**Risk Factors Comparison 2025-03-20 to 2024-03-14 Form: 10-K**

**Legend:** **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

**Investing in** ~~Risks Related to~~ the **Company'** ~~Merger with Tectonic The exchange ratio will not change or otherwise be adjusted based on the market price of AVROBIO common stock as the exchange ratio depends on AVROBIO' s net cash at the closing and not the market price of AVROBIO common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed. The Merger Agreement has set an exchange ratio for Tectonic capital stock being converted into AVROBIO'~~ s common stock **involves** ~~, 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~~ **high degree** of **risk. Careful consideration should be given to** the ~~combined company~~ following **risk factors** ~~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 **addition** ~~either AVROBIO or Tectonic paying a termination fee~~ to the other **information** ~~party, and could harm the AVROBIO common stock price and future business and operations of each company. If the merger is not completed, AVROBIO and Tectonic are subject to the following risks: • if the Merger Agreement is terminated under specified circumstances, AVROBIO could be required to pay Tectonic a termination fee of $ 2, 712, 500, and Tectonic could be required to pay AVROBIO a termination fee of $ 4, 900, 000; • if the Merger Agreement is terminated by AVROBIO or Tectonic due to AVROBIO stockholders voting on and failing to approve certain proposals, AVROBIO will be required to reimburse Tectonic for merger- related expenses up to $ 650, 000. The expense reimbursement, to the extent paid, will be credited against any termination fee payable by AVROBIO in the transaction; • the price of AVROBIO common stock may decline and could fluctuate significantly; and • costs related to the merger, such as financial advisor, legal and accounting fees, a majority of which must be paid even if the merger is not completed. If the Merger Agreement is terminated and the AVROBIO Board or the Tectonic board of directors, or Tectonic Board, determines to seek another business combination, there can be no assurance that either AVROBIO or Tectonic will be able to find another third party to transact a business combination with, yielding comparable or greater benefits. If the conditions to the merger are not satisfied or waived the merger may not occur. Certain proposals are a condition to completion of the merger. Therefore, the merger cannot be consummated without the approval of such proposals. If the AVROBIO stockholders do not approve such proposals, failure to consummate the merger may harm AVROBIO and / or Tectonic. Even if the merger is approved by the Tectonic stockholders and the requisite proposals are approved by the AVROBIO stockholders, specified conditions must be satisfied or, to the extent permitted by applicable law, waived to complete the merger, as~~ set forth in ~~the Merger Agreement. AVROBIO and Tectonic cannot provide any assurance that all of the conditions to the consummation of the merger will be satisfied or waived. If the conditions are not satisfied or waived, the merger may not occur or the closing may be delayed. The merger may be completed even though a material adverse effect may result from the announcement of the merger, industry- wide changes or other causes. In general, neither AVROBIO nor Tectonic is obligated to complete the merger if there is a material adverse effect affecting the other party between January 30, 2024 (the date of the Merger Agreement), and the closing of the merger. However, certain types of causes are excluded from the concept of a " material adverse effect. " Such exclusions include but are not limited to changes in general economic or political conditions, industry wide changes, changes resulting from the announcement of the merger, natural disasters, pandemics (including the COVID- 19 pandemic), other force majeure events, acts or threat of terrorism or war and changes in GAAP. Therefore, if any of these events were to occur and adversely affect AVROBIO or Tectonic, the other party would still be obliged to consummate the closing notwithstanding such material adverse effect. If any such adverse effects occur and AVROBIO and Tectonic consummate the closing, the stock price of the combined company may suffer. This in turn may reduce the value of the merger to the AVROBIO stockholders, Tectonic stockholders or both. If AVROBIO and Tectonic complete the merger, the combined company will need to raise additional capital by issuing equity securities or additional debt~~

~~or through licensing arrangements, which may cause significant dilution to the combined company' s stockholders or restrict the combined company' s operations. On January 30, 2024, Tectonic entered into the Subscription Agreement with certain investors named therein, pursuant to which such investors agreed to purchase shares of Tectonic common stock, at a purchase price currently estimated at approximately $ 96. 6 million in the aggregate, for an aggregate purchase price among the transactions contemplated by the Subscription Agreement and the Tectonic SAFEs of approximately $ 130. 