023, Mr. Clark held options to purchase an aggregate of 172,734 shares of AVROBIO common stock, of which 155,091 shares were vested as of such date.

(4) As of December 31, 2023, Mr. Donenberg held options to purchase an aggregate of 112,455 shares of AVROBIO common stock, of which 94,812 shares were vested as of such date.

(5) As of December 31, 2023, Dr. Farfel held options to purchase an aggregate of 98,037 shares of AVROBIO common stock, of which 80,394 shares were vested as of such date.

(6) As of December 31, 2023, Dr. Jenkins held options to purchase an aggregate of 133,223 shares of AVROBIO common stock, of which 115,580 shares were vested as of such date.

(7) As of December 31, 2023, Dr. Paige held options to purchase an aggregate of 93,712 shares of AVROBIO common stock, of which 76,069 shares were vested as of such date.

(8) As of December 31, 2023, Dr. Vickers held options to purchase an aggregate of 112,455 shares of AVROBIO common stock, of which 94,812 shares were vested as of such date.

Non-Employee Director Compensation Policy

The AVROBIO Board has adopted a non-employee director compensation policy that is designed to enable AVROBIO to attract and retain, on a long-term basis, highly qualified non-employee directors. Pursuant to AVROBIO's director compensation policy, each director who is not an employee will be paid cash compensation as set forth below:

	NON-CHAIRPERSON MEMBER ANNUAL FEE ($)	CHAIRPERSON ANNUAL FEE ($)
Board of Directors	40,000	72,500
Audit Committee	7,500	15,000
Compensation Committee	5,000	10,000
Nominating and Corporate Governance Committee	4,000	8,000
Science and Technology Committee	7,500	15,000

Pursuant to AVROBIO's director compensation policy, each non-employee director first elected or appointed to serve on the AVROBIO Board is granted an option award for a number of shares of AVROBIO common stock equivalent to 0.08% of the total number of common stock shares outstanding on the date of grant, which vests in 36 equal monthly installments over a three-year period, subject to the director's continued service through such vesting dates. In addition, on the date of each annual meeting of stockholders, each continuing non-employee director is now granted an option award for a number of shares of AVROBIO common stock equivalent to 0.04% of the total number of common stock shares outstanding on the date of grant, which vests in full upon the earlier to occur of the first anniversary of the date of grant or the date of AVROBIO's following annual meeting of stockholders, subject to continued service as a director through such vesting date.

The AVROBIO Board and Compensation Committee, in consultation with AVROBIO's compensation consultant, will continue to review non-employee director compensation from time to time.

On January 29, 2024, the AVROBIO Board approved a special one-time cash payment of $20,000 for each of Bruce Booth, Ian Clark, Phillip Donenberg, Gail Farfel and Philip Vickers in their capacity as members of the Transaction Committee. This payment will be paid to each such member of the Transaction Committee immediately prior to the closing of the transactions contemplated by the Merger Agreement.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information, to the extent known by AVROBIO or ascertainable from public filings, with respect to the beneficial ownership of AVROBIO common stock as of March 7, 2024, by:

- each of AVROBIO's directors;
- each of AVROBIO's named executive officers;
- all of AVROBIO's directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by AVROBIO to beneficially own greater than 5% of AVROBIO common stock.

The column titled "Shares Beneficially Owned" is based on a total of 44,860,515 shares of AVROBIO common stock outstanding as of March 7, 2024.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to AVROBIO common stock. Shares of AVROBIO common stock subject to options that are currently exercisable or exercisable within 60 days of March 7, 2024 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of AVROBIO common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of AVROBIO, Inc., 100 Technology Square, 6th Floor, Cambridge, Massachusetts 02139.

Name and address of beneficial owner	Shares beneficially owned	
	Number	Percentage
5% or Greater Stockholders:		
Affiliates of Atlas Venture Fund[(1)]	4,541,381	10.12 %
BML Investment, L.P.[(2)]	4,401,627	9.81 %
Affiliates of ADAR1 Fund[(3)]	3,276,498	7.30 %
Newtyn Management, LLC[(4)]	2,734,175	6.09 %
Named Executive Officers and Directors:		
Geoff MacKay[(5)]	213,938	*
Azadeh Golipour[(6)]	393,780	*
Erik Ostrowski[(7)]	799,975	1.75 %
Essra Ridha[(8)]	300,069	*
Bruce Booth, DPhil[(9)]	76,069	*
Ian T. Clark[(10)]	155,091	*
Phillip Donenberg[(11)]	96,812	*
Gail M. Farfel, PhD[(12)]	80,394	*
Annalisa Jenkins, MBBS, FRCP[(13)]	115,580	*
Christopher Paige, PhD[(14)]	328,581	*
Philip J. Vickers, PhD[(15)]	99,612	*
All current executive officers and directors as a group (11 persons)[(16)]	3,011,597	6.34 %

* Represents beneficial ownership of less than one percent.

(1) Based in part on a Schedule 13D filed with the SEC on July 30, 2019 and a Form 4 filed with the SEC on February 18, 2020. 3,710,052 shares are held directly by Atlas Venture X, 810,811 shares are held directly by Atlas Venture Opportunity and 20,518 shares are held directly by AVA X LP. AVA X LP is the general partner of Atlas Venture X, and AVA X LLC is the general partner of AVA X LP. AVA Opportunity LP is the general partner of Atlas Venture Opportunity and AVA Opportunity LLC is the general partner of AVA Opportunity LP. Bruce Booth is a member of AVA X LLC and AVA Opportunity LLC and a member of the AVROBIO Board. Dr. Booth disclaims beneficial ownership of such shares, except to the extent of his proportionate pecuniary interest therein, if any. The address for Atlas Venture X is 300 Technology Square, 8th Floor, Cambridge, MA 02139.

(2) Based solely on a Schedule 13G/A filed with the SEC on February 7, 2024. The report was filed by BML Investment Partners, L.P. and Braden M. Leonard. The address for these persons is 65 E Cedar, Suite 2, Zionsville, IN 46077.

(3) Based solely on a Schedule 13G filed with the SEC on February 23, 2024. The report was filed by ADAR1 Partners, LP, ADAR1 Capital Management, LLC, ADAR1 Capital Management GP, LLC, and Daniel Schneeberger. 3,276,498 shares are directly held by ADAR1 Partners, LP. ADAR1 Capital Management, LLC acts as an investment adviser to, and manages investment and trading accounts of, ADAR1 Partners, LP. ADAR1 Capital Management GP, LLC acts as the general partner of ADAR1 Partners, LP. Mr. Schneeberger is the manager of ADAR1 Capital Management, LLC and ADAR1 Capital Management GP, LLC. ADAR1 Capital Management, LLC, ADAR1 Capital Management GP, LLC and Mr. Schneeberger may be deemed to indirectly beneficially own securities held by ADAR1 Partners, LP. The address of the principal business office of each of these persons is 3503 Wild Cherry Drive, Building 9, Austin, Texas 78738.

(4) Based solely on a Schedule 13G filed with the SEC on February 14, 2024. The report was filed by Newtyn Management, LLC. 1,332,500 shares are held directly by Newtyn Partners, LP and 1,401,675 shares are held directly by Newtyn TE Partners, LP. Newtyn Management, LLC is the investment manager to Newtyn Partners, LP and Newtyn TE Partners, LP and may be deemed to beneficially own the 2,734,175 shares held in aggregate by Newtyn Partners, LP and Newtyn TE Partners, LP. The address for Newtyn Management, LLC is 60 East 42nd Street, 9th Floor, New York, NY 10165.

(5) Consists of 213,938 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.

(6) Consists of (i) 37,700 shares of AVROBIO common stock and (ii) 356,080 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.

(7) Consists of (i) 29,285 shares of AVROBIO common stock and (ii) 770,690 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.

(8) Consists of (i) 15,881 shares of AVROBIO common stock and (ii) 284,188 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.

(9) Consists of 76,069 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.
(10) Consists of 155,091 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.
(11) Consists of (i) 2,000 shares of AVROBIO common stock and (ii) 94,812 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.
(12) Consists of 80,394 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.
(13) Consists of 115,580 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.
(14) Consists of (i) 252,512 shares of AVROBIO common stock and (ii) 76,069 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.
(15) Consists of (i) 4,800 shares of AVROBIO common stock and (ii) 94,812 shares of AVROBIO common stock issuable upon exercise of options within 60 days of March 7, 2024.
(16) Includes an aggregate of 2,647,397 shares issuable upon exercise of stock options within 60 days of March 7, 2024 held by AVROBIO's current executive officers and directors as a group. Excludes shares held by Mr. MacKay, who is not a current executive officer.

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2023 regarding shares of AVROBIO common stock that may be issued under AVROBIO's equity compensation plans, consisting of AVROBIO's 2018 Plan, AVROBIO's 2015 Plan, AVROBIO's 2019 Inducement Plan, AVROBIO's 2020 Inducement Plan, and AVROBIO's 2018 Employee Stock Purchase Plan, or 2018 ESPP.

Plan Category	Number of Shares of Common Stock to be Issued Upon Exercise of Outstanding Options and RSUs (#)		Weighted-Average Exercise Price of Outstanding Options ($)[1]	Number of Shares of Common Stock Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column) (#)	
Equity compensation plans approved by security holders [2]	5,111,846	[2]	7.29	9,750,415	[3]
Equity compensation plans not approved by security holders	966,784	[4]	8.15	3,107,211	[5]
Total	6,078,630		7.33	12,857,626	

(1) Since RSUs do not have any exercise price, such units are not included in the weighted average exercise price calculations above.
(2) Includes (i) 4,175488 shares of AVROBIO common stock issuable upon the exercise of outstanding options and (ii) 936,358 shares of AVROBIO common stock issuable upon vesting of RSUs.
(3) As of December 31, 2023, there were 7,978,667 shares of AVROBIO common stock available for grant under AVROBIO's 2018 Plan, no shares available for grant under AVROBIO's 2015 Plan, and 1,771,748 shares of AVROBIO common stock available for grant under AVROBIO's 2018 ESPP (which number excludes any shares that would have been added to the plan as a result of the automatic annual increase on January 1, 2024). AVROBIO's 2018 ESPP provides that the number of shares reserved and available for issuance under the plan automatically increases each January 1 by the least of 1,115,700 shares of AVROBIO common stock, 1% of the outstanding number of shares of AVROBIO common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Compensation Committee. However, the Compensation Committee opted to reduce the number of shares that would otherwise have automatically been made available for issuance under the 2018 ESPP on January 1, 2024 to zero.
(4) Consists of (i) 484,700 shares of AVROBIO common stock underlying non-qualified stock options that were granted prior to the adoption of AVROBIO's Inducement Plans as one-time awards to various new employees in accordance with Nasdaq Listing Rule 5635(c)(4) and (ii) 482,084 shares of AVROBIO common stock issuable upon exercise of outstanding options granted under AVROBIO's 2019 Inducement Plan. There are no shares of AVROBIO common stock issuable upon exercise of outstanding options granted under AVROBIO's 2020 Inducement Plan.

(5) Consists of (i) 1,407,211 shares of AVROBIO common stock issuable under AVROBIO's 2019 Inducement Plan and (ii) 1,700,000 issuable under AVROBIO's 2020 Inducement Plan.

