UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

OR

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

For the transition period from _____ to

Commission File Number: 001-38537

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.)**
One Broadway Fourteenth Floor Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	**(Zip Code)**

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

100 Technology Square
Sixth Floor
Cambridge, Massachusetts 02139
(Former name, former address and former fiscal year, if changed since last report)

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

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

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, 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☒ No ☐

As of May 2, 2024, the registrant had 44,893,750 shares of common stock, $0.0001 par value per share, outstanding.

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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 Quarterly Report on Form 10-Q, 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.

Note Regarding Forward-looking Statements

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q that modify or impact any of the forward-looking statements contained in this Quarterly Report on Form 10-Q will be deemed to modify or supersede such statements in this Quarterly Report on Form 10-Q.

Note Regarding Trademarks

All brand names or trademarks appearing in this Quarterly Report are the property of their respective holders. Unless the context requires otherwise, references in this Quarterly Report to the "Company," "AVROBIO," "we," "us," and "our" refer to AVROBIO, Inc.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except per share data)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 90,481	$ 98,020
Restricted cash	283	283
Prepaid expenses and other current assets	1,074	1,958
Total current assets	91,838	100,261
Operating lease assets	110	432
Restricted cash, net of current portion	400	400
Total assets	$ 92,348	$ 101,093
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 243	$ 27
Accrued expenses and other current liabilities	3,042	5,449
Operating lease liabilities	224	878
Total current liabilities	3,509	6,354
Total liabilities	3,509	6,354
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000 shares authorized and no shares issued or outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 150,000 shares authorized; 44,882 and 44,654 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	572,918	572,010
Accumulated deficit	(484,083)	(477,275)
Total stockholders' equity	88,839	94,739
Total liabilities and stockholders' equity	$ 92,348	$ 101,093

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

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 683	$ 17,333
General and administrative	7,258	7,887
Total operating expenses	7,941	25,220
Loss from operations	(7,941)	(25,220)
Other income:		
Interest income, net	1,146	248
Other (expense) income, net	(13)	15
Total other income, net	1,133	263
Net loss and comprehensive loss attributable to common stockholders—basic and diluted	$ (6,808)	$ (24,957)
Earnings per share:		
Net loss per share — basic and diluted	$ (0.15)	$ (0.57)
Shares used in computing earnings per share:		
Weighted-average number of common shares outstanding — basic and diluted	44,791	44,037

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

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands)

	Three Months Ended March 31, 2023				
	Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance as of December 31, 2022	**43,916**	**$ 4**	**$ 564,798**	**$ (489,432)**	**$ 75,370**
Vesting of restricted stock units	105	—	—	—	—
Exercise of stock options	46	—	42	—	42
Issuance of common stock under the 2018 employee stock purchase plan	21	—	13	—	13
Stock-based compensation expense	—	—	2,530	—	2,530
Net loss	—	—	—	(24,957)	(24,957)
Balance as of March 31, 2023	**44,088**	**$ 4**	**$ 567,383**	**$ (514,389)**	**$ 52,998**

	Three Months Ended March 31, 2024				
	Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance as of December 31, 2023	**44,654**	**$ 4**	**$ 572,010**	**$ (477,275)**	**$ 94,739**
Vesting of restricted stock units	191	—	—	—	—
Exercise of stock options	33	—	26	—	26
Issuance of common stock under the 2018 employee stock purchase plan	4	—	4	—	4
Stock-based compensation expense	—	—	878	—	878
Net loss	—	—	—	(6,808)	(6,808)
Balance as of March 31, 2024	**44,882**	**$ 4**	**$ 572,918**	**$ (484,083)**	**$ 88,839**