7 million. The closings of the private placement financings are conditioned upon the satisfaction or waiver of the conditions to the closing as well as certain other conditions. The shares of AVROBIO common stock upon the exchange at closing of the private financing shares issued in the private financings will result in dilution to all securityholders of the combined company (i. e., both the pre- merger AVROBIO securityholders and former Tectonic securityholders). Additional financing may not be available to the combined company when it is needed or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such financing will cause additional dilution to all securityholders of the combined company, including AVROBIO' s pre- merger securityholders and Tectonic' s former securityholders. It is also possible that the terms of any new equity securities may have preferences over the combined company' s common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company' s assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to the combined company. Some AVROBIO and Tectonic directors and executive officers have interests in the merger that are different from AVROBIO stockholders and that may influence them to support or approve the merger without regard to AVROBIO stockholders' interests. Directors and executive officers of AVROBIO and Tectonic may have interests in the merger that are different from, or in addition to, the interests of other AVROBIO stockholders generally. These interests with respect to AVROBIO' s directors and executive officers may include, among others: acceleration or vesting of certain AVROBIO stock options or AVROBIO RSUs, retention bonus payments, extension of exercisability periods of previously issued AVROBIO stock option grants, severance payments if employment is terminated in a qualifying termination in connection with the merger and rights to continued indemnification, expense advancement and insurance coverage. One member of the AVROBIO Board will continue as a director of the combined company after the effective time, and, following the closing, will be eligible to be compensated as a non- employee director of the combined company. All of AVROBIO' s directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. These interests, among others, may influence the officers and directors of AVROBIO and cause them to view the merger differently from how AVROBIO stockholders generally may view it. Tectonic' s directors and executive officers may also have interests in the merger that are different from, or in addition to, the interests of other AVROBIO stockholders generally. Such interests may include, among others, certain of Tectonic' s directors and executive officers have options, subject to vesting, to purchase shares of Tectonic common stock which, after the effective time, will be converted into and become options to purchase shares of the common stock of the combined company, Tectonic' s executive officers are expected to continue as executive officers of the combined company after the effective time and all of Tectonic' s directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. Current members of the Tectonic Board may continue as directors of the combined company after the effective time, and, following the closing, will be eligible to be compensated as non- employee directors of the combined company pursuant to the combined company' s non- employee director compensation policy. The AVROBIO Board and Tectonic Board were aware of and considered those interests, among other matters, in reaching their decisions to approve and adopt the Merger Agreement, approve the merger, and recommend the approval of the Merger Agreement to AVROBIO and Tectonic stockholders. These interests, among other factors, may have influenced the directors and executive officers of AVROBIO and Tectonic to support or approve the merger. AVROBIO stockholders and Tectonic stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger, including the issuance of Tectonic common stock in the private financings. If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the merger, AVROBIO stockholders and Tectonic stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the merger. If the merger is not completed, AVROBIO' s stock price may decline significantly. The market price of AVROBIO common stock is subject to significant fluctuations. Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market price of AVROBIO common stock will likely be volatile based on whether stockholders and other investors believe that AVROBIO can complete the merger or otherwise raise additional capital to support AVROBIO' s operations if the merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market price of AVROBIO common stock has been and is expected to continue to be exacerbated by low trading volume. Additional factors that may cause the market price of AVROBIO common stock to fluctuate include: • the entry into, or termination of, key agreements, including strategic licensing or commercial partner agreements; • announcements by partners or competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments; • the loss of key employees; • future sales of its common stock; • general and industry- specific economic conditions that may affect its research and development expenditures; • the failure to meet industry analyst expectations; and • period- to- period fluctuations in financial results. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of AVROBIO common stock. In the past, following periods of volatility in the market price of**