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

Certain Relationships and Transactions

Other than the compensation agreements and other arrangements described under *"Executive Compensation"* and *"Director Compensation"* included elsewhere in this Annual Report on Form 10-K and the transactions described below, since January 1, 2022, there has not been and there is not currently proposed, any transaction or series of similar transactions to which AVROBIO is, or will be, a party in which the amount involved exceeded, or will exceed, $120,000 (or, if less, one percent of the average of AVROBIO's total assets amounts at December 31, 2022 and 2023) and in which any director, executive officer, holder of five percent or more of any class of AVROBIO's capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

License Agreements and Related Agreements with University Health Network

Fabry License Agreement

On January 27, 2016, AVROBIO entered into an option agreement with UHN, pursuant to which UHN granted AVROBIO an exclusive option to enter into an exclusive license under certain intellectual property rights related to Fabry disease. On November 4, 2016, AVROBIO executed its option and entered into an exclusive license agreement with UHN. Under this agreement, or the Fabry license agreement, UHN granted AVROBIO an exclusive worldwide license under certain intellectual property rights and a non-exclusive worldwide license under certain know-how, in each case subject to certain retained rights, to develop, commercialize and sell products for use in the treatment of Fabry disease. Under the terms of the Fabry license agreement, AVROBIO paid to UHN a one-time upfront fee and was obligated to pay an annual maintenance fee until the first sale of a licensed product in certain markets. AVROBIO was also required to make payments to UHN in connection with the achievement of certain development and regulatory milestones in an aggregate amount of up to CAD$2.45 million, as well as royalties on a country-by-country basis of a low to mid-single digit percentage on annual sales of licensed products and a lower single digit royalty in certain circumstances. Additionally, AVROBIO was required to pay a low double digit percentage of all sublicensing revenue. AVROBIO also made a philanthropic commitment to donate funds to organizations for the benefit of the Canadian Fabry community in an amount equal to a low double digit percentage of AVROBIO's royalty payments and regulatory milestone payments, up to a maximum of CAD$500,000 in any calendar year. In connection with this agreement, AVROBIO also entered into three separate letter agreements with UHN, dated November 4, 2016, June 2, 2017 and December 11, 2019, pursuant to which AVROBIO agreed to provide certain funding and costs and expenses associated with a clinical trial conducted by UHN for the treatment of Fabry disease. For the years ended December 31, 2022 and 2023, AVROBIO paid $161 and $93 thousand, respectively, to UHN in connection with these agreements, which consists of reimbursable funded study trial costs and license maintenance fees. Effective as of January 4, 2024, AVROBIO terminated the Fabry license agreement with UHN. Following the termination of the Fabry license agreement, AVROBIO does not have any remaining financial obligations to UHN pursuant to the Fabry license agreement.

Interleukin-12 Agreement

On January 27, 2016, AVROBIO entered into an exclusive license agreement, or the IL-12 Agreement, with UHN pursuant to which UHN granted AVROBIO an exclusive license to certain intellectual property rights relating to Interleukin-12 proteins, or IL-12. AVROBIO entered into an amendment to the IL-12 Agreement on September 28, 2017. Under the IL-12 Agreement, as amended, or the Amended IL-12 Agreement, AVROBIO paid an upfront license fee and reimbursement of certain patent expenses, and AVROBIO was also obligated to pay an annual license fee as well as payments in connection with the achievement of certain performance and development milestones for an aggregate total of up to CAD$19.275 million in milestone payments. Additionally, the Amended IL-12 Agreement required AVROBIO to pay a low to mid-single digit royalty percentage on annual sales of licensed products, and a low double digit percentage of all sublicensing revenue. For the years ended December 31, 2022 and 2023, AVROBIO paid $39 and $37 thousand to UHN under the Amended IL-12 Agreement, respectively, which consists of license maintenance fees. Effective as of August 24, 2023, AVROBIO and UHN agreed to terminate the Amended IL-12 Agreement. Following the termination of the Amended IL-12 Agreement, AVROBIO does not have any remaining financial obligations to UHN pursuant to the Amended IL-12 Agreement.

In connection with the Amended IL-12 Agreement, AVROBIO has also entered into two separate sponsored research agreements with UHN, one in March 2017 and one in July 2017. The March 2017 agreement was amended and restated and subsequently amended in November 2017. Pursuant to each of these sponsored research agreements, AVROBIO agreed to fund certain research projects related to IL-12 and Fabry disease, including salaries of certain researchers of up to CAD$200,000 and CAD$164,652 under the March 2017 and July 2017 agreements, respectively.

At the time AVROBIO entered into each of the above agreements with UHN, other than the letter agreement dated December 11, 2019, UHN was a greater than 5% beneficial owner of AVROBIO's outstanding capital stock. Additionally, Christopher Paige is a senior scientist at UHN and is currently a member of the AVROBIO Board. As an inventor of certain of the intellectual property rights related to IL-12 that AVROBIO licenses from UHN, Dr. Paige would have been entitled to a portion of the consideration that AVROBIO would have been required to pay to UHN pursuant to the Amended IL-12 Agreement.

Agreements with Stockholders

In connection with AVROBIO's prior preferred stock financings, AVROBIO entered into investors' rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of AVROBIO preferred stock and certain holders of AVROBIO common stock. These stockholder agreements terminated upon the closing of AVROBIO's IPO, except for the registration rights granted under its investors' rights agreement, which terminated five years following AVROBIO's IPO.

Concurrently with the execution of the Merger Agreement, certain stockholders of AVROBIO holding approximately 10.8% of the outstanding shares of AVROBIO common stock as of January 30, 2024 entered into support agreements with AVROBIO. These stockholders include executive officers and directors of AVROBIO, as well as certain other stockholders owning a significant portion of the outstanding shares of AVROBIO's capital stock.

Indemnification Agreements

AVROBIO has entered into and in the future plans to enter into agreements to indemnify AVROBIO's directors and executive officers. These agreements, among other things, require AVROBIO to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in AVROBIO's right, on account of any services undertaken by such person on behalf of AVROBIO or that person's status as a member of the AVROBIO Board or as an officer of AVROBIO to the maximum extent allowed under Delaware law.

Lock-Up Agreements

Concurrently with the execution of the Merger Agreement, certain executive officers, directors and stockholders of AVROBIO and Tectonic have entered into lock-up agreements with AVROBIO, pursuant to which such parties have agreed not to, except in limited circumstances, sell or transfer their shares of AVROBIO common stock, for the 180-day period following the closing.

The AVROBIO stockholders who have executed lock-up agreements as of January 30, 2024, owned in the aggregate, approximately 10.8% of the shares of AVROBIO's then outstanding capital stock.

Related Person Transaction Policy

The AVROBIO Board reviews and approves transactions with directors, officers and holders of five percent or more of AVROBIO's voting securities and their affiliates, each a related party. AVROBIO adopted a written related person transaction policy that requires related party transactions to be approved by the Audit Committee. Pursuant to this policy, the Audit Committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between AVROBIO and related persons in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person will be defined as a director, executive officer, nominee for director, or greater than 5% beneficial owner of AVROBIO common stock, in each case since the beginning of the most recently completed year, and their immediate family members.

Director Independence

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq rules require that, subject to specified exceptions, each member of a listed company's Audit, Compensation and Nominating and Corporate Governance Committees be independent and that Audit Committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act and that Compensation Committee members satisfy independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an Audit Committee of a listed company may not, other than in his or her capacity as a member of the Audit Committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In addition, in affirmatively determining the independence of any director who will serve on a company's Compensation Committee, Rule 10C-1 under the Exchange Act requires that a company's board of directors must consider all factors specifically relevant to determining whether a director has a relationship to such company which is

material to that director's ability to be independent from management in connection with the duties of a Compensation Committee member, including: the source of compensation to the director, including any consulting, advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

The AVROBIO Board has determined that all members of the AVROBIO Board, except Dr. Farfel, are independent directors, including for purposes of the rules of Nasdaq and the SEC. In making such independence determination, the AVROBIO Board considered the relationships that each non-employee director has with AVROBIO and all other facts and circumstances that the AVROBIO Board deemed relevant in determining their independence, including the beneficial ownership of AVROBIO's capital stock by each non-employee director. In considering the independence of the directors listed above, the AVROBIO Board considered the association of AVROBIO's directors with the holders of more than 5% of AVROBIO common stock. There are no family relationships among any of the directors or executive officers of AVROBIO. Dr. Farfel is not an independent director under these rules because an immediate family member is employed by Ernst & Young LLP, AVROBIO's independent registered public accounting firm.

Item 14. Principal Accounting Fees and Services.

The following table sets forth all fees paid or accrued by AVROBIO for professional audit services and other services rendered by Ernst & Young LLP during the years ended December 31, 2023 and December 31, 2022.

	2023	2022
Audit fees[1]	$ 560,900	$ 598,408
Audit-related fees	—	—
Tax fees[2]	$ 152,503	$ 64,166
All other fees[3]	—	3,600
Total fees	$ 713,403	$ 666,174

(1) Audit fees consist of fees for professional services provided by Ernst & Young LLP for the audit of AVROBIO's annual financial statements, the review of interim consolidated financial statements and consultations on accounting matters directly related to the audit, and comfort letters, consents and assistance with and review of documents filed with the SEC.

(2) Tax fees consist of fees for professional services in connection with tax compliance, tax planning, and tax advice, including the review and preparation of AVROBIO's federal, state and foreign income tax returns and requests for rulings or technical advice from tax authorities.

(3) Other fees consist of aggregate fees billed for products and services provided by Ernst & Young LLP other than those fees disclosed above. For the year ended December 31, 2022, the other fees relate to AVROBIO's Ernst & Young research website membership.

Audit Committee Pre-approval Policy and Procedures

The Audit Committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by AVROBIO's independent registered public accounting firm. This policy provides that AVROBIO will not engage its independent registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by the Audit Committee or the engagement is entered into pursuant to the pre-approval procedure described below.

From time to time, the Audit Committee may pre-approve specified types of services that are expected to be provided to AVROBIO by its independent registered public accounting firm during the next 12 months. The Audit Committee has delegated authority to the Chair of the Audit Committee to pre-approve services up to a designated amount. A summary of any new services pre-approved by the Chair is reported to the full Audit Committee in connection with its next scheduled meeting.

During AVROBIO's 2023 and 2022 fiscal years, no services were provided to AVROBIO by Ernst & Young LLP other than in accordance with the pre-approval policies and procedures described.

The Audit Committee meets with representatives of Ernst & Young LLP periodically, but no less than quarterly throughout the year. The Audit Committee reviews audit, non-audit and tax services rendered by and the performance of Ernst & Young LLP, as well as fees charged by Ernst & Young LLP for such services. In engaging Ernst & Young LLP for the services described above, the Audit Committee considered whether the provision of such services is compatible with maintaining Ernst & Young LLP's independence.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are included in this Annual Report on Form 10-K:

1. The following Report and Consolidated Financial Statements of the Company are included in this Annual Report:

   Report of Independent Registered Public Accounting Firm

   Consolidated Balance Sheets

   Consolidated Statements of Operations and Comprehensive Loss

   Consolidated Statements of Stockholders' Equity

   Consolidated Statements of Cash Flows

   Notes to Consolidated Financial Statements

2. All financial schedules have been omitted because the required information is either presented in the consolidated financial statements or the notes thereto or is not applicable or required.

3. The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Item 16. Form 10-K Summary

Not Applicable.

AVROBIO, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of AVROBIO, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of AVROBIO, Inc. (the Company) as of December 31, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with 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.