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

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (6,808)	$ (24,957)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	878	2,530
Depreciation and amortization expense	—	328
Non-cash interest expense	—	80
Non-cash lease expense	322	592
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	884	2,187
Accounts payable	216	207
Current and non-current operating lease liabilities	(654)	(600)
Accrued expenses and other current liabilities	(2,407)	(651)
Net cash used in operating activities	(7,569)	(20,284)
Cash flows from investing activities:		
Purchases of property and equipment	—	(8)
Net cash used in investing activities	—	(8)
Cash flows from financing activities:		
Proceeds from exercise of stock options	26	42
Proceeds from issuance of ESPP shares	4	13
Net cash provided by financing activities	30	55
Net decrease in cash, cash equivalents and restricted cash	(7,539)	(20,237)
Cash, cash equivalents and restricted cash at beginning of period	98,703	92,846
Cash, cash equivalents and restricted cash at end of period	$ 91,164	$ 72,609
Supplemental disclosure of non-cash investing and financing activities:		
Interest paid	$ —	$ 463
Lease liability arising from obtaining right-of-use assets	—	2,392
Reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets:		
Cash and cash equivalents, end of period	$ 90,481	$ 72,326
Restricted cash	683	283
Cash, cash equivalents and restricted cash, end of period	$ 91,164	$ 72,609

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

AVROBIO, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share data)

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. On January 30, 2024, the Company entered into the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), with Alpine Merger Subsidiary, Inc. ("Merger Sub"), a direct, wholly owned subsidiary of the Company, and Tectonic Therapeutic, Inc. ("Tectonic") pursuant to which Merger Sub will merge with and into Tectonic, with Tectonic surviving as a wholly-owned subsidiary of the Company (the "Merger").

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 March 31, 2024, the Company had an accumulated deficit of $484,083. The Company expects that its cash and cash equivalents of $90,481 as of March 31, 2024 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 Quarterly Report on Form 10-Q 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 on June 9, 2023 and recognized $83,736 as a gain on asset sale, net of $3,764 transaction costs, in the condensed consolidated statement of operations and comprehensive income (loss) for the three months ended March 31, 2024. 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, December 2023 Workforce Reduction, and February 2024 Workforce Reduction were offered separation benefits, including severance payments. See Note 12 for further discussion.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements (the "unaudited condensed 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 the FASB.

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements as of and for the year ended December 31, 2023, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of March 31, 2024, and the results of its operations for the three months ended March 31, 2024 and 2023, its statements of stockholders' equity for the three months ended March 31, 2024 and 2023 and its statement of cash flows for the three months ended March 31, 2024 and 2023.

The results for the three months ended March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024, any other interim periods, or any future year or period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2023, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 14, 2024.

The unaudited condensed consolidated financial statements reflect the application of certain significant accounting policies as described below and elsewhere in these notes to the unaudited condensed consolidated financial statements. As of March 31, 2024, there have been no changes to the Company's significant accounting policies as described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

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 the unaudited condensed consolidated 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 ongoing 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.

Significant estimates relied upon in preparing the unaudited condensed consolidated financial statements include the determination of the fair value of share-based awards issued and the estimation of accrued research and development expenses.

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.

Prior to the adoption of ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, the measurement date for non-employee awards was generally the date the services are 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 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. 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.

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.

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 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 had 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 expected 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 three months ended March 31, 2024, the Company did not incur costs related to the CRFA. For the three months ended March 31, 2023, the Company incurred $1,610 related to the CRFA.

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 is also required to pay UHN future annual license maintenance fees until

the first sale of a licensed product in certain markets. The Company is 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 has agreed to pay a low double-digit royalty percentage of all sublicensing revenue.

The agreement requires the Company to meet certain performance milestones within specified timeframes. UHN may terminate the agreement if the Company fails 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 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 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 expires upon the expiration of the Company's royalty obligation for all licensed products. UHN can terminate the agreement if the Company fails 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 may 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 can 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 three months ended March 31, 2024, the Company did not incur research and development expense related to this agreement with UHN. For the three months ended March 31, 2023 the Company recorded research and development expense related to this agreement with UHN of $34, which consists of reimbursable funded study trial costs. No milestone or maintenance fees were incurred related to this agreement in the three months ended March 31, 2024 and 2023.

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 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 three months ended March 31, 2024, the Company did not incur research and development expense related to this agreement with UHN. For the three months ended March 31, 2023 the Company recorded research and development expense related to this agreement with UHN of $37. No milestone fees were incurred related to this agreement in the three months ended March 31, 2024 and 2023.

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 has 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 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.

The Company has recognized no expenses related to the license for the three months ended March 31, 2024 and 2023.

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 Therapeutics, Inc. ("Papillon"). On June 9, 2023, in connection with the close of the Asset Purchase Agreement, discussed and defined above, the Company transferred this agreement to Novartis.

The Company has recognized no expenses related to this agreement for the three months ended March 31, 2024 and 2023.