a company' s securities, stockholders have often instituted class action securities litigation against such companies. AVROBIO and Tectonic securityholders will generally have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the merger as compared to their current ownership and voting interests in the respective companies. After the completion of the merger, the current AVROBIO stockholders and Tectonic stockholders will generally own a smaller percentage of the combined company than their ownership of their respective companies prior to the merger. Following the merger and after giving further effect to the proposed private financings, AVROBIO securityholders as of immediately prior to the merger are expected to own approximately 22. 3 % of the outstanding shares of capital stock of the combined company, former Tectonic securityholders are expected to own approximately 39. 8 % of the outstanding shares of capital stock of the combined company, and purchasers of Tectonic common stock in the private financings are expected to represent approximately 38. 0 % of the outstanding shares of capital stock of the combined company, subject to certain assumptions. Under certain circumstances further described in the Merger Agreement, the ownership percentages may be adjusted up or down including, but not limited to, if AVROBIO' s net cash as of closing is lower than $ 64. 5 million or greater than $ 65. 5 million. AVROBIO management currently anticipates AVROBIO' s net cash as of closing will be approximately $ 65. 0 million to $ 75. 0 million and the currently estimated ownership percentages are based on an assumption of AVROBIO' s net cash of approximately $ 65. 0 million at closing. The Chief Executive Officer of Tectonic will serve as the Chief Executive Officer of the combined company following the completion of the merger. In addition, the board of directors of the combined company will initially include one member of the AVROBIO Board. Consequently, former securityholders of AVROBIO will not be able to exercise the same influence over the management and policies of the combined company following the closing of the merger than they currently exercise over the management and policies of AVROBIO. The Merger Agreement contains provisions that limit AVROBIO' s and Tectonic' s ability to pursue alternatives to the merger, could discourage a potential competing acquiror of AVROBIO or Tectonic from making an alternative transaction proposal and, in specified circumstances, could require AVROBIO or Tectonic to pay a termination fee, which could significantly harm the market price of AVROBIO' s common stock and negatively affect the financial condition, future business and operations of each company. Covenants in the Merger Agreement impede the ability of AVROBIO and Tectonic to make acquisitions during the pendency of the merger, subject to specified exceptions. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, seeking, initiating or knowingly encouraging, inducing or facilitating the communication, making, submission or announcement of any Acquisition Proposal or Acquisition Inquiry (each as defined in the Merger Agreement) or taking any action that could reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Any such transactions could be favorable to such party' s stockholders, but the parties may be unable to pursue them. If the merger is not completed and the Merger Agreement is terminated under certain circumstances, AVROBIO may be required to pay Tectonic a termination fee of $ 2, 712, 500, or Tectonic may be required to pay AVROBIO a termination fee of $ 4, 900, 000. Additionally, if the Merger Agreement is terminated by AVROBIO or Tectonic due to AVROBIO stockholders voting on and failing to approve certain proposals, AVROBIO will be required to reimburse Tectonic for merger- related expenses up to $ 650, 000. The expense reimbursement, to the extent paid, will be credited against any termination fee payable by AVROBIO in the transaction. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, each of AVROBIO and Tectonic will have incurred significant fees and expenses, which must be paid whether or not the merger is completed. Further, if the proposed merger is not completed, it could significantly harm the market price of AVROBIO common stock. In addition, if the Merger Agreement is terminated and AVROBIO or Tectonic determines to seek another business combination, there can be no assurance that either AVROBIO or Tectonic will be able to find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement. Because the lack of a public market for Tectonic common stock makes it difficult to evaluate the fair market value of Tectonic' s capital stock, the value of the AVROBIO common stock to be issued to Tectonic stockholders may be more or less than the fair market value of Tectonic common stock. The outstanding capital stock of Tectonic is privately held and is not traded in any public market. The lack of a public market makes it difficult to determine the fair market value of Tectonic' s capital stock. Because the percentage of AVROBIO equity to be issued to Tectonic stockholders was determined based on negotiations between the parties, it is possible that the value of the AVROBIO common stock to be issued to Tectonic stockholders will be more or less than the fair market value of Tectonic' s capital stock. The tax treatment of the CVRs is subject to substantial uncertainty. There is substantial uncertainty as to the U. S. federal income tax treatment of the CVRs and payments (if any) thereon. There is no legal authority directly addressing the U. S. federal income tax treatment of the receipt of, holding of, or payments under, the CVRs, and there can be no assurance that the Internal Revenue Service, or the IRS, would not assert, or that a court would not sustain, a position that could result in adverse U. S. federal income tax consequences to holders of the CVRs. AVROBIO does not intend to report the issuance of the CVRs as a current distribution of property with respect to its stock, but it is possible that the IRS could assert that AVROBIO stockholders are treated as having received a distribution of property equal to the fair market value of