Critical Audit Matters

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.
Boston, Massachusetts
March 14, 2024

AVROBIO, INC.
CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except per share data)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 98,020	$ 92,563
Restricted cash	283	283
Prepaid expenses and other current assets	1,958	7,112
Total current assets	100,261	99,958
Operating lease assets	432	1,057
Property and equipment, net	—	2,894
Restricted cash, net of current portion	400	—
Other assets	—	40
Total assets	$ 101,093	$ 103,949
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 27	$ 384
Accrued expenses and other current liabilities	5,449	11,732
Operating lease liabilities	878	999
Total current liabilities	6,354	13,115
Note payable, net of discount	—	15,276
Operating lease liabilities, net of current portion	—	188
Total liabilities	6,354	28,579
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000 shares authorized and no shares issued or outstanding as of December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value; 150,000 shares authorized as of December 31, 2023 and 2022; 44,654 and 43,916 shares issued and outstanding as of December 31, 2023 and 2022, respectively	4	4
Additional paid-in capital	572,010	564,798
Accumulated deficit	(477,275)	(489,432)
Total stockholders' equity	94,739	75,370
Total liabilities and stockholders' equity	$ 101,093	$ 103,949

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

AVROBIO, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(amounts in thousands, except per share data)

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 47,700	$ 72,186
General and administrative	23,967	33,248
Total operating expenses	71,667	105,434
Gain on asset sale	83,736	—
Loss on impairment	(1,877)	—
Income (loss) from operations	10,192	(105,434)
Other income (expense):		
Interest income (expense), net	2,420	(299)
Other expense, net	(78)	(157)
Total other income (expense), net	2,342	(456)
Income (loss) before income taxes	12,534	(105,890)
Provision for income tax expense	377	—
Net income (loss) and comprehensive income (loss) attributable to common stockholders—basic and diluted	$ 12,157	$ (105,890)
Earnings per share:		
Net income (loss) per share applicable to common stockholders—basic	$ 0.27	$ (2.42)
Net income (loss) per share applicable to common stockholders—diluted	$ 0.27	$ (2.42)
Shares used in computing earnings per share:		
Weighted-average common shares outstanding—basic	44,327	43,739
Weighted-average common shares outstanding—diluted	44,568	43,739

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

AVROBIO, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(amounts in thousands)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2021	43,652	$ 4	$ 553,014	$ (383,542)	$ 169,476
Vesting of restricted stock awards and units	1	—	—	—	—
Exercise of stock options	142	—	58	—	58
Issuance of common stock under 2018 employee stock purchase plan	121	—	204	—	204
Stock-based compensation expense	—	—	11,522	—	11,522
Net loss	—	—	—	(105,890)	(105,890)
Balance as of December 31, 2022	43,916	4	564,798	(489,432)	75,370
Vesting of restricted stock units	306	—	—	—	—
Exercise of stock options	298	—	235	—	235
Issuance of common stock under 2018 employee stock purchase plan	134	—	86	—	86
Stock-based compensation expense	—	—	6,891	—	6,891
Net loss	—	—	—	12,157	12,157
Balance as of December 31, 2023	44,654	$ 4	$ 572,010	$ (477,275)	$ 94,739

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

AVROBIO, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net income (loss)	$ 12,157	$ (105,890)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on asset sale	(83,736)	—
Stock-based compensation expense	6,891	11,522
Depreciation and amortization expense	617	1,440
Non-cash asset impairment charges	1,877	—
Loss on disposal of property and equipment	—	59
Non-cash interest expense	1,074	331
Non-cash income tax expense	377	—
(Gain)/loss on impairment of leasehold improvements	—	86
(Gain)/loss on extinguishment of operating lease	(72)	(81)
Non-cash lease expense	1,912	2,726
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	5,154	2,466
Other assets	40	34
Accounts payable	(357)	(3,102)
Current and non-current operating lease liabilities	(2,464)	(2,893)
Accrued expenses and other current liabilities	(6,660)	(3,906)
Net cash used in operating activities	(63,190)	(97,208)
Cash flows from investing activities:		
Proceeds from asset sale, net	83,736	—
Proceeds from the sale of property, plant, and equipment	1,348	—
Purchases of property and equipment	(8)	(267)
Net cash provided by (used in) investing activities	85,076	(267)
Cash flows from financing activities:		
Repayment of note payable, including end of term charge	(16,350)	—
Exercise of stock options	235	58
Proceeds from issuance of common stock under 2018 employee stock purchase plan	86	204
Net cash (used in) provided by financing activities	(16,029)	262
Net increase (decrease) in cash, cash equivalents and restricted cash	5,857	(97,213)
Cash, cash equivalents and restricted cash at beginning of period	92,846	190,059
Cash, cash equivalents and restricted cash at end of period	$ 98,703	$ 92,846
Supplemental Cash:		
Interest paid	$ 831	$ 1,425
Supplemental disclosure of non-cash investing and financing activities:		
Right of use asset obtained in exchange for operating lease liabilities	$ 2,392	$ 4,319
Reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets:		
Cash and cash equivalents, end of period	$ 98,020	$ 92,563
Restricted cash	683	283
Cash, cash equivalents and restricted cash, end of period	$ 98,703	$ 92,846

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

1. Nature of the Business

AVROBIO, Inc. (the "Company" or "AVROBIO") is a gene therapy company which has been focused on developing potentially curative hematopoietic stem cell, or HSC, gene therapies to treat rare diseases following a single dose treatment regimen.

On July 12, 2023, following a comprehensive review of the Company's business by its Board of Directors (the "Board"), the Company announced its intention to halt development of its programs and explore strategic alternatives focused on maximizing stockholder value, which may include, but are not limited to, an acquisition, a merger, business combination or divestiture. The decision was not related to any safety or medical issues or negative regulatory feedback related to the Company's programs. See Note 15 for further discussion. On January 30, 2024, the Company entered into the Merger Agreement with Tectonic Therapeutic, Inc. ("Tectonic") pursuant to which a wholly-owned subsidiary of the Company will merge with and into Tectonic, with Tectonic surviving as a wholly-owned subsidiary of the Company (the "Merger"). See Note 16 for further discussion.

The Company is subject to risks and uncertainties including, should it resume development of its product candidates, risks and uncertainties common to early-stage companies in the biotechnology industry, including but not limited to, risks associated with completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Should the Company resume development of its product candidates, significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization, would be required. These efforts would require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, should the Company resume development of its product candidates, it is uncertain when, if ever, the Company would realize revenue from product sales.

In accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

The Company has devoted substantially all of its efforts to research and development, business planning, acquiring operating assets, seeking protection for its technology and product candidates, and raising capital. Since inception, the Company has had recurring losses and has funded its operations through sales of preferred stock and common stock, a term loan facility and the sale of the Company's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of the Company specifically related to this program. As of December 31, 2023, the Company had an accumulated deficit of $477,275. The Company expects that its cash and cash equivalents of $98,020 as of December 31, 2023 will be sufficient to fund current planned operations and capital expenditure requirements for at least the next twelve months from the filing date of this Annual Report on Form 10-K with the Securities and Exchange Commission ("SEC").

On May 19, 2023, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Novartis Pharma AG and Novartis Pharmaceuticals Corporation (collectively, "Novartis"), providing for the sale of the Company's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of the Company specifically related to this program. The aggregate consideration to the Company consisted of a cash payment of $87,500 upon closing of the transaction. The Company completed the Asset Sale (as defined below) on June 9, 2023 and recognized $83,736 as a gain on asset sale, net of $3,764 transaction costs, in the consolidated statement of operations and comprehensive income (loss). See Note 3 for further discussion.

In July 2023, the Board approved a reduction in the Company's workforce by approximately 50% across different areas and functions in the Company (the "July 2023 Workforce Reduction"). The July 2023 Workforce Reduction was substantially completed by the end of July 2023. The Company informed affected employees in the July 2023 Workforce Reduction on July 12, 2023. Since the date of the July 2023 Workforce Reduction, the Company's remaining employees have

primarily focused on activities relating to halting further development of the Company's programs, the pursuit of strategic alternatives, and the provision of services under the previously disclosed Separation Services Agreement between the Company and Novartis in connection with the sale to Novartis of the Company's cystinosis gene therapy program. The Company's remaining workforce was further reduced by 11 employees in a workforce reduction implemented effective as of October 31, 2023 (the "October 2023 Workforce Reduction"). The Company's workforce was further reduced by 8 employees in the December 2023 Workforce Reduction effective as of December 31, 2023 (the "December 2023 Workforce Reduction"). Affected employees in the July 2023 Workforce Reduction, October 2023 Workforce Reduction, and December 2023 Workforce Reduction were offered separation benefits, including severance payments. See Note 15 for further discussion.

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 United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and ASU of FASB.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of AVROBIO, Inc. and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer ("CEO"). The Company and the CEO view the Company's operations and manage its business as one operating segment. All material long-lived assets of the Company reside in the United States.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires that the Company make estimates and judgments that may affect the reported amounts of assets, liabilities and expenses and the related disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. On an on-going basis, the Company evaluates its estimates, judgments and methodologies. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less at acquisition to be cash equivalents. As of December 31, 2023 and 2022, cash and cash equivalents were primarily held in interest-bearing money market funds.

Concentrations of Credit Risk

The Company has no significant off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and restricted cash. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash and cash equivalents in financial institutions that it believes have high credit quality and has 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.

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— Fair values are determined utilizing prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access.
- 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.

The carrying amounts of the Company's financial instruments, which include cash equivalents, accounts payable, and accrued expenses, approximated their fair values as of December 31, 2023 and 2022 due to the short-term nature of these instruments.

The Company has evaluated the estimated fair value of financial instruments using available market information. The use of different market assumptions, estimation methodologies, or both, could have a significant effect on the estimated fair value amounts. See Note 4 *"Fair Value of Financial Assets and Liabilities"* for further discussion.

Property and Equipment

Property and equipment are recorded at cost. Depreciation and amortization is calculated using the straight-line method over the following estimated useful lives of the assets:

	Estimated Useful Life
Laboratory and office equipment	5 years
Computer equipment	2 years
Leasehold improvements	Lesser of lease term or 10 years

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. During the year ended December 31, 2023 the Company recognized a $937 loss on impairment of property, plant, and equipment as a result of the reclassification of these assets to held for sale. The Company did not record any impairment loss during the year ended December 31, 2022.

Leases

Prior to January 1, 2022, the Company accounted for leases in accordance with FASB ASC 840, Leases. At lease inception, the Company determined if an arrangement was an operating or capital lease. For operating leases, the Company recognized rent expense, inclusive of rent escalations, on a straight-line basis over the lease term.

Effective on January 1, 2022, the Company accounts for leases in accordance with ASC Topic 842, Leases ("ASC 842"). Upon transition, the Company applied the package of practical expedients permitted under ASC 842 transition guidance to its entire lease portfolio at January 1, 2022. As a result, the Company was not required to reassess (i) whether any expired or existing contracts are or contain leases, (ii) the classification of any expired or existing leases, and (iii) initial direct costs for any existing leases. Furthermore, as a lessee the Company elected to combine lease and non-lease components together for the majority of its leases. As a result, for these applicable classes of underlying assets, the Company accounted for each separate lease component and the non-lease components associated with that lease component as a single lease component.

In accordance with ASC 842, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company records leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right-of-use ("ROU") asset and a lease liability on the consolidated balance sheet for all leases with a lease term of greater than twelve months. The Company has elected to not recognize leases with a lease term of twelve months or less on the balance sheet and will recognize lease payments for such short-term leases as an expense on a straight-line basis.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include items such as maintenance, utilities, or other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Operating lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes its incremental borrowing rate based upon the available information at the lease commencement date. ROU assets are further adjusted for items such as initial direct costs, prepaid rent, or lease incentives. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend the lease when it is reasonably certain that the Company will exercise that option. Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term. Finance lease payments are bifurcated into (i) a portion that is recorded as interest expense and (ii) a portion that reduces the finance lease liability associated with the lease.

During the year ended December 31, 2023 the Company recognized a $940 loss on impairment of ROU assets as a result of the discontinued use of lab space in Cambridge, Massachusetts, United States. The Company did not record any impairment loss during the year ended December 31, 2022.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in stockholders' equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income (loss) includes net income (loss) as well as other changes in stockholders' equity (deficit) which includes certain changes in equity that are excluded from net income (loss). Comprehensive loss has been disclosed in the accompanying consolidated statements of operations and comprehensive loss and equals the Company's net loss for all periods presented.