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.

(in thousands, except share and per share data)

The Company has recognized no expenses related to this agreement for the three months ended March 31, 2024 and 2023.

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. During the year ended December 31, 2023, 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 Measurement

The following table presents information about the Company's financial assets 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 March 31, 2024 and December 31, 2023:

	Fair Value Measurements as of March 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents ─ money market funds	$ 89,229	$ —	$ —	$ 89,229
	$ 89,229	$ —	$ —	$ 89,229

	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

The fair value of cash equivalents was determined through quoted prices by third-party pricing services.

During the three months ended March 31, 2024, 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:

	March 31, 2024	December 31, 2023
Other current assets	$ 626	$ 570
Prepaid insurance	411	816
Prepaid research and development expenses	37	572
Prepaid expenses and other current assets	$ 1,074	$ 1,958

Restricted cash

As of March 31, 2024 and December 31, 2023, the Company had restricted cash as presented in the table below, which consists of cash used to secure letters of credit for the benefit of the landlord in connection with the Company's lease agreements as well as

(in thousands, except share and per share data)

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.

	March 31, 2024	December 31, 2023
Restricted cash	$ 283	$ 283
Restricted cash, net of current portion	400	400

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2024	December 31, 2023
Consulting and professional fees	$ 1,630	$ 892
Compensation and benefit costs	686	3,463
Research and development expenses	396	711
Other liabilities	330	383
Accrued expenses and other current liabilities	$ 3,042	$ 5,449

6. Leases

On August 31, 2018, the Company entered into a sublease agreement for office and lab space located in Cambridge Massachusetts, United States, which originally was set to expire in October 2020 but was subsequently amended and expired on April 30, 2024. In July 2022, the Company moved its corporate headquarters to this subleased location. Effective January 24, 2023, the Company amended the terms of the sublease, which expired on April 30, 2024. In accordance with the sublease agreement, the Company was required to maintain a security deposit of $283, which was recorded in restricted cash as of March 31, 2024 and December 31, 2023. In July 2023, the Company ceased use of the lab space. This resulted in an impairment of the right of use asset of $940, recognized in the third quarter of 2023. Effective as of April 22, 2024, the Company moved its corporate headquarters to its current location at One Broadway, 14th Floor, Cambridge, Massachusetts 02142.

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. In accordance with the lease agreement, the Company was required to maintain a security deposit of CAD$27. 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 was set to expire 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:

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Operating lease costs	$ 339	$ 670
Sublease income	—	(23)
Total lease costs	$ 339	$ 647

During the three months ended March 31, 2024 and 2023, the Company made cash payments for operating leases of $672 and $687, respectively.

As of March 31, 2024, future minimum payments of operating lease liabilities are as follows:

(in thousands, except share and per share data)

	March 31, 2024
2024	$ 224
2025	—
2026	—
2027	—
Thereafter	—
Total lease payments	$ 224
Less: interest	—
Present value of lease liabilities	$ 224

As of March 31, 2024, the weighted average remaining lease term was 0.1 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 16.15%. As of March 31, 2023, the weighted average remaining lease term was 1.2 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 15.67%.

7. Commitments and Contingencies

Legal Proceedings

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 three months ended March 31, 2024 and 2023 and to the best of the Company's 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 at March 31, 2024 and December 31, 2023, or royalties on future sales. No milestone or royalty payments under these agreements are expected to be payable in the immediate future, except as disclosed in Note 3 *"License Agreements."*

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. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of March 31, 2024. The Company does not anticipate recognizing any significant losses relating to these arrangements. 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.

(in thousands, except share and per share data)

8. Stockholders' Equity

Common Stock

As of March 31, 2024 and December 31, 2023, 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 March 31, 2024 and December 31, 2023, no undesignated preferred stock was outstanding.

Through March 31, 2024, no cash dividends have been declared or paid.