the CVRs on the date the CVRs are distributed, which could be taxable to AVROBIO stockholders without the corresponding receipt of cash. In addition, it is possible that the IRS or a court could determine that the issuance of the CVRs (and / or any payments thereon) and the reverse stock split constitute a single " recapitalization " for U. S. federal income tax purposes with the CVRs constituting taxable " boot " received in such recapitalization exchange. In such case, the tax consequences of the CVRs and the reverse stock split would differ from the anticipated consequences, including with respect to the timing and character of income. Risks Related to the Proposed Reverse Stock Split The reverse stock split may not increase the combined company' s stock price over the long- term. The principal purposes of the reverse stock split are to (i) increase the per- share market price of AVROBIO common stock above the Nasdaq minimum bid price requirement so that the listing of AVROBIO and the shares of

AVROBIO common stock being issued in the merger on Nasdaq will be approved and (ii) increase the number of authorized and unissued shares available for future issuance in connection with the merger. It cannot be assured, however, that the reverse stock split will accomplish any increase in the per- share market price of AVROBIO common stock for any meaningful period of time. While it is expected that the reduction in the number of outstanding shares of common stock will proportionally increase the market price of AVROBIO common stock, it cannot be assured that the reverse stock split will increase the market price of its common stock by a multiple of the reverse stock split ratio mutually agreed by AVROBIO and Tectonic, or result in any permanent or sustained increase in the market price of AVROBIO common stock, which is dependent upon many factors, including AVROBIO' s business and financial performance, general market conditions and prospects for future success. Thus, while the stock price of AVROBIO common stock might meet the listing requirements for Nasdaq initially after the reverse stock split, it cannot be assured that it will continue to do so. The reverse stock split may decrease the liquidity of the combined company' s common stock. Although the AVROBIO Board believes that the anticipated increase in the market price of the combined company' s common stock resulting from the proposed reverse stock split could encourage interest in its common stock and possibly promote greater liquidity for its stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the reverse stock split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for the combined company' s common stock. In addition, the reverse stock split may not result in an increase in the combined company' s stock price necessary to satisfy Nasdaq' s initial listing requirements for the combined company. The reverse stock split may lead to a decrease in the combined company' s overall market capitalization. Should the market price of the combined company' s common stock decline after the reverse stock split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the reverse stock split. A reverse stock split is often viewed negatively by the market and, consequently, can lead to a decrease in the combined company' s overall market capitalization. If the per share market price does not increase in proportion to the reverse stock split ratio, then the value of the combined company, as measured by its stock capitalization, will be reduced. In some cases, the per- share stock price of companies that have effected reverse stock splits subsequently declined back to pre- reverse split levels, and accordingly, it cannot be assured that the total market value of the combined company' s common stock will remain the same after the reverse stock split is effected, or that the reverse stock split will not have an adverse effect on the combined company' s stock price due to the reduced number of shares outstanding after the reverse stock split. Risks Related to AVROBIO' s Strategic Alternative Process and Potential Strategic Transaction Failure to complete, or delays in completing, the proposed merger with Tectonic could materially and adversely affect AVROBIO' s results of operations, business, financial results and / or stock price. In July 2023, AVROBIO announced that it was undertaking a comprehensive exploration of strategic alternatives focused on maximizing stockholder value, which may include, but are not limited to, an acquisition, a merger, business combination or divestiture. After a comprehensive review of strategic alternatives, including identifying and reviewing potential candidates for the merger, on January 30, 2024, AVROBIO entered into the Merger Agreement with Tectonic and Merger Sub, pursuant to which, subject to the satisfaction or waiver of the conditions therein, Merger Sub will merge with and into Tectonic, with Tectonic continuing as the surviving company and a wholly- owned subsidiary of AVROBIO. The closing is subject to approval by the AVROBIO stockholders and Tectonic stockholders as well as other customary closing conditions, including the effectiveness of a registration statement filed with the SEC in connection with the transaction. If the merger is completed, the business of Tectonic will continue as the business of the combined company. Any failure to satisfy a required condition to closing may prevent, delay or otherwise materially and adversely affect the completion of the transaction, which could materially and adversely affect AVROBIO' s results of operations, business, financial results and / or stock price. AVROBIO cannot