Foreign Currency Translation

The functional currency of the Company's international operations in Canada and Australia is the U.S. dollar. Accordingly, all operating assets and liabilities of these international subsidiaries are remeasured into U.S. dollars using the exchange rates in effect at the balance sheet date or historical rates, as appropriate, while expenses are remeasured into U.S. dollars at the average rates in effect during the period. Any differences resulting from the remeasurement of assets, liabilities, and operations of the Canadian and Australian subsidiaries are recorded within other (expense) income, net in the consolidated statements of operations and comprehensive loss. During the years ended December 31, 2023 and 2022, the Company recorded foreign exchange losses of $122 and $92, respectively, in other expense in the consolidated statements of operations and comprehensive loss.

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 recognized as an expense 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.

The Company has entered into various research and development related contracts with parties both inside and outside of the United States. The payments related to these agreements are recorded 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 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. The Company's historical accrual estimates have not been materially different from the actual costs.

Stock-Based Compensation

For stock-based awards issued to employees and members of the Company's Board for their services on the Board, the Company measures the estimated fair value of the stock-based award on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company issues stock-based awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company has not issued any stock-based awards with performance- or market-based vesting conditions. The Company accounts for forfeitures as they occur.

The measurement date for non-employee awards is the later of the adoption date of ASU 2018-07, or the date of grant. For stock-based awards granted to nonemployees subject to graded vesting that only contain service conditions, the Company has elected to recognize stock-based compensation expense using the straight-line recognition method.

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.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. As there was no public market for its common stock prior to June 21, 2018, which was the first day of trading, and as the trading history of the Company's common stock was limited through December 31, 2022, the Company determined 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 has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. 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.

Income Taxes

Deferred tax assets and liabilities are determined on the basis of 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 loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by adjusting the weighted-average shares outstanding for the potential dilutive effects of common stock equivalents outstanding during the period calculated in accordance with the treasury stock method. For purposes of the diluted net loss per share calculation, stock options and restricted stock units are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

Subsequent Event Considerations

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required. See Note 16.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, or ASU 2016-13. ASU 2016-13 requires that credit losses be reported as an allowance using an expected losses model, representing the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. On January 1, 2023 the Company adopted this standard, which had no impact on its financial position or results of operations.

In November 2019, the FASB issued ASU 2019-11, "Codification Improvements to Topic 326, Financial Instruments – Credit Losses," or ASU 2019-11. ASU 2019-11 is an accounting pronouncement that amends ASU 2016-13, "Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments." The amendments update guidance on reporting credit losses for financial assets. These amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. On January 1, 2023 the Company adopted this standard, which had no impact on its financial position or results of operations.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued Accounting Standard Update ASU 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the United States and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively. Early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statement disclosures.

In October 2023, the FASB issued ASU 2023-06 "Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative." which incorporates certain SEC disclosure requirements into the FASB Accounting Standards Codification ("Codification"). The amendments in the ASU are expected to clarify or improve disclosure and presentation requirements of a variety Codification topics, allow investors to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the requirements, and align the requirements in the Codification with the SEC's regulations. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The amendments in this ASU should be applied prospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statement disclosures.

3. License and Purchase Agreements

Agreement with The University of Manchester

On September 30, 2020, the Company entered into an agreement ("MPSII License Agreement") with The University of Manchester, England ("UoM"), whereby UoM granted to the Company an exclusive worldwide license under certain patent

and other intellectual property rights, subject to certain retained rights, to develop, commercialize and sell an *ex vivo* lentiviral gene therapy for use in the treatment of Hunter syndrome, or mucopolysaccharidosis type II ("MPSII"). As consideration for the MPSII License Agreement, the Company agreed to pay UoM an upfront, one-time fee of $8,000, which was recognized as research and development expense during the year ended December 31, 2020.

As part of the agreement, the Company was obligated to make milestone payments of up to an aggregate of $80,000 upon the achievement of specified development and regulatory milestones, to pay royalties, on a product-by-product and country-by-country basis, of a mid-single digit percentage based on net sales of products licensed under the agreement and to pay a low double-digit percentage of any sublicense fees received by the Company. During the third quarter of 2022, a $2,000 milestone payment under the MPSII License Agreement became due following the date of regulatory approval of the CTA for the investigator-sponsored Phase 1/2 clinical trial sponsored by UoM.

Concurrently with the MPSII License Agreement, the Company entered into a collaborative research funding agreement with UoM ("CRFA"). Under the CRFA, the Company has agreed to fund the budgeted costs of an investigator-sponsored Phase 1/2 clinical trial to be sponsored by UoM in connection with the development activities under the MPSII License Agreement, which were estimated to equal approximately £9,900 in the aggregate.

On September 8, 2023 the Company and UoM terminated the MPSII License Agreement and the CFRA, and in connection with such termination, the Company paid UoM £3,900. Following the termination of the MPSII License Agreement and the CFRA, the Company does not have any remaining financial obligations to UoM.

For the years ended December 31, 2023 and 2022, the Company recognized $1,610 and $2,346, respectively, of costs related to the CRFA, excluding the payment made in connection with the termination.

Agreements with University Health Network ("UHN")

Fabry License Agreement—

On January 27, 2016, the Company entered into an agreement with UHN, pursuant to which UHN granted the Company an option to enter into an exclusive license under the UHN intellectual property related to Fabry disease in accordance with the pre-negotiated licensing terms. On November 4, 2016, the Company exercised its option and entered into a license agreement with UHN, pursuant to which UHN granted the Company an exclusive worldwide license under certain intellectual property rights and a non-exclusive worldwide license under certain know-how, in each case subject to certain retained rights, to develop, commercialize and sell products for use in the treatment of Fabry disease. In addition, for three years following the execution of the agreement, UHN granted the Company an exclusive option to obtain a license under certain improvements to the licensed intellectual property rights as well as an option to negotiate a license under certain other improvements.

Under this agreement, the Company paid an option fee of CAD$20, an upfront license fee of CAD$75, plus the annual license maintenance fee for the first year. Thereafter, the Company was also required to pay UHN future annual license maintenance fees until the first sale of a licensed product in certain markets. The Company was also obligated to make future milestone payments in an aggregate amount of up to CAD$2,450 upon the achievement of specified milestones as well as royalties on a country-by-country basis of a low to mid-single-digit percentage of annual net sales of licensed products and a lower single-digit royalty percentage in certain circumstances. Additionally, the Company had agreed to pay a low double-digit royalty percentage of all sublicensing revenue.

The agreement required the Company to meet certain performance milestones within specified timeframes. UHN could terminate the agreement if the Company failed to meet these performance milestones despite using commercially reasonable efforts and the Company is unable to reach agreement with UHN on revised timeframes. The Company's royalty obligation was to expire on a licensed product-by-licensed product and country-by-country basis upon the latest to occur of the expiration or termination of the last valid claim under the licensed intellectual property rights in such country, the tenth anniversary of the first commercial sale of such licensed product in such country and the expiration of any applicable regulatory exclusivity in such country.

Unless terminated earlier, the agreement was to expire upon the expiration of the Company's royalty obligation for all licensed products. UHN could terminate the agreement if the Company failed to make any payments within a specified period after receiving written notice of such failure, or in the event that the Company fails to obtain or maintain insurance. Either the Company or UHN could terminate the license agreement in the event of a material breach by the other party and

failure to cure such breach within a certain period of time. The Company could voluntarily terminate the agreement with prior notice to UHN.

Effective January 4, 2024, AVROBIO terminated the Fabry license agreement with UHN, and in connection with such termination, the Company paid UHN CAD$194. Following the termination of the agreement, AVROBIO does not have any remaining financial obligations to UHN pursuant to the Fabry license agreement. For the years ended December 31, 2023 and 2022, the Company recorded research and development expense related to this agreement with UHN of $93 and $161, respectively, which consists of reimbursable funded study trial costs and license maintenance fees. No milestone fees were incurred related to the Fabry license agreement in the years ended December 31, 2023 and 2022.

Interleukin 12 License Agreement—

On January 27, 2016, the Company entered into an exclusive license agreement with UHN, pursuant to which UHN granted the Company a license to certain patent rights for the commercial development, manufacture, distribution and use of any products or processes resulting from development of those patent rights related to Interleukin 12. Upon execution of this agreement, the Company paid an upfront license fee of CAD $264. In addition, as part of the initial consideration for the license, the Company issued to UHN 1,161,665 shares of the Company's common stock and agreed to pay UHN up to $2,000 upon the closing of an IPO if certain criteria are met. The fair value of the shares issued to UHN of $480 and the upfront fee was expensed upon the execution of the agreement. Upon the closing of the Company's initial public offering (the "IPO") in 2018, as the criteria were met, the Company paid UHN $2,000. The Company was also required to pay UHN future annual license maintenance fees of CAD $50 on each anniversary of the effective date of the license agreement prior to expiration or termination and potential future milestone payments of up to CAD $19,275 upon the achievement of specified clinical and regulatory milestones. The Company also agreed to pay UHN royalties of a low single-digit percentage of net sales of licensed products sold by the Company. If the Company granted any sublicense rights under the license agreement, the Company agreed to pay UHN a low double-digit royalty percentage of any sublicense income received by the Company. The agreement also required the Company to meet certain diligence requirements based upon specified milestones.

Effective as of August 24, 2023, the Company and UHN agreed to terminate the Interleukin 12 License Agreement, and in connection with such termination there were no payments made to UHN. Following the termination of the agreement, the Company does not have any remaining financial obligations to UHN pursuant to the Interleukin 12 License Agreement.

For the years ended December 31, 2023 and 2022, the Company recorded research and development expense related to this agreement with UHN of $37 and $39, respectively, which consists of license maintenance fees. No milestone fees were incurred related to the Interleukin 12 license agreement in the years ended December 31, 2023 and 2022.

Agreement with BioMarin Pharmaceutical Inc. ("BioMarin")

On August 31, 2017, the Company entered into a license agreement with BioMarin, pursuant to which BioMarin granted the Company an exclusive worldwide license under certain intellectual property rights owned or controlled by BioMarin to develop, commercialize and sell products for use in the treatment of Pompe disease. The license agreement was amended in February 2018 and again in January 2020 to, among things, provide that BioMarin would supply the Company with certain technology materials. As consideration for this agreement, the Company paid an upfront license fee of $500 in cash and issued 233,765 shares of Series B Preferred Stock to BioMarin at the time of the Company's Series B Preferred Stock financing in January 2018. The Company is also obligated to make future milestone payments of up to $13,000 upon the achievement of certain specified milestones and agreed to pay BioMarin royalties of a low single-digit percentage of net sales of licensed products sold by the Company or its affiliates covered by patent rights in a relevant country. No expenses related to the license were recorded for the years ended December 31, 2023 and 2022.

Unless terminated earlier, the agreement expires upon the expiration of the Company's royalty obligation for all licensed products throughout the world. BioMarin and the Company can terminate the agreement in the event of a material breach by the other party and failure to cure such breach within a certain period of time. The Company may terminate the agreement at will upon written notice to BioMarin. BioMarin has the right to terminate the agreement upon the Company's bankruptcy or insolvency, or in the event of any challenge or opposition to the licensed patent rights or related actions brought by the Company or its affiliates or sublicensees, or if the Company, its affiliates or sublicensees knowingly assist a third-party in challenging or otherwise opposing the licensed patent rights, except as required under a court order or subpoena.

Agreement with Papillon Therapeutics, Inc. (previously GenStem Therapeutics, Inc.)