Common Stock Reserved for Future Issuance

As of March 31, 2024 and December 31, 2023, the Company has reserved the following shares of common stock for future issuance:

	March 31, 2024	December 31, 2023
Shares reserved for exercise of outstanding stock options	4,812,817	5,142,272
Shares reserved for vesting of restricted stock units	677,785	936,358
Shares reserved for issuance under the 2018 Stock Option and Grant Plan	8,299,245	7,978,667
Shares reserved for issuance under the 2018 Employee Stock Purchase Plan	1,771,748	1,771,748
Shares reserved for issuance under the 2019 Inducement Plan	1,511,183	1,407,211
Shares reserved for issuance under the 2020 Inducement Plan	1,700,000	1,700,000
Total shares of authorized common stock reserved for future issuance	18,772,778	18,936,256

9. Stock-based Compensation

Stock Option Valuation

The following table summarizes the Company's stock option activity for the three months ended March 31, 2024:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	5,142,272	$ 7.33	6.24	$ 663
Granted	—	$ —		
Exercised	(32,756)	$ 0.79		
Cancelled or forfeited	(296,699)	$ 9.71		
Outstanding as of March 31, 2024	4,812,817	$ 7.23	6.09	$ 519
Exercisable as of March 31, 2024	3,639,245	$ 8.45	5.46	$ 346

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 three months ended March 31, 2024 and 2023 was $16 and $1, respectively.

(in thousands, except share and per share data)

Restricted Stock Units

The following table summarizes the Company's restricted common stock units for the three months ended March 31, 2024:

	Number of Shares	Weighted-Average Grant Date Fair Value
Issued and unvested as of December 31, 2023	936,358	$ 2.13
Granted	60,251	$ 1.31
Vested	(190,973)	$ 1.71
Forfeited, cancelled or expired	(127,851)	$ 2.49
Issued and unvested as of March 31, 2024	677,785	$ 2.11

The total fair value of restricted stock units vested during the three months ended March 31, 2024 and 2023 was $326 and $194, respectively.

Stock-Based Compensation

Stock-based compensation expense was allocated as follows:

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 170	$ 622
General and administrative	708	1,908
Total stock-based compensation expense	$ 878	$ 2,530

As of March 31, 2024, total unrecognized compensation cost related to the unvested stock-based awards was $2,911, which is expected to be recognized over a weighted-average period of 1.91 years.

10. Net Income (Loss) Per Share

For purposes of the diluted net loss per share calculation, stock options and unvested restricted stock 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 loss per share 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 loss per share for the periods indicated:

	Three Months Ended March 31,	
	2024	2023
Options to purchase common stock	4,812,817	9,154,769
Restricted stock units	677,785	2,026,338

11. Related Party Transactions

UHN

For the three months ended March 31, 2024, the Company did not recognize research and development expense related to the license agreements with UHN. For the three months ended March 31, 2023, the Company recognized $71 of research and development expense related to the license agreements with UHN. Refer to Note 3 "*License Agreements*" for additional information regarding the UHN license agreements.

Others

In the first quarter of 2023, the sublease for space that was previously provided by an entity affiliated with a member of the Company's Board was assigned to Novartis. Therefore, for the three months ended March 31, 2024 the Company did not record expense related to a sublease to rent office and lab space provided by an entity affiliated with a member of the Company's Board. For

(in thousands, except share and per share data)

the three months ended March 31, 2023 the Company recorded $652 related to the sublease to rent office and lab space previously provided by an entity affiliated with a member of the Company's Board.

12. Restructuring Activities

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). For the three months ended March 31, 2024 and 2023, no related expense was recognized. 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 as of March 31, 2024.

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). For the three months ended March 31, 2024 and 2023, no related expense was recognized. 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 as of March 31, 2024.

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). For the three months ended March 31, 2024 the Company recognized $74 and $9 of research and development and general and administrative expense, respectively, in the consolidated statement of operations and comprehensive loss. For the three months ended March 31, 2023, no related expense was recognized. 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 as of March 31, 2024.

The Company's workforce was reduced by 2 employees in the February 2024 Workforce Reduction effective as of February 29, 2024. Under the February 2024 Workforce Reduction, the Company recognized total restructuring expenses of $241 for the three months ended March 31, 2024 recognized as $146 and $96 of research and development and general and administrative expense, respectively, in the consolidated statement of operations and comprehensive loss. For the three months ended March 31, 2023, no related expense was recognized. 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 as of March 31, 2024.