predict with certainty whether or when any of the required closing conditions will be satisfied or if another uncertainty may arise and cannot assure you that the proposed merger will be successfully consummated or that AVROBIO will be able to successfully consummate the proposed merger as currently contemplated under the Merger Agreement or at all. AVROBIO' s efforts to complete the merger could cause substantial disruptions in, and create uncertainty surrounding, AVROBIO' s business, which may materially adversely affect AVROBIO' s results of operations and AVROBIO' s business. Uncertainty as to whether the merger will be completed may affect AVROBIO' s ability to recruit prospective employees or to retain and motivate existing employees. Employee retention may be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following the transaction. A substantial amount of AVROBIO' s management' s and employees' attention is being directed toward the completion of the transaction and thus is being diverted from AVROBIO' s day- to- day operations. Uncertainty as to AVROBIO' s future could adversely affect AVROBIO' s business and AVROBIO' s relationship with collaborators, suppliers, vendors, regulators and other business partners. For example, vendors, collaborators and other counterparties may defer decisions about working with AVROBIO or seek to change existing business relationships with AVROBIO. Changes to, or termination of, existing business relationships could adversely affect AVROBIO' s results of operations and financial condition, as well as the market price of AVROBIO' s common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction or termination of the Merger Agreement. Risks related to the failure to consummate, or delay in consummating, the proposed merger with Tectonic include, but are not limited to, the following: • AVROBIO may not realize any or all of the potential benefits of the merger, which could have a negative effect on AVROBIO' s results of operations, business or stock price; • under some circumstances, AVROBIO may be required to pay a termination fee to Tectonic of $ 2, 712, 500; • AVROBIO would remain liable for significant transaction costs, including legal, accounting, financial advisory and other costs relating to the merger regardless of whether the merger is consummated; • the trading price of AVROBIO common stock may decline to the extent that the current market price for AVROBIO common stock reflects a market assumption that the merger will be completed; • the attention of AVROBIO' s management and employees may have been diverted to the merger rather than to AVROBIO' s operations and the pursuit of other opportunities that could have been beneficial to AVROBIO; • AVROBIO

could be subject to litigation related to any failure to complete the merger; • AVROBIO could potentially lose key personnel during the pendency of the merger as employees and other service providers may experience uncertainty about their future roles with AVROBIO following completion of the merger; and • under the Merger Agreement, AVROBIO is subject to certain customary restrictions on the conduct of AVROBIO' s business prior to completing the merger, which restrictions could adversely affect AVROBIO' s ability to conduct AVROBIO' s business as AVROBIO otherwise would have done if AVROBIO was not subject to these restrictions. The occurrence of any of these events individually or in combination could materially and adversely affect AVROBIO' s results of operations, business, and AVROBIO' s stock price. AVROBIO cannot be sure if or when the merger will be completed. The consummation of the merger is subject to the satisfaction or waiver of various conditions, including the authorization of the merger by AVROBIO stockholders and Tectonic stockholders. AVROBIO cannot guarantee that the closing conditions set forth in the Merger Agreement will be satisfied. If AVROBIO is unable to satisfy certain closing conditions or if other mutual closing conditions are not satisfied, Tectonic will not be obligated to complete the merger. Under certain circumstances, AVROBIO would be required to pay Tectonic a termination fee of $ 2, 712, 500. Additionally, if the Merger Agreement is terminated by AVROBIO or Tectonic due to AVROBIO stockholders voting on and failing to approve certain proposals, AVROBIO will be required to reimburse Tectonic for merger- related expenses up to $ 650, 000. The expense reimbursement, to the extent paid, will be credited against any termination fee payable by AVROBIO in the transaction. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, AVROBIO will have incurred significant fees and expenses, which must be paid whether or not the merger is completed. If the merger is not completed, the AVROBIO Board, in discharging its fiduciary obligations to AVROBIO stockholders, would evaluate other strategic alternatives or financing options that may be available, which alternatives may not be as favorable to AVROBIO stockholders as the merger, including a liquidation and dissolution. Any future sale or merger, financing or other transaction, including a liquidation or dissolution, may be subject to further stockholder approval. AVROBIO may also be unable to find, evaluate or complete other strategic alternatives, which may have a materially adverse effect on AVROBIO' s business. Until the merger is completed, the Merger Agreement restricts Tectonic and AVROBIO from taking specified actions without the consent of the other party, and requires AVROBIO to operate in the ordinary course of business consistent with past practice. These restrictions may prevent Tectonic and AVROBIO from making