On October 2, 2017, the Company entered into a license agreement with GenStem, pursuant to which GenStem granted the Company an exclusive worldwide license, subject to certain retained rights, under certain intellectual property rights owned or controlled by GenStem to develop, commercialize and sell products for use in the treatment of cystinosis. Under this agreement, the Company paid an upfront license fee of $1,000 and is required to make payments upon completion of certain milestones up to an aggregate of $16,000. The Company also agreed to pay GenStem a tiered mid to high single-digit royalty percentage on annual net sales of licensed products as well as a low double-digit percentage of sublicense income received from certain third-party licensees. The Company's royalty obligation expires on a licensed product-by-licensed product and country-by-country basis on the eleventh anniversary of the first commercial sale of such licensed product in such country or the expiration of the last valid claim under the licensed patent rights covering such licensed product in such country, whichever is later. Unless terminated earlier, the agreement expires upon the expiration of the Company's royalty obligation for all licensed products throughout the world. GenStem and the Company can terminate the agreement in the event of a material breach by the other party and failure to cure such breach within a certain period of time. The Company may terminate the agreement at will upon the specified prior written notice to GenStem. In October 2021, the Company received notice that the license agreement with GenStem had been assigned to Papillon. The license agreement with Papillon was assigned to Novartis on May 19, 2023 in conjunction with the Company's Asset Purchase Agreement with Novartis which provided for the sale of the Company's cystinosis gene therapy program and all other assets of the Company specifically related to this program (see "Sale of Cystinosis Program" below).

No expenses related to the license were recorded for the years ended December 31, 2023 and 2022.

Agreement with Lund University Rights Holders

On November 17, 2016, the Company entered into a license agreement with affiliates of Lund University, along with certain other relevant rights holders that may be added from time to time, pursuant to which such rights holders granted to the Company an exclusive worldwide license, subject to certain retained rights, under certain intellectual property rights to develop, commercialize and sell products in any and all uses relevant to Gaucher disease. As consideration for the license, the Company is required to make payments in connection with the achievement of certain milestones up to an aggregate of $550. The agreement expires on the latest of (i) the twentieth anniversary of the end of a certain research project the Company is funding pursuant to an agreement with Lund University, (ii) the expiration of the term of any patent filed on the licensed rights that covers a licensed product, (iii) the expiration of any applicable marketing exclusivity right and (iv) such time that neither the Company nor any sublicensees, partners or contractors are commercializing a licensed product. Either the Company or the rights holders acting together may terminate the license agreement if the other such party commits a material breach and fails to cure such breach within a certain period of time, or if the other party enters into liquidation, becomes insolvent, or enters into composition or statutory reorganization proceedings. No expenses related to the license were recorded for the years ended December 31, 2023 and 2022.

Sale of Cystinosis Program

On May 19, 2023, the Company entered into the Asset Purchase Agreement with Novartis, providing for the sale of the Company's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of the Company specifically related to this program. In addition, pursuant to the Asset Purchase Agreement, the Company has granted an exclusive license to Novartis to use certain intellectual property of the Company, which consists of certain proprietary elements of the Company's plato®gene therapy platform technology specifically within the field of cystinosis. The foregoing transactions contemplated by the Asset Purchase Agreement are referred to as the "Asset Sale." The Company has also agreed not to assert claims against Novartis for violations of certain other Company intellectual property rights in connection with Novartis's exercise of the exclusive license granted to it under the Asset Purchase Agreement, and for violations of the licensed intellectual property, except in connection with activities by Novartis in the fields of Gaucher disease, Pompe disease, Hunter syndrome and Fabry disease, or indemnification claims under the Asset Purchase Agreement. The aggregate consideration to the Company consisted of a cash payment of $87,500 upon closing of the transaction. The Company recognized $83,736 as a gain on asset sale, net of $3,764 in transaction costs, in the consolidated statement of operations and comprehensive income (loss).

4. 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 as of December 31, 2023 and 2022:

	Fair Value Measurements as of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	$ 96,707	$ —	$ —	$ 96,707
	$ 96,707	$ —	$ —	$ 96,707

	Fair Value Measurements as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	$ 91,095	$ —	$ —	$ 91,095
	$ 91,095	$ —	$ —	$ 91,095

During the years ended December 31, 2023 and 2022, there were no transfers between levels.

5. Supplemental Balance Sheet Information

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2023	2022
Prepaid research and development expenses	$ 572	$ 4,509
Prepaid insurance	816	999
Prepaid compensation benefits	—	327
Tax incentive refund, net of reserve	—	269
Other current assets	570	1,008
Prepaid expenses and other current assets	$ 1,958	$ 7,112

Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2023	2022
Laboratory and office equipment	$ 5,973	$ 5,967
Leasehold improvements	629	629
Computer equipment	104	102
	6,706	6,698
Less: Accumulated depreciation and amortization	(4,421)	(3,804)
Impairment	(937)	—
Sale of assets	(1,348)	—
Property and equipment, net	$ —	$ 2,894

Depreciation and amortization expense for the years ended December 31, 2023 and 2022 was $617 and $1,440, respectively.

Restricted Cash

As of December 31, 2023 and 2022, the Company had restricted cash as presented in the table below, which consists of cash used to secure a letter of credit for the benefit of the landlord in connection with the Company's lease agreement as well as restricted cash related to the Company's corporate credit card program. The cash will be restricted until the termination or modification of the lease arrangement and corporate credit card program, respectively.

	December 31,	
	2023	2022
Restricted cash	$ 283	$ 283
Restricted cash, net of current portion	400	—

Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2023	2022
Research and development expenses	$ 711	$ 6,122
Compensation and benefit costs	3,463	4,175
Consulting and professional fees	892	1,224
Other liabilities	383	211
	$ 5,449	$ 11,732

6. Leases

On August 31, 2018, the Company entered into a sublease agreement for lab space located in Cambridge Massachusetts, United States, which was set to expire in October 2020. On June 9, 2020, the Company amended the terms of the sublease, which was set to expire in April 2022. Effective January 1, 2022, the Company amended the terms of the sublease, to extend the term through April 2023. In July 2022, the company moved its corporate headquarters to our subleased space in this location. Effective January 24, 2023, the Company amended the terms of the sublease, which is now set to expire in April 2024. The annual lease payments are subject to a 5% increase each year. In accordance with the lease agreement, the Company is required to maintain a security deposit of $283, which was recorded in restricted cash as of December 31, 2023 and 2022.

On June 1, 2020, the Company entered into a lease agreement for office space located in Toronto, Ontario, Canada, which was set to expire in June 2025. On October 31, 2023, the lease agreement was terminated. The annual lease payments were fixed for years 1 and 2, and then subject to a 6.67% increase for years 3 through 5. In accordance with the lease agreement, the Company was required to maintain a security deposit of CAD$27, which was recorded in other long-term assets as of December 31, 2022. In October 2022, the Company entered into a sublease agreement to sublease this space. The term of the sublease agreement commenced on October 1, 2022 and expires on June 29, 2025. The sublease was also terminated on October 31, 2023.

The following table summarizes the effect of lease costs in the Company's consolidated statement of operations and comprehensive loss:

	Year Ended December 31,	
	2023	2022
Operating lease costs	$ 2,195	$ 2,994
Sublease income	(77)	(23)
Total lease costs	$ 2,118	$ 2,971

During the years ended December 31, 2023 and 2022 the Company made cash payments for operating leases of $2,771 and $3,167, respectively.

As of December 31, 2023, future minimum payments of operating lease liabilities are as follows (in thousands):

	As of December 31, 2023
2024	896
2025	—
2026	—
2027	—
Thereafter	—
Total lease payments	$ 896
Less: interest	(18)
Present value of lease liabilities	$ 878

As of December 31, 2023, the weighted average remaining lease term was 0.3 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 16.15%. As of December 31, 2022, the weighted average remaining lease term was 0.9 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 10.58%.

7. Note Payable

On November 2, 2021 (the "Closing Date"), the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank pursuant to which a term loan in an aggregate principal amount of up to $50,000 (the "Term Loan Facility") was available to the Company in three tranches, subject to certain terms and conditions. The first tranche of $15,000 was advanced to the Company on the Closing Date. Subject to the terms and conditions of the Loan Agreement, the first tranche allowed the Company to borrow an additional $15,000 through October 31, 2023. Upon satisfaction of certain milestones, the second and third tranches were available under the Term Loan Facility which allowed the Company to borrow an additional amount up to $10,000 in each tranche through October 31, 2023. Additionally, the Company could seek to borrow up to an additional $15,000 at the sole discretion of the lender through the term of the Loan Agreement. The Loan Agreement provided for an October 1, 2026 maturity date (the "Maturity Date"). The Company was required to pay an end of term fee ("End of Term Charge") equal to 9.00% of the aggregate principal amount of the Term Loan advances upon repayment.

Advances under the Term Loan Facility bore interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 4.85%, and (ii) 8.10%. The Company was obligated to make interest only payments through November 1, 2024. Following the interest only period, the Company was to repay the principal balance and interest of the advances in equal monthly installments through October 1, 2026.

The Company could prepay advances under the Loan Agreement, in whole or in part, at any time subject to a prepayment charge (the "Prepayment Premium") equal to: (a) 1.50% of amounts so prepaid, if such prepayment occurred during the first year following the Closing Date; (b) 1.00% of the amount so prepaid, if such prepayment occurred during the second year following the Closing Date, and (c) 0.00% of the amount so prepaid, if such prepayment occurred after the second year following the Closing Date.

Upon prepayment or repayment of all or any of the term loans under the Term Loan Facility, the Company was required to pay (in addition to any Prepayment Premium) an end of term charge of 9.0% of the aggregate funded amount under the Term Loan Facility.

The Term Loan Facility was secured by substantially all of the Company's assets, other than the Company's intellectual property. The Company agreed to not pledge or secure its intellectual property to others.

The End of Term Charge is recorded as a debt discount with an initial carrying balance of $1,350. During the year ended December 31, 2021 the Company recognized $103 of debt issuance costs related to legal expenses that has been included in the debt discount balance. The debt discount costs are being accreted to the principal amount of debt and being amortized from the date of issuance through the Maturity Date to interest expense using the effective-interest rate method. The effective interest rate of the outstanding debt under the Loan Agreement was approximately 16.29%.

On June 9, 2023, upon the closing of the Asset Sale, all outstanding amounts due and owed, including principal, interest, and other charges, under the Term Loan Facility, dated as of November 2, 2021, by and among the Company, Silicon Valley Bank, a division of First-Citizens Bank & Trust and the other parties thereto, were repaid in full and the Term Loan Facility was terminated. Upon repayment, the obligations of the Company under the Term Loan Facility were satisfied in full, the Term Loan Facility and all related loan documents were terminated and all liens and security interests granted thereunder were released and terminated (excluding certain indemnification obligations that expressly survive termination of the Term Loan Facility).

As of December 31, 2022 the carrying value of the note payable consists of the following:

	December 31, 2022
Note payable, including End of Term Charge	$ 16,350
Debt discount, net of accretion	(1,074)
Note payable, net of discount, long-term	$ 15,276

During the year ended December 31, 2023, the Company recognized $1,917 of interest expense related to the Loan Agreement, of which $939 is related to the loss on the extinguishment of debt due to the write off of the debt discount balance, which is reflected in other expense, net on the consolidated statements of operations and comprehensive loss. During year ended December 31, 2022, the Company recognized $1,808 of interest expense related to the Loan Agreement.

8. Common Stock

As of December 31, 2023 and 2022, the authorized capital stock of the Company included 150,000,000 shares of common stock, $0.0001 par value, and 10,000,000 shares of undesignated preferred stock. As of December 31, 2023 and 2022, no undesignated shares of preferred stock were outstanding.