	Three Months Ended March 31, 2024
Restructuring expenses	$ 5,299
Cash payments	(4,820)
Non-cash expenses	(479)
Liability included in accrued expenses and other current liabilities at March 31, 2024	$ —

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes for the year ended December 31, 2023 included in our Annual Report on Form 10-K for the year ended December 31, 2023. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties and assumptions. Factors that might cause future results to differ materially from those projected in the forward-looking statements include, but are not limited to, those set forth in our Annual Report on Form 10-K for the year ended December 31, 2023, as supplemented by our subsequent filings with the SEC.

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 our Board of Directors, or 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, or Hunter syndrome, 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 Pharma AG and Novartis Pharmaceuticals Corporation, or collectively Novartis. As of the date of the filing of this Quarterly 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, we entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Alpine Merger Subsidiary, Inc., our direct, wholly owned subsidiary, or Merger Sub, and Tectonic pursuant to which Merger Sub will merge with and into Tectonic, with Tectonic surviving as our 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, we anticipate 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 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. The closing of the merger is conditioned upon the satisfaction or waiver of the receipt of cash proceeds not less than $114.5 million in connection with the consummation of the transactions contemplated by the private financings. 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 our company.

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 March 31, 2024, 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 initial public offering, or IPO, and follow-on offerings; gross cash proceeds, before deducting commissions and expenses, of $23.5 million from sales of our common stock through our prior "at-the-market" facility, or our prior ATM facility; $15.0 million drawn in term loans under the Term Loan Agreement (as defined below), 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 the Company's 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 loss was $6.8 million and $25.0 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $484.1 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 contract research organizations, or CROs, contract manufacturing organizations, or 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):

	Three Months Ended March 31,	
	2024	2023
Fabry	$ (34)	$ 1,256
Gaucher	(25)	5,119
Cystinosis	—	456
Hunter	—	1,653
Pompe	—	24
Other research activities	(12)	45
Unallocated research and development expenses	754	8,780
Total research and development expenses	$ 683	$ 17,333

Research and development activities will be central to our business model, should we resume development of our product candidates. 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. As a result, should we resume development of our product candidates, we expect that our research and development expenses will increase substantially over the next several years, particularly as we increase personnel costs, including stock-based compensation, contractor costs and facilities costs, as we continue to advance the development of our product candidates. Should we resume development of our product candidates, we 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. See “Risk Factors—Risks related to our

business, financial position and need for additional capital—We have incurred net losses since inception. We expect to incur net losses for the foreseeable future and may never achieve or maintain profitability."

The successful development and commercialization of our product candidates is highly uncertain. At this time, should we resume development of our product candidates, 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 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 Quarterly Report on Form 10-Q.

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 U.S. Food and Drug Administration, or 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 (Expense) Income, 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 the Term Loan Agreement.

Consolidated Results of Operations

Comparison of the three months ended March 31, 2024 and 2023

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

	Three Months Ended March 31,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 683	$ 17,333	$ (16,650)
General and administrative	7,258	7,887	(629)
Total operating expenses	7,941	25,220	(17,279)
Loss from operations	(7,941)	(25,220)	17,279
Other income:			
Interest income, net	1,146	248	898
Other (expense) income, net	(13)	15	(28)
Total other income, net	1,133	263	870
Net loss	$ (6,808)	$ (24,957)	$ 18,149

Research and Development Expenses

Research and development expenses decreased by approximately $16.7 million to $0.7 million for the three months ended March 31, 2024, from $17.3 million for the three months ended March 31, 2023. This decrease was driven by a $6.7 million decrease in personnel-related and consulting costs, including non-cash stock-based compensation, a $5.7 million decrease in development costs, a $2.7 million decrease in manufacturing costs, a $0.2 million decrease in preclinical costs, and a $1.2 million decrease in allocated facility expense.

General and Administrative Expenses

General and administrative expenses were $7.3 million for the three months ended March 31, 2024, compared to $7.9 million for the three months ended March 31, 2023. This decrease of $0.6 million was driven by a $2.5 million decrease in personnel-related and consulting costs, including non-cash stock-based compensation, a $0.4 million decrease in rent expense, a $0.3 million decrease in depreciation expense, and a $0.3 million decrease in information technology-related costs which were partially offset by a $1.7 million increase in legal expenses and a $1.2 million increase in allocated facility expense.

Other Income, Net

Other income, net, was $1.1 million for the three months ended March 31, 2024, compared to $0.3 million for the three months ended March 31, 2023. This change is primarily due to the elimination of interest expense related to the Term Loan Agreement, which was paid off in the second quarter of 2023.