appropriate changes to AVROBIO respective businesses or pursuing attractive business opportunities that may arise prior to the completion of the merger. Further, if AVROBIO' s net cash at closing is lower than anticipated, either because expenses exceed current estimates or due to delays prior to closing, then the pre- merger AVROBIO stockholders will own less of the combined company pursuant to the exchange ratio adjustment set forth in the Merger Agreement. Any delay in completing the proposed merger may materially and adversely affect the timing and benefits that are expected to be achieved from the proposed merger. Lawsuits may be filed against AVROBIO and the members of the AVROBIO Board arising out of the proposed merger, which may delay or prevent the proposed merger. Putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against AVROBIO, the AVROBIO Board, Tectonic, the Tectonic Board and others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, and AVROBIO may not be successful in defending against any such future claims. Lawsuits that may be filed against AVROBIO, the AVROBIO Board, Tectonic or the Tectonic Board could delay or prevent the merger, divert the attention of AVROBIO' s management and employees from AVROBIO' s day- to- day business and otherwise adversely affect AVROBIO' s financial condition. Litigation may also impact AVROBIO' s ability to consummate a potential strategic transaction or the ultimate value its stockholders receive in any such transaction. In connection with the proposed merger, one action has been filed in the United States District Court for the Southern District of New York captioned Garofalo v. Avrobio, Inc. et al., 24- cv- 1493 (filed February 27, 2024). The foregoing complaint is referred to as the " Merger Action. " The Merger Action alleges that the Form S- 4 registration statement filed by AVROBIO on February 14, 2024 in connection the merger misrepresents and / or omits certain purportedly material information relating to the analyses performed by AVROBIO and the financial advisor to AVROBIO in connection with the merger, potential conflicts of interest of AVROBIO' s officers and directors, and the events that led to the signing of the Merger Agreement. The Merger Action asserts violations of Section 14 (a) of the Exchange Act and Rule 14a- 9 promulgated thereunder against all defendants (AVROBIO and the AVROBIO Board) and violations of Section 20 (a) of the Exchange Act against AVROBIO' s directors. The Merger Action seeks, among other things, an injunction enjoining the consummation of the merger, costs of the action, including plaintiff' s attorneys' fees and experts' fees, and other relief the court may deem just and proper. Also in connection with the Merger Agreement, AVROBIO has received demand letters from four purported AVROBIO stockholders demanding that AVROBIO disclose certain additional information relating to the merger, or the Demands. AVROBIO cannot predict the outcome of the Merger Action or the Demands. AVROBIO believes that the allegations and claims asserted in the Merger Action and the Demands are without merit and intends to defend against them vigorously. Additional lawsuits and demand letters arising out of the merger may also be filed or received in the future, though AVROBIO will not provide additional disclosures unless those new complaints or letters contain material differences from those received to date. AVROBIO stockholders potentially may not receive any payment on the CVRs and the CVRs may otherwise expire valueless. The Merger Agreement contemplates that, at or prior to the effective time, AVROBIO, the holders' representative and a rights agent will execute and deliver the CVR Agreement, pursuant to which AVROBIO stockholders of record as of immediately prior to the effective time (including holders of shares of AVROBIO common stock issued upon settlement of the AVROBIO RSUs) will receive one non- transferable CVR for each outstanding share of AVROBIO common stock held by such stockholder on such date, subject to and in accordance with the terms and conditions of the CVR Agreement. Pursuant to the CVR Agreement, each CVR holder is entitled to certain rights to receive a pro rata portion of 80 % of the net proceeds (as defined in the CVR Agreement), if any, received by AVROBIO as a result of an AVROBIO disposition (including a license) of AVROBIO' s pre- closing assets after the effective date and prior to the 18- month anniversary of the closing, received within a 10- year period following the closing; provided that

~~no contingent payment will be payable to any holder of the CVRs until such time as the then- outstanding and undistributed proceeds exceeds $ 350, 000 in the aggregate. Such proceeds are subject to certain permitted deductions, including for applicable tax payments, certain expenses incurred by AVROBIO or its affiliates, losses incurred or reasonably expected to be incurred by AVROBIO or its subsidiaries due to a third party proceeding in connection with a disposition and certain wind- down costs. The contingent payments under the CVR Agreement, if they become payable, will become payable to the rights agent for subsequent distribution to the holders of the CVRs. In the event that no proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that any holders of CVRs will receive payments with respect thereto. The CVR Agreement provides that AVROBIO will use commercially reasonable efforts (as defined in the CVR Agreement) during the 18- month period following the closing to effect dispositions of AVROBIO' s pre- closing assets to a third party that has delivered inbound interest (as defined in the CVR