In accordance to the Fourth Amended and Restated Certificate of Incorporation, the holders of the common stock shall have the exclusive right to vote for the election of directors of the Company and on all other matters requiring stockholder action, each outstanding share entitling the holder thereof to one vote on each matter properly submitted to the stockholders of the Company for their vote; provided, however, that, except as otherwise required by law, holders of common stock, as such, shall not be entitled to vote on any amendment to any amendment to a certificate of designations of any series of undesignated preferred stock that alters or changes the powers, preferences, rights or other terms of one or more outstanding series of undesignated preferred stock if the holders of such affected series of undesignated preferred stock are entitled to vote, either separately or together with the holders of one or more other such series, on such amendment pursuant to a certificate of designations of any series of undesignated preferred stock.

Through December 31, 2023, no cash dividends have been declared or paid.

Public Offerings

In July 2019, the Company closed an underwritten public offering of 7,475,000 shares of its common stock at a public offering price of $18.50 per share (the “July 2019 Follow-on Offering”), which included 975,000 shares of the Company’s common stock resulting from the full exercise of the underwriters’ option to purchase additional shares at the public offering price, less underwriting discounts and commissions. The net proceeds to the Company from the July 2019 Follow-on Offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, were $129,464.

In February 2020, the Company closed an underwritten public offering of 4,350,000 shares of its common stock at a public offering price of $23.00 per share (the “February 2020 Follow-on Offering”). The net proceeds to the Company from the February 2020 Follow-on Offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, were $93,627.

In June 2020, the Company sold an aggregate of 384,140 shares of common stock under its 2019 “at-the-market” facility (the “2019 ATM Facility”) for net proceeds, after deducting commissions and other offering expenses payable by the Company, of $8,130.

In November 2020, the Company closed an underwritten public offering of 5,000,000 shares of its common stock at a public offering price of $15.00 per share (the "November 2020 Follow-on Offering"). The net proceeds to the Company from the November 2020 Follow-on Offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, were $70,221.

In May 2021, the Company sold an aggregate of 1,829,268 shares of common stock under the 2019 ATM Facility for net proceeds, after deducting commissions and other offering expenses payable by the Company, of $14,550.

There were no public offerings during the years ended December 31, 2023 and 2022.

Common Stock Reserved for Future Issuance

As of December 31, 2023 and 2022, the Company has reserved the following shares of common stock for future issuance:

	December 31,	
	2023	2022
Shares reserved for exercise of outstanding stock options	5,142,272	9,423,271
Shares reserved for vesting of restricted stock units	936,358	940,392
Shares reserved for issuance under the 2018 Stock Option and Incentive Plan	7,978,667	5,005,295
Shares reserved for issuance under the 2018 Employee Stock Purchase Plan	1,771,748	1,467,026
Shares reserved for issuance under the 2019 Inducement Plan	1,407,211	786,656
Shares reserved for issuance under the 2020 Inducement Plan	1,700,000	1,637,000
Total shares of authorized common stock reserved for future issuance	18,936,256	19,259,640

9. Stock-Based Compensation

Amended and Restated 2015 Stock Option and Grant Plan

The Company's Amended and Restated 2015 Stock Option and Grant Plan, (the "2015 Plan") provides for the Company to issue restricted stock awards and restricted stock units, or to grant incentive stock options or non-statutory stock options. Incentive stock options may be granted only to the Company's employees including officers and members of the Board who are also employees. Restricted stock awards and restricted stock units and non-statutory stock options may be granted to employees, members of the Board, outside advisors, and consultants of the Company.

The total number of common shares that may be issued under the 2015 Plan was 2,008,564 shares. Following the IPO, no further grants have been made under 2015 plan.

Shares that expire, are terminated, surrendered or cancelled under the 2015 Plan without having been fully exercised will be available for future awards under the 2018 Plan (as defined below). In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for future awards.

The 2015 Plan is administered by the Board. Equity awards granted to employees and members of the Board typically vest over four years.

2018 Stock Option and Incentive Plan

The Company's 2018 Stock Option and Incentive Plan (the "2018 Plan") was adopted by the Board on June 1, 2018 and approved by stockholders on June 7, 2018 and became effective upon the effectiveness of the Company's Registration Statement on Form S-1. The 2018 Plan replaced the 2015 Plan as the Board determined not to make additional awards under the 2015 Plan following the pricing of the Company's IPO. The 2018 Plan allows the Board, compensation committee or

other designated committee to make equity-based and cash-based incentive awards to its officers, employees, directors and other key persons (including consultants).

The Company initially reserved 616,300 shares of its common stock for the issuance of awards under the 2018 Plan. The 2018 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by its Board or compensation committee (the "Plan Evergreen"). This number is subject to adjustment in the event of a stock split, stock dividend or other change in its capitalization.

On April 16, 2020, the Board adopted an amendment to the 2018 Plan (the "Amendment"), to (i) increase the number of shares of common stock currently reserved for issuance under the 2018 Plan by 3,300,000 shares and (ii) automatically terminate the 2018 Plan's annual increase (or "evergreen") provision after January 2022. The Amendment was approved by the Board on June 4, 2020 and the Company's stockholders on June 4, 2020.

The number of shares of common stock available for future grant under the 2018 Plan was 7,978,667 as of December 31, 2023, which does not include the shares added to the 2018 Plan reserve on January 1, 2024 as a result of the Plan Evergreen for the year ended December 31, 2023.

During the years ended December 31, 2023 and 2022, the Company granted options to purchase 123,501 and, 5,369,650 shares, respectively, of common stock to employees, nonemployees and members of the Board.

2018 Employee Stock Purchase Plan

The Company's 2018 Employee Stock Purchase Plan (the "ESPP") was adopted by the Board on June 1, 2018 and approved by stockholders on June 7, 2018 and became effective upon the effectiveness of the Company's Registration Statement on Form S-1. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of 223,200 shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2019 and each January 1 thereafter through January 1, 2028, by the least of (i) 1% of the outstanding number of shares of our common stock on the immediately preceding December 31; (ii) 1,115,700 shares or (iii) such number of shares as determined by the ESPP administrator (the "ESPP Evergreen"). With respect to the January 1, 2024 ESPP Evergreen, the Company's Compensation Committee opted to allocate zero additional shares to the ESPP share reserve. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization.

During the years ended December 31, 2023 and 2022, the Company issued 134,439 and 120,947 shares, respectively of common stock. The total number of shares of common stock available for future grant was 1,771,748 as of December 31, 2023.

2019 Inducement Plan

The Company's 2019 Inducement Plan (the "2019 Plan") was adopted by the Board on December 11, 2019. The purpose of the 2019 Plan is to allow the Company to grant equity awards to new employees as inducements material to such new employee's acceptance of employment with the Company. The Company intends that the shares underlying the 2019 Plan be reserved for persons to whom the Company may issue securities without stockholder approval as an inducement pursuant to Rule 5635(c)(4) of the Nasdaq marketplace rules.

The Company initially reserved 1,800,000 shares of its common stock for the issuance of awards under the 2019 Plan.

The number of shares of common stock available for future grant under the 2019 Plan was 1,407,211 as of December 31, 2023.

2020 Inducement Plan

The Company's 2020 Inducement Plan (the "2020 Plan") was adopted by the Board on December 9, 2020. The purpose of the 2020 Plan is to allow the Company to grant equity awards to new employees as inducements material to such new employee's acceptance of employment with the Company. The Company intends that the shares underlying the 2020 Plan be

reserved for persons to whom the Company may issue securities without stockholder approval as an inducement pursuant to Rule 5635(c)(4) of the Nasdaq marketplace rules.

The Company initially reserved 1,700,000 shares of its common stock for the issuance of awards under the 2020 Plan.

The number of shares of common stock available for future grant under the 2020 Plan was 1,700,000 as of December 31, 2023.

Stock Option Valuation

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

	Year Ended December 31,	
	2023	2022
Expected option life (years)	6.00	5.98
Risk-free interest rate	3.82%	2.47%
Expected volatility	83.36%	80.43%
Expected dividend yield	— %	— %

The following table summarizes the Company's stock option activity for the year ended December 31, 2023:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	9,423,271	$ 7.26	8.14	$ 22
Granted	123,501	$ 1.09		
Exercised	(297,604)	$ 0.79		
Cancelled or forfeited	(4,106,896)	$ 7.44		
Outstanding as of December 31, 2023	5,142,272	$ 7.33	6.24	$ 663
Exercisable as of December 31, 2023	3,670,053	$ 8.84	5.44	$ 376

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

The aggregate intrinsic value of options exercised during the years ended December 31, 2023 and 2022 was $123 and $50, respectively.

The weighted-average grant-date fair value of the Company's stock options granted during the years ended December 31, 2023 and 2022 was $0.79 and $0.99, respectively.

Restricted Common Stock

The Company has granted restricted common stock (or restricted stock awards) with time-based vesting conditions to certain employees of the Company. The purchase price of the restricted stock awards are determined by the Board. Unvested shares of restricted stock awards may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting conditions of each award. The Company has the option to repurchase the restricted stock awards at the original purchase price if the grantee terminates its working relationship with the Company prior to the vesting date. There were no unvested restricted stock awards as of December 31, 2023.

Restricted Stock Units

Restricted stock units represent an unsecured promise to grant at no cost a set number of shares of common stock upon vesting. With respect to restricted stock units, recipients are not entitled to cash dividends and have no voting rights during the vesting period.

The following table summarizes the Company's restricted stock award and restricted stock unit activity for the year ended December 31, 2023:

	Number of Shares	Weighted-Average Grant Date Fair Value
Issued and unvested as of December 31, 2022	940,392	$ 3.62
Granted	1,548,117	1.65
Vested	(305,502)	4.74
Forfeited, cancelled or expired	(1,246,649)	2.02
Issued and unvested as of December 31, 2023	936,358	$ 2.13

The total fair value of restricted stock awards and restricted stock units vested during the years ended December 31, 2023 and 2022 was $1,449 and $9, respectively.

Stock-Based Compensation

Stock-based compensation expense was allocated as follows:

	Year Ended December 31,	
	2023	2022
Research and development	$ 1,927	$ 2,785
General and administrative	4,964	8,737
Total stock-based compensation expense	$ 6,891	$ 11,522

As of December 31, 2023, total unrecognized compensation cost related to unvested stock-based awards was $4,221, which is expected to be recognized over a weighted-average period of 1.6 years.

10. 401(k) Savings Plan

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. Eligible employees may make pretax contributions to the 401(k) Plan up to statutory limits. At the election of the Board, the Company may elect to match employee contributions. Currently, the Company makes matching contributions at a rate of 50% of the first 8% of employee contributions. The Company recorded $388 and $599 of expenses related to its 401(k) match for the years ended December 31, 2023 and 2022, respectively.

11. Commitments and Contingencies

Lease Agreements

Refer to Note 6 "*Leases*" for discussion of the commitments associated with the Company's lease portfolio.

Other Funding Commitments

The Company enters into contracts in the normal course of business with contract research organizations and clinical sites for the conduct of clinical trials, professional consultants for expert advice and other vendors for clinical supply manufacturing or other services. These contracts are generally cancellable, with notice, at the Company's option and do not have significant cancellation penalties.

Guarantees

The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with directors and officers, business partners, contractors,

landlords and clinical sites. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal.

Litigation

The Company, from time to time, may 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, 2023 and 2022, and to the best of its knowledge, no material legal proceedings are currently pending or threatened.

Other

The Company is also party to various agreements, principally relating to licensed technology, that require future payments relating to milestones not met as of December 31, 2023 and 2022, or royalties on future sales of specified products. No milestone or royalty payments under these agreements are expected to be payable in the immediate future. See Note 3 *"Licenses Agreements"* for discussion of these arrangements.

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to the 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.