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 March 31, 2024, 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 March 31, 2024, 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, or the Term Loan Agreement, were repaid in full and the Term Loan Agreement was terminated. Upon repayment, the obligations of the Company under the Term Loan Agreement were satisfied in full, the Term Loan Agreement 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 Agreement).

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 March 31, 2024, we had cash and cash equivalents of $90.5 million. Cash in excess of immediate requirements is invested primarily with a view to liquidity and capital preservation.

Cash Flows

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

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	$ (7,569)	$ (20,284)
Net cash used in investing activities	—	(8)
Net cash provided by financing activities	30	55
Net decrease in cash and cash equivalents	$ (7,539)	$ (20,237)

Operating Activities

During the three months ended March 31, 2024, operating activities used $7.6 million of cash, cash equivalents and restricted cash, resulting from our net loss of $6.8 million and from cash used by changes in our operating assets and liabilities of $2.0 million, which was offset by non-cash charges of $1.2 million. The net change in our operating assets and liabilities was primarily due to a $2.4 million decrease in accrued expenses and other current liabilities and a $0.7 million decrease in current and non-current operating lease liabilities, which were partially offset by a $0.9 million decrease in prepaids and other current assets. The non-cash charges primarily included $0.9 million of stock-based compensation expense and $0.3 million in non-cash lease expense.

During the three months ended March 31, 2023, operating activities used $20.3 million of cash, cash equivalents and restricted cash, resulting from our net loss of $25.0 million and cash provided by changes in our operating assets and liabilities of $1.1 million and partially offset by non-cash charges of $3.5 million. The net changes in our operating assets and liabilities were primarily due to a $2.2 million decrease in prepaids and other current assets, offset by a $0.7 million decrease in accrued expenses and other current liabilities and a $0.6 million decrease in current and non-current operating lease liabilities. The non-cash charges primarily included $2.5 million of stock-based compensation expense, $0.6 million in non-cash lease expense, and $0.3 million of depreciation and amortization expense.

Investing Activities

No cash was provided by, or used in, investing activities for the three months ended March 31, 2024 compared to cash used in investing activities of less than ($0.1) million for the three months ended March 31, 2023.

Financing Activities

Net cash provided by financing activities was less than $0.1 million for the three months ended March 31, 2024 compared to cash provided by financing activities of $0.1 million for the three months ended March 31, 2023.

Funding Requirements

Should we resume development of our product candidates, we may not be able to resume activities at the same costs as previously, and we expect our expenses would increase substantially, particularly as we advance the preclinical activities and clinical trials of our product candidates. Our expenses would also increase, should we resume development of our product candidates, as we:

- initiate additional clinical trials and preclinical studies for our product candidates;
- seek to identify and develop or in-license or acquire additional product candidates and technologies;
- seek to industrialize our *ex vivo* lentiviral 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, medical, manufacturing, quality, commercial 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.

Contractual Obligations and Commitments

The disclosure of our contractual obligations and commitments is set forth under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 14, 2024.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting 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. During the three months ended March 31, 2024, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which was filed with the SEC on March 23, 2023, and the notes to the consolidated financial statements included in Item 1, “*Condensed Consolidated Unaudited Financial Statements*,” of this Quarterly Report on Form 10-Q.

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 consolidated financial statements appearing at the beginning of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Risk

As of March 31, 2024, we had cash and cash equivalents of $90.5 million, which consisted of primarily money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are in held in short-term money market funds. Due to short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

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 the three months ended March 31, 2024 and 2023, we recognized foreign currency transaction losses of $13 and $28, respectively. 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, Great British Pound, and Canadian dollar would not have a material impact on our financial position or results of operations.

As we continue to grow our business, 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 4. 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 March 31, 2024. 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 officer and principal financial officer, 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. While we continue to evaluate our disclosure controls and procedures, including new procedures and processes relating to our internal control over financial reporting, based on the evaluation of our disclosure controls and procedures as of March 31, 2024, our interim Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2024.

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 three months ended March 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become 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 March 31, 2024, 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 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q.