Agreement) with respect to such assets. As a result, AVROBIO will have no obligations to affirmatively sell or market such assets, in the absence of such inbound interest. AVROBIO may not be able to achieve successful results from the disposition of such assets as described above. If~~ this ~~is not achieved for any reason within the time periods specified in the CVR Agreement, no payments will be made under the CVRs, and the CVRs will expire valueless. If AVROBIO does not successfully consummate the merger or another strategic transaction, the AVROBIO Board may decide to pursue a dissolution and liquidation of AVROBIO. In such an event, the amount of cash available for distribution to AVROBIO stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities, as to which AVROBIO can give you no assurance. There can be no assurance that the merger will be completed. If the merger is not completed, the AVROBIO Board may decide to pursue a dissolution and liquidation of AVROBIO. In such an event, the amount of cash available for distribution to AVROBIO stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as AVROBIO funds its operations while pursuing the merger. In addition, if the AVROBIO Board were to approve and recommend, and AVROBIO stockholders were to approve, a dissolution and liquidation of the company, AVROBIO would be required under Delaware corporate law to pay AVROBIO' s outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to stockholders. AVROBIO' s commitments and contingent liabilities may include obligations under AVROBIO' s employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of the company, litigation against AVROBIO, and other various claims and legal actions arising in the ordinary course of business, and other unexpected and / or contingent liabilities. As a result of this requirement, a portion of AVROBIO' s assets would need to be reserved pending the resolution of such obligations. In addition, AVROBIO may be subject to litigation or other claims related to a dissolution and liquidation of AVROBIO. If a dissolution and liquidation were to be pursued, the AVROBIO Board, in consultation with AVROBIO' s advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of AVROBIO common stock could lose all or a significant portion of their investment in the event of liquidation, dissolution or winding up of the company. A liquidation would be a lengthy and uncertain process with no assurance of any value ever being returned to AVROBIO stockholders. AVROBIO is substantially dependent on AVROBIO' s remaining employees to facilitate the consummation of the merger. AVROBIO' s ability to consummate a strategic transaction depends upon its ability to retain its employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In January 2022, and then between July 2023 and February 2024, AVROBIO implemented reductions in force that significantly reduced its workforce in order to conserve its capital resources. As of March 7, 2024, AVROBIO had only 13 full- time employees. AVROBIO' s ability to successfully complete the merger depends in large part on AVROBIO' s ability to retain certain remaining personnel. Despite AVROBIO' s efforts to retain these employees, one or more may terminate their employment with AVROBIO on short notice. AVROBIO' s cash conservation activities may yield other unintended consequences, such as attrition beyond its planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. The loss of the services of certain employees could potentially harm AVROBIO' s ability to consummate the merger, to run AVROBIO' s day- to- day business operations and to fulfill AVROBIO' s reporting obligations as a public company. Risks Related to AVROBIO' s Financial Position and Need for Additional Capital in Event the Merger is Not Consummated AVROBIO has incurred net losses since inception, expects to incur net losses for the foreseeable future and may never achieve or maintain profitability. Since inception, with the exception of the current year, AVROBIO has incurred annual~~ **Annual** ~~net losses. AVROBIO incurred net income (loss) of $ 12. 2 million and $ (105. 9) million for the years ended December 31, 2023 and 2022, respectively. AVROBIO historically financed AVROBIO' s operations primarily through private placements of AVROBIO preferred stock and, more recently, AVROBIO' s initial public offering, or IPO, and follow- on public offerings of AVROBIO common stock, as well as sales of AVROBIO common stock under AVROBIO' s " at- the- market " facility, or the ATM facility. Although AVROBIO had established its ATM facility, as of the filing date of its Quarterly~~ Report on Form 10- ~~Q for~~ **K and in** ~~the~~ **other** ~~quarter ended September 30~~ **documents that were filed and will be filed with the SEC** , ~~2023, AVROBIO had~~ **in evaluating the Company and its business. Additional risks and uncertainties** not ~~made~~ **presently known to or that are currently seen as immaterial may also harm Company' s business. If** any **of these risks occur** ~~sales under its ATM facility~~ , **business, growth prospects, operating results** and ~~AVROBIO~~ **financial condition could be materially and adversely affected, the trading price of the Company' s common stock could decline, and investors could lose part or all of their investment. Risk Factor Summary The risk factors summarized below could materially and adversely affect our business, financial condition, operating results and prospects, and / or cause the price of our common stock to decline. These risks are discussed more fully below. Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock including the following: • We have a limited operating history, have**