12. Income Taxes

For the year ended December 31, 2023, the Company recorded $377 of current income tax expense as a result of the Asset Sale completed on June 9, 2023, and for the year ended December 31, 2022, the Company did not record a current income tax expense or (benefit) due to current and historical losses incurred by the Company. For the years ended December 31, 2023 and 2022 the Company did not record a deferred income tax expense or (benefit) due to current and historical losses incurred by the Company. The Company's operations are predominantly based in the United States and the Company's foreign subsidiaries generated *de minimis* losses for the years ended December 31, 2023 and 2022.

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

	Year Ended December 31,	
	2023	2022
Federal income tax expense at statutory rate	21.0%	21.0%
State income taxes, net of federal benefit	3.7	5.2
Permanent differences	4.4	(1.2)
Foreign rate differential	(0.4)	—
Research and development tax credits	(4.3)	0.8
Change in valuation allowance	(48.2)	(25.8)
Stock based compensation	37.0	—
State rate changes	(8.0)	—
Deferred true ups	(2.2)	—
Provision to return	—	—
Effective income tax rate	3.0%	— %

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 are comprised of the following:

	December 31,	
	2023	2022
Deferred tax assets:		
U.S., foreign and state net operating loss carryforwards	$ 80,185	$ 91,416
Research and development credits	8,356	8,471
Capitalized start up and organizational costs	21	23
Equity based compensation	313	3,610
Licensing agreements	3,710	3,929
Section 174 R&D capitalization	25,045	16,307
Lease liability	240	227
Accruals and other	906	1,032
Total deferred tax assets	118,776	125,015
Valuation allowance	(118,658)	(124,695)
Net deferred tax assets	$ 118	$ 320
Deferred tax liabilities:		
Property and equipment	$ —	$ (102)
ROU Asset	(118)	(218)
Total deferred tax liabilities	(118)	(320)
Net deferred tax liabilities	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. As of December 31, 2023 and 2022 based on the Company's history of operating losses, the Company has concluded that it is not more likely than not that the benefit of its deferred tax assets will be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2023 and 2022. The valuation allowance decreased by $6,037 during the year ended December 31, 2023, due primarily to net operating income, and increased by $23,802 during the year ended December 31, 2022, due primarily to net operating losses generated.

As of December 31, 2023 and 2022, the Company had U.S. federal net operating loss carryforwards of $298,282 and $340,350, respectively, that may be available to offset future income tax liabilities. All of the U.S. federal tax operating losses can be carried forward indefinitely. As of December 31, 2023 and 2022, the Company also had U.S. state net operating loss carryforwards of $277,626 and $316,668, respectively, which may be available to offset future taxable income. These losses expire at various dates beginning in 2041.

As of December 31, 2023 and 2022, the Company had federal research and development tax credit carryforwards of $6,395 and $6,824, respectively. Included in the $6,395 of federal tax credit carryforwards are $2,162 of orphan drug credits. Through the year ended December 31, 2020 the Company qualifies for, and has elected to, apply part of its federal research credits against its payroll tax liability in accordance with certain provisions of the Internal Revenue Code. The amount applied towards the Company's payroll tax liability is capped at $250 per year. The federal research credits generated in excess of the $250 cap are able to be carried forward for 20 years. As of December 31, 2023 and 2022, the Company had state research and development tax credit carryforwards of approximately $2,482 and $2,084, respectively, available to reduce future tax liabilities which expire at various dates beginning in 2035. For all years through December 31, 2023, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percentage points, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. The Company performed an analysis to determine if an ownership change and subsequent limitation of its attributes had occurred. Subsequent ownership changes may further affect the limitation in future years. The Company has completed numerous financings since its inception, which may have

resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future and may result in a limitation in future years.

The Company files income tax returns in the United States, Australia and Canada, and in several states. The foreign, federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2020 through December 31, 2023. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by foreign tax authorities, the Internal Revenue Service, or state tax authorities to the extent utilized in a future period.

13. 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, 2023 and 2022 (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2023	2022
Numerator:		
Net income (loss) attributable to common stockholders—basic and diluted	$ 12,157	$ (105,890)
Denominator:		
Weighted-average common shares outstanding—basic	44,327,204	43,738,739
Effect of dilutive securities:		
Options to purchase common shares	119,677	—
Unvested restricted stock units	95,010	—
Employee stock purchase plan	26,027	—
Weighted-average common shares outstanding—diluted	44,567,918	43,738,739
Net income (loss) per share applicable to common stockholders—basic	$ 0.27	$ (2.42)
Net income (loss) per share applicable to common stockholders—diluted	$ 0.27	$ (2.42)

Diluted earnings per share includes the assumed exercise of dilutive options, the assumed issuance of unvested restricted stock units, and the assumed issuance of shares under the employee stock purchase plan using the treasury stock method unless the effect is anti-dilutive. The treasury stock method assumes that proceeds, including cash received from the exercise of employee stock options and the average unrecognized compensation expense for unvested share-based compensation awards, would be used to purchase the Company's common stock at the average market price during the period.

For the year ended December 31, 2022, for purposes of the diluted net income (loss) per share calculation, stock options, unvested restricted stock units are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net income (loss) per share attributable to common stockholders is the same.

The following potentially dilutive common stock equivalents, presented based on amounts outstanding at each period end, were excluded from the computation of diluted net income (loss) per share attributable to common stockholders for the periods indicated:

	Year Ended December 31,	
	2023	2022
Options to purchase common stock	3,765,482	9,423,271
Restricted stock units	662,103	940,392
Total anti-dilutive shares	4,427,585	10,363,663

14. Related Party Transactions

UHN

In connection with the Company's entry into a license agreement with UHN on January 27, 2016, the Company issued UHN 1,161,665 shares of its common stock. Upon the closing of the IPO in 2018, as UHN's fully-diluted percentage ownership of the Company was reduced within a range of specified percentages, the Company was obligated to pay UHN an amount of $2,000, which was paid in July 2018. For the years ended December 31, 2023 and 2022, the Company recognized

$130 and $200, respectively, of research and development expense related to the license agreements with UHN. Refer to Note 3 *"License and Purchase Agreements"* for additional information regarding the UHN license agreements.

Others

For the years ended December 31, 2023 and 2022, the Company recorded expenses of $934 and $3,200, respectively, related to a sublease to rent lab space, provided by an entity affiliated with a member of the board.

15. Restructuring

In July 2023, the Board approved a reduction in the Company's workforce by approximately 50% across different areas and functions in the Company's July 2023 Workforce Reduction. The July 2023 Workforce Reduction was substantially completed by the end of July 2023. The Company informed affected employees in the July 2023 Workforce Reduction on July 12, 2023. Since the date of the July 2023 Workforce Reduction, the Company's remaining employees have primarily focused on activities relating to halting further development of the Company's programs, the pursuit of strategic alternatives, and the provision of services under the previously disclosed Separation Services Agreement between the Company and Novartis in connection with the sale to Novartis of the Company's cystinosis gene therapy program. Under the July 2023 Workforce Reduction, the Company recognized total restructuring expenses of $3,015 for the year ended December 31, 2023, recognized as $1,800 and $1,215 of research and development and general and administrative expense, respectively, in the consolidated statement of operations and comprehensive income (loss). These one-time employee termination benefits are related to affected employees, who were offered separation benefits, including severance payments. Approximately $479 of these expenses were related to non-cash stock-based compensation expense and there are no remaining accrued payments at December 31, 2023.

The Company's workforce was reduced by 11 employees in the October 2023 Workforce Reduction effective as of October 31, 2023. Under the October 2023 Workforce Reduction, the Company recognized total restructuring expenses of $1,093 for the year ended December 31, 2023 recognized as research and development expense in the consolidated statement of operations and comprehensive income (loss). These one-time employee termination benefits are related to affected employees, who were offered separation benefits, including severance payments. There are no remaining accrued payments at December 31, 2023.

The Company's workforce was reduced by 8 employees in the December 2023 Workforce Reduction effective as of December 31, 2023. Under the December 2023 Workforce Reduction, the Company recognized total restructuring expenses of $950 for the year ended December 31, 2023 recognized as $866 and $64 of research and development and general and administrative expense, respectively, in the consolidated statement of operations and comprehensive income (loss). The Company estimates an additional $86 of expense related to future one-time employee benefits. These one-time employee termination benefits are related to affected employees, who were offered separation benefits, including severance payments. As of December 31, 2023, the Company had $521 in accrued payments. The Company expects that payments of these costs will substantially be made through the end of the first quarter of 2024.

	Employee Severance and Other Benefits
Restructuring expenses	$ 5,058
Cash payments	(4,058)
Non-cash expenses	(479)
Liability included in accrued expenses and other current liabilities at December 31, 2023	$ 521

16. Subsequent Events

On January 30, 2024, following a comprehensive review of strategic alternatives, the Company entered into the Merger Agreement with Tectonic pursuant to which a wholly-owned subsidiary of the Company will merge with and into Tectonic, with Tectonic surviving as a wholly-owned subsidiary of the Company. The Merger was unanimously approved by the Company's Board, and the Company's Board resolved to recommend approval of the Merger Agreement to the Company's stockholders.

The closing of the Merger is subject to approval by the Company's and Tectonic's stockholders as well as other customary closing conditions, including the effectiveness of a registration statement on Form S-4 filed with the SEC in connection with the transaction and Nasdaq's approval of the listing of the shares of the Company's common stock to be

issued in connection with the Merger. If the Company is unable to satisfy certain closing conditions or if other mutual closing conditions are not satisfied, Tectonic will not be obligated to complete the Merger. The Merger Agreement contains certain termination rights of each of the Company and Tectonic. Under certain circumstances detailed in the Merger Agreement, the Company could be required to pay Tectonic a termination fee of approximately $2,713 or Tectonic could be required to pay the Company a termination fee of approximately $4,900. In addition, in certain circumstances upon the termination of the Merger Agreement, the Company could be required to pay the costs and expenses of Tectonic in an amount not to exceed $650. If the Merger is completed, the business of Tectonic will continue as the business of the combined company.

EXHIBIT NO.	EXHIBIT INDEX
2.1**	Asset Purchase Agreement by and among Novartis Pharma AG, Novartis Pharmaceuticals Corporation and, the Registrant, dated May 19, 2023 (filed as Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 10, 2023 (File No. 001-38537) and incorporated herein by reference)
2.2^	Agreement and Plan of Merger, dated as of January 30, 2024, by and among the Registrant, Alpine Merger Subsidiary, Inc. and Tectonic Therapeutic, Inc. (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on January 30, 2024 (File No. 001-38537) and incorporated herein by reference)
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 25, 2018 (File No. 001-38537) and incorporated herein by reference)
3.2	Certificate of Change of Registered Agent and/or Registered Office of the Registrant (filed as Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 5, 2020 (File No. 001-38537) and incorporated herein by reference)
3.3	Amended and Restated By-laws (filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on June 25, 2018 (File No. 001-38537) and incorporated herein by reference)
4.1	Form of Specimen Common Stock Certificate (filed as Exhibit 4.1 to the Registrant's Second Amendment to the Registration Statement on Form S-1 filed on June 11, 2018 (File No. 333-225213) and incorporated herein by reference)
4.2	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (filed as Exhibit 4.3 to the to the Registrant's Annual Report on Form 10-K filed on March 16, 2020 (File No. 001-38537) and incorporated herein by reference)
10.1#	2015 Amended and Restated Stock Option and Grant Plan, as amended, and forms of award agreements thereunder (filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 filed on May 25, 2018 (File No. 333-225213) and incorporated herein by reference)
10.2#	2018 Stock Option and Incentive Plan and forms of award agreements thereunder (filed as Exhibit 10.2 to the Registrant's Second Amendment to the Registration Statement on Form S-1 filed on June 11, 2018 (File No. 333-225213) and incorporated herein by reference)
10.3#	First Amendment to the AVROBIO, Inc. 2018 Stock Option and Incentive Plan (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 9, 2020 (File No. 001-38537) and incorporated herein by reference)
10.4#	Second Amendment to the AVROBIO, Inc. 2018 Stock Option and Incentive Plan (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 10, 2022 (File No. 001-38537) and incorporated herein by reference)
10.5#	Senior Executive Cash Incentive Bonus Plan (filed as Exhibit 10.3 to the Registrant's Second Amendment to the Registration Statement on form S-1 filed on June 11, 2018 (File No. 333-225213) and incorporated herein by reference)
10.6#	Form of Indemnification Agreement (filed as Exhibit 10.4 to the Registrant's Second Amendment to the Registration Statement on Form S-1 filed on June 11, 2018 (File No. 333-225213) and incorporated herein by reference)
10.7†	Exclusive License Agreement, by and between the Registrant and University Health Network, dated November 4, 2016, as amended (filed as Exhibit 10.5 to the Registrant's First Amendment to the Registration Statement on Form S-1 filed on June 1, 2018 (File No. 333-225213) and incorporated herein by reference)
10.8†	License Agreement, by and between the Registrant and BioMarin Pharmaceutical Inc., dated August 31, 2017 (filed as Exhibit 10.6 to the Registrant's Second Amendment to the Registration Statement on Form S-1 filed on June 11, 2018 (File No. 333-225213) and incorporated herein by reference)
10.9††	Amendment No. 1 to License Agreement, by and between the Registrant and BioMarin Pharmaceutical Inc., dated February 21, 2018 (filed as Exhibit 10.7 to the to the Registrant's Annual Report on Form 10-K filed on March 16, 2020 (File No. 001-38537) and incorporated herein by reference)