Risks Related to the Merger

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. For example, the closing of the merger is conditioned upon the satisfaction or waiver of the receipt of cash proceeds not less than $114.5 million in connection with the consummation of the transactions contemplated by the private financings. As of the date of this Quarterly Report on Form 10-Q, AVROBIO and Tectonic do not intend to waive this or any other condition. However, AVROBIO and Tectonic may ultimately determine, in their sole discretion, to waive such condition.

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 financings are conditioned upon the satisfaction or waiver of the conditions to the closing as well as certain other conditions. The closing of the merger is conditioned upon the satisfaction or waiver of the receipt of cash proceeds not less than $114.5 million in connection with the consummation of the transactions contemplated by the private financings. While, as of the date of this Quarterly Report on Form 10-Q, AVROBIO and Tectonic do not intend to waive this or any other condition, there can be no assurance that AVROBIO and Tectonic will ultimately determine, in their sole discretion, not to waive such condition or that the private financings will close in a timely manner or at all. If such condition is waived, the private financings fail to close at all or less than $114.5 million in cash proceeds is received from the private financings, the combined company may need to seek alternative financing. In such scenario, the combined company's cash runway would be shortened such that the combined company will need to raise significant capital following the closing of the merger. Additionally, the shares of AVROBIO common stock issuable upon the exchange at closing of the private financing 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.

Transfers of the combined company's securities utilizing Rule 144 of the Securities Act may be limited.

Following the closing of the proposed merger with Tectonic, a significant portion of the combined company's securities will be restricted from immediate resale. Securityholders of the combined company should be aware that transfers of the combined company's securities pursuant to Rule 144 under the Securities Act, or Rule 144, may be limited as Rule 144 is not available, subject to certain exceptions, for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. AVROBIO's disposal of certain of its historical assets and operations, the halting of its remaining programs and the proposed merger with Tectonic will make AVROBIO subject to the SEC requirements applicable to reporting shell company business combinations. AVROBIO anticipates that following the consummation of the merger, the combined company will no longer be a shell company. As a result, AVROBIO anticipates that securityholders of the combined company (excluding non-affiliate AVROBIO stockholders as of the date of the filing of this Quarterly Report on Form 10-Q) will not be able to sell their restricted combined company securities pursuant to Rule 144 without registration until one year after the combined company files the Current Report on Form 8-K following the closing of the merger that includes the required Form 10 information that reflects the combined company is no longer a shell company.

AVROBIO's disposal of certain of its historical assets and operations, the halting of its remaining programs and the proposed merger with Tectonic resulting in the conversion of Tectonic into a public company shall make AVROBIO subject to the SEC requirements applicable to reporting shell company business combinations. As a result, the combined company will be subject to more stringent reporting requirements, offering limitations and resale restrictions.

According to SEC guidance, the requirements applicable to reporting shell company business combinations apply to any company that sells or otherwise disposes of its historical assets or operations in connection with or as part of a plan to combine with a non-shell private company in order to convert the private company into a public one. AVROBIO has halted development of its remaining programs and had previously, in June 2023, sold its cystinosis gene therapy program to Novartis. As such, AVROBIO's plan to merge with Tectonic, resulting in the conversion of Tectonic into a public company, shall be subject to the SEC requirements applicable to reporting shell company business combinations, which are as follows:

- the combined company will need to file a Form 8-K to report the Form 10 type information after the closing of the merger with the SEC reflecting its status as an entity that is not a shell company;
- the combined company will not be eligible to use a Form S-3 until 12 full calendar months after the closing of the merger;
- the combined company will need to wait at least 60 calendar days after the closing of the merger to file a Form S-8 for any equity plans or awards;
- the combined company will be an "ineligible issuer" for three years following the closing of the merger, which will prevent the combined company from (i) incorporating by reference in its Form S-1 filings, (ii) using a free writing prospectus or (iii) taking advantage of the well-known seasoned issuer status despite its public float;
- investors who (i) were affiliates of Tectonic at the time the merger was submitted for the vote or consent of Tectonic's stockholders, (ii) receive securities of the combined company in the merger (i.e., Rule 145(c) securities) and (iii) publicly offer or sell such securities will be deemed to be engaged in a distribution of such securities, and therefore to be underwriters with respect to resales of those securities, and accordingly such securities may not be included in the Form S-1 resale shelf registration statement anticipated to be filed after the closing of the merger unless such securities are sold only in a fixed price offering in which such investors are named as underwriters in the prospectus; and
- Rule 144(i)(2) will limit the ability to publicly resell Rule 145(c) securities per Rule 145(d), as well as any other "restricted" or "control" securities of the combined company per Rule 144 (e.g., holders of restricted securities and any affiliates of the public company are also affected) until one year after the Form 10 information is filed with the SEC.