EXHIBIT NO.	EXHIBIT INDEX
10.10††	Amendment No. 2 to License Agreement, by and between the Registrant and BioMarin Pharmaceutical Inc., dated January 7, 2020 (filed as Exhibit 10.8 to the to the Registrant's Annual Report on Form 10-K filed on March 16, 2020 (File No. 001-38537) and incorporated herein by reference)
10.11†	Exclusive License Agreement, by and among the Registrant, Stefan Karlsson and Maria Dahl, dated January 30, 2017 (filed as Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 filed on May 25, 2018 (File No. 333-225213) and incorporated herein by reference)
10.12#	Amended and Restated Employment Agreement, by and between the Registrant and Geoff MacKay, effective as of June 25, 2018 (filed as Exhibit 10.9 to the Registrant's Second Amendment to the Registration Statement on Form S-1 filed on June 11, 2018 (File No. 333-225213) and incorporated herein by reference)
10.13#	Amendment to Employment Agreement, by and between the Registrant and Geoff MacKay, dated April 5, 2021 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 13, 2021 (File No. 001-38537) and incorporated herein by reference)
10.14#	Employment Agreement, by and between the Registrant and Erik Ostrowski, dated December 17, 2018 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 21, 2018 (File No. 001-38537) and incorporated herein by reference)
10.15#	Amendment to Employment Agreement, by and between the Registrant and Erik Ostrowski, dated April 5, 2021 (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 13, 2021 (File No. 001-38537) and incorporated herein by reference)
10.16#	Employment Agreement, by and between the Registrant and Steven Avruch, dated December 17, 2018 (filed as Exhibit 10.13 to the Registrant's Annual Report on Form 10-K filed on March 25, 2019 (File No. 001-38537) and incorporated herein by reference)
10.17#	Amendment to Employment Agreement, by and between the Registrant and Steven Avruch, dated April 5, 2021 (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on May 13, 2021 (File No. 001-38537) and incorporated herein by reference)
10.18#	Employment Agreement, by and between the Registrant and Deanna Petersen, dated September 1, 2018 (filed as Exhibit 10.16 to the Registrant's Annual Report on Form 10-K filed on March 16, 2020 (File No. 001-38537) and incorporated herein by reference)
10.19#	Amendment to Employment Agreement, by and between the Registrant and Deanna Petersen, dated April 5, 2021 (filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed on May 13, 2021 (File No. 001-38537) and incorporated herein by reference)
10.20#	Employment Agreement, by and between the Registrant and Essra Ridha, dated October 6, 2021 (filed as Exhibit 10.22 to the Registrant's Annual Report on Form 10-K filed on March 17, 2022 (File No. 001-38537) and incorporated herein by reference)
10.21#	2018 Employee Stock Purchase Plan (filed as Exhibit 10.14 to the Registrant's Second Amendment to the Registration Statement on Form S-1 filed on June 11, 2018 (File No. 333-225213) and incorporated herein by reference)
10.22	Lease Agreement, dated as of January 12, 2018, by and between the Registrant and ARE-MA Region No. 59, LLC (filed as Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 filed on May 25, 2018 (File No. 333-225213) and incorporated herein by reference)
10.23#	2019 Inducement Plan and form of award agreement thereunder (filed as Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 filed on December 20, 2019 (File No. 333-235643) and incorporated herein by reference)
10.24#	Form of 2019 Inducement Stock Option Award (filed as Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 filed on March 25, 2019 (File No. 333-230493) and incorporated herein by reference)
10.25#	2020 Inducement Plan and form of award agreement thereunder (filed as Exhibit 10.25 to the Registrant's Annual Report on Form 10-K filed on March 18, 2021 (File No. 001-38537) and incorporated herein by reference)

EXHIBIT NO.	EXHIBIT INDEX
10.26††	Amended and Restated Master Services Agreement, by and between the Registrant and Miltenyi Biotec, Inc., dated November 20, 2021 (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2022 (File No. 001-38537) and incorporated herein by reference)
10.27	Form of the AVROBIO Support Agreement (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on January 30, 2024 (File No. 001-38537) and incorporated herein by reference)
10.28	Form of Lock-Up Agreement (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on January 30, 2024 (File No. 001-38537) and incorporated herein by reference)
10.29#	Employment Agreement, by and between the Registrant and Azadeh Golipour, dated January 26, 2022 (filed as Exhibit 10.21 to the Registrant's Registration Statement on Form S-4 filed on February 14, 2024 (File No. 333-277048) and incorporated herein by reference)
10.30#	Employment Relocation and Transition Benefits Agreement, by and between the Registrant and Azadeh Golipour, dated January 31, 2022 (filed as Exhibit 10.22 to the Registrant's Registration Statement on Form S-4 filed on February 14, 2024 (File No. 333-277048) and incorporated herein by reference)
21.1	Subsidiaries of the Registrant
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature page)
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Compensation Recovery (Clawback) Policy adopted October 5, 2023
101.INS	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL")
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

* Indicates the exhibit is being furnished, not filed, with this report.

**Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(2)(ii). Such excluded information is not material and is the type that the Registrant customarily and actually treats as private or confidential.

^Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally copies of any of the omitted exhibits and schedules upon request by the SEC; *provided*, *however*, that the Registrant may request confidential treatment pursuant to Rule 24b-2 under the Exchange Act for any exhibits or schedules so furnished.

† Confidential treatment has been granted for portions of this Exhibit pursuant to Rule 406 promulgated under the Securities Act of 1933, as amended.

†† Portions of this exhibit have been omitted because they are both (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 14th day of March, 2024.

AVROBIO, INC.

By: /s/ Erik Ostrowski
Erik Ostrowski
President, Interim Chief Executive Officer, Chief Financial Officer and Treasurer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Erik Ostrowski as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Erik Ostrowski Erik Ostrowski	President, Interim Chief Executive Officer, Chief Financial Officer, and Treasurer *(Principal Executive, Financial, and Accounting Officer)*	March 14, 2024
/s/ Bruce Booth Bruce Booth, D.Phil.	Chairman of the Board of Directors	March 14, 2024
/s/ Ian T. Clark Ian T. Clark	Director	March 14, 2024
/s/ Gail Farfel, Ph.D. Gail Farfel	Director	March 14, 2024
/s/ Phillip B. Donenberg Phillip B. Donenberg	Director	March 14, 2024
/s/ Annalisa Jenkins Annalisa Jenkins, M.B.B.S., F.R.C.P	Director	March 14, 2024
/s/ Christopher Paige Christopher Paige, Ph.D.	Director	March 14, 2024
/s/ Philip J. Vickers Philip J. Vickers, Ph.D.	Director	March 14, 2024

Exhibit 21.1

List of Subsidiaries

Subsidiary	Jurisdiction of incorporation or organization
AVROBIO Inc.	Ontario, Canada
AVROBIO Australia Pty Ltd	Australia
AVROBIO Securities Corporation	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-225788) pertaining to the Amended and Restated 2015 Stock Option and Grant Plan, the 2018 Stock Option and Incentive Plan, and the 2018 Employee Stock Purchase Plan of AVROBIO, Inc.,

(2) Registration Statements (Form S-8 Nos. 333-230493 and 333-234641) pertaining to the Inducement Stock Option Agreement of AVROBIO, Inc.,

(3) Registration Statements (Form S-8 Nos. 333-230494, 333-237203 and 333-263655) pertaining to the 2018 Stock Option and Incentive Plan and the 2018 Employee Stock Purchase Plan of AVROBIO, Inc.,

(4) Registration Statement (Form S-8 No. 333-235643) pertaining to the 2019 Inducement Plan and the Inducement Stock Option Agreement of AVROBIO, Inc.,

(5) Registration Statements (Form S-8 Nos. 333-241400 and 333-266710) pertaining to the 2018 Stock Option and Incentive Plan of AVROBIO, Inc.,

(6) Registration Statement (Form S-8 No. 333-254466) pertaining to the 2020 Inducement Plan, the 2018 Stock Option and Incentive Plan and the 2018 Employee Stock Purchase Plan of AVROBIO, Inc.,

(7) Registration Statement (Form S-8 No. 333-270799) pertaining to the 2018 Employee Stock Purchase Plan of AVROBIO, Inc., and

(8) Registration Statement (Form S-4 No. 333.277048) of AVROBIO, Inc.;

of our report dated March 14, 2024, with respect to the consolidated financial statements of AVROBIO, Inc. included in this Annual Report (Form 10-K) of AVROBIO, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 14, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Erik Ostrowski, certify that:

1. I have reviewed this Annual Report on Form 10-K of AVROBIO, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 14, 2024

By: /s/ Erik Ostrowski

Erik Ostrowski
President, Interim Chief Executive Officer, Chief Financial Officer and Treasurer
(Principal Executive, Financial, and Accounting Officer)

Exhibit 32.1

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

In connection with the Annual Report of AVROBIO, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his or her knowledge that:

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

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

Date: March 14, 2024

By: /s/ Erik Ostrowski

Erik Ostrowski
President, Interim Chief Executive Officer,
Chief Financial Officer and Treasurer
(Principal Executive, Financial, and Accounting Officer)

Exhibit 97.1

AVROBIO, INC.

COMPENSATION RECOVERY POLICY

Adopted as of October 5, 2023

AVROBIO, Inc., a Delaware corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market LLC. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any Executive Officer and any other person designated by the Board or the Committee as being subject to this Policy. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be

considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means October 2, 2023.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs.

h. "Exchange" means the Nasdaq Stock Market LLC.

i. An "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation and received Incentive-Based Compensation after beginning service in any such role (regardless of whether such Incentive-Based Compensation was received during or after such person's service in such role): the president, principal executive officer, principal financial officer, principal accounting officer (or, if there is no such accounting officer, the controller), any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the Company. Executive officers of subsidiaries of the Company may be deemed Executive Officers of the Company if they perform such policy making functions for the Company. As used herein, "policy-making function" is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this section would include at a minimum executive officers identified pursuant to 17 CFR 229.401(b).

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure

l. A "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

m. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement, or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee; provided, however, that the Board shall have exclusive authority to authorize the Company to prepare a Financial Restatement. In doing so, the Board may rely on a recommendation of the Audit Committee of the Board. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments Not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.

Adopted: October 5, 2023