Non-affiliate AVROBIO stockholders prior to the closing of the proposed merger with Tectonic will not be subject to such restrictions on public resales of their shares.

The foregoing SEC requirements will increase the combined company's time and cost of raising capital, offering stock under equity plans, and complying with securities laws.

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 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 short- or long-term, which may further impact the combined company's ability to obtain or maintain listing on Nasdaq.

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 AVROBIO Board determined that the minimum size of the reverse stock split, within the range of ratios approved by the AVROBIO Board, that is necessary to maintain AVROBIO's Nasdaq listing and to accommodate the additional shares of AVROBIO common stock required to be issued in connection with the transaction is 1:3. The AVROBIO Board intends to take into account various factors prevailing at the time of its determination of the final ratio for the reverse stock split, including the resulting trading price that the AVROBIO Board determines in good faith would be in the best interests of AVROBIO and all of its stockholders. The AVROBIO Board has not determined to necessarily use the minimum ratio required for the transaction.

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. 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 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 May 2, 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, except for the year ended December 31, 2023, 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 IPO and follow-on public offerings of AVROBIO common stock, as well as sales of AVROBIO common stock under AVROBIO's ATM facilities. Although AVROBIO had established its 2022 ATM facility, as of the filing date of this Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, AVROBIO has not made any sales under its 2022 ATM facility, and AVROBIO will not make sales under its 2022 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 Term Loan Agreement. In May 2023, AVROBIO announced that it had entered into an asset purchase agreement with 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 for the license and development of a gene therapy for MPSII (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 preliminary results observed to date in products manufactured using AVROBIO's proprietary LV2 lentiviral vector or manufactured using this automated system will be replicated in future studies or trials, should AVROBIO resume development of any of its product candidates. 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 United States National Institutes of Health, or 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, that institution's review board, or 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 European Medicines Agency, or 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 Center for Biologics Evaluation and Research, or 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 Risk Evaluation and Mitigation Strategy, or 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 biologics license application, or 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 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 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 good clinical practices, or 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 regenerative medicine advanced therapy, or 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 Federal Food, Drug, and Cosmetic 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 current good manufacturing practices, or 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 good laboratory practices 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*" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

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 Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services 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*" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

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*" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009, or 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 European Economic Area, or 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 European Union General Data Protection Regulation, or GDPR (references to the GDPR include both the "EU GDPR" and "UK GDPR" unless specified otherwise). 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, when 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 Standard Contractual Clauses, or the SCCs, and the UK International Data Transfer Agreement/Addendum, or 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 the 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 U.S. Patent and Trademark Office, or 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), and AVROBIO's Fabry license agreement with UHN was terminated as of

January 4, 2024. In addition, AVROBIO has in-licensed patents and patent applications from BioMarin Pharmaceutical Inc., or 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 May 2, 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 May 2, 2024, AVROBIO's executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 38.3% 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None of our directors or "officers," as defined in Rule 16a-1(f) under the Securities Act, adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, as defined in Item 408(c) or Regulation S-K, during the quarter ended March 31, 2024.

(in thousands, except share and per share data)

Item 6. Exhibits.

Exhibit Number	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to our 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 our 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 of the Registrant (filed as Exhibit 3.2 to our Current Report on Form 8-K filed on June 25, 2018 (File No. 001-38537) and incorporated herein by reference).
31.1	Certification of Principal Executive Officer and Principal Financial 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.
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 Document 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AVROBIO, INC.

Date: May 9, 2024

By: /s/ Erik Ostrowski

Erik Ostrowski
President, Interim Chief Executive Officer, Chief Financial Officer and Treasurer
(Principal Executive, Financial, and Accounting Officer)

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 Quarterly Report on Form 10-Q 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: May 9, 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 Quarterly Report of AVROBIO, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer 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 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: May 9, 2024

By: /s/ Erik Ostrowski

Erik Ostrowski
President, Interim Chief Executive Officer, Chief Financial Officer and Treasurer
(Principal Executive, Financial, and Accounting Officer)