**incurred net losses in every year since our inception, and expect to continue to incur net losses in the future. • We** will **need** ~~not make sales under its ATM facility unless and until a new shelf registration statement on Form S- 3 is filed and declared effective. In addition, on November 2, 2021, AVROBIO entered into the Loan and Security Agreement, or the Term Loan Agreement, by and among AVROBIO, the lenders party thereto from time to time and Silicon Valley Bank or its successor, Silicon Valley Bank, a division of First- Citizens Bank & Trust company. In May 2023, AVROBIO announced that it had entered into an asset purchase agreement, or the Asset Purchase Agreement, with Novartis Pharma AG and Novartis Pharmaceuticals Corporation, collectively referred to herein as Novartis, providing for the sale of AVROBIO' s cystinosis gene therapy program (designated AVR- RD- 04) and all other assets of AVROBIO specifically related to this program for an aggregate cash payment of $ 87. 5 million upon closing of the transaction, or the Asset Sale. In June 2023, AVROBIO announced the closing of this transaction, as well as the pay- off of all outstanding amounts due and owed, including principal, interest and other charges, under the Term Loan Agreement and the termination thereof. AVROBIO has devoted substantially --~~ **substantial additional funding in order** ~~all of AVROBIO' s efforts~~ to ~~research and~~ **complete the** development ~~, including clinical~~ and ~~preclinical development~~ **commence commercialization** of **our** ~~AVROBIO' s~~ product candidates , as well as assembling AVROBIO'..... on acceptable terms, or at all . Failure to obtain this necessary capital when needed may force ~~AVROBIO us~~ to delay, ~~limit~~ **reduce or eliminate certain of** ~~or~~ **our** ~~terminate AVROBIO' s~~ product development ~~efforts~~ or ~~other~~ **research** operations. ~~Should AVROBIO resume~~ **• We have limited experience in therapeutic discovery and** development **and our GEODe ™ platform may never result in the regulatory approval** of ~~its~~ **a product candidate. • All of our** product candidates **are in discovery** , **preclinical or early clinical** ~~particularly if AVROBIO continues the research and~~ development ~~of~~ **. Clinical trials are difficult to design and implement** , ~~initiate further~~ **and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of TX45 or any future product candidates. • Our** clinical trials **may fail to demonstrate substantial evidence** of **the safety, efficacy, purity and potency of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization. • If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed. • Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection. • We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business. • We currently rely and expect to rely in the future on the use of manufacturing suites in third- party facilities or on third parties to manufacture TX45 and any other product candidates, and we may rely on third parties to produce and process our products, if approved. • Our business could be adversely affected if we are unable to use third- party manufacturing suites or if the third- party manufacturers encounter difficulties in production. • We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. • The market price of our common stock is expected to be volatile, and the market price of the common stock may drop. • If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan. Risks Related to Our Financial Position and Cash Needs We have a limited operating history and have incurred net losses in every year since our inception. We expect to continue to incur net losses in the future. We are a biotechnology company with a limited operating history. Since our inception in 2019, we have invested most of our resources in organizing and staffing our company, developing our technology and product candidates, building our intellectual property portfolio, conducting business planning, raising capital and providing general and administrative support for these operations. We also completed the Merger in June 2024 and have been operating under this structure for only a short time. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products. We continue to incur significant research and clinical development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. For the years ended December 31, 2024 and 2023, we reported a net loss of $ 58. 0 million and $ 42. 8 million, respectively. As of December 31, 2024, we had an accumulated deficit of $ 148. 6 million. We expect to continue to incur significant losses for the foreseeable future, and expect these losses to increase as we continue our research and development of,** and seek **regulatory approvals for, our lead product candidate, TX45, along with any future product candidates we may develop. We anticipate that our expenses will increase substantially if, and as, we: • continue the research and development of our clinical- and preclinical- stage product candidates and discovery- stage programs, including the continued development of our lead product candidate TX45; • increase the amount of research and development activities to identify and develop product candidates using our proprietary discovery approach; • make milestone, royalty or other payments under in- license or collaboration agreements; • maintain, expand and protect our intellectual property portfolio; • expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; • establish sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties; • invest in or in- license other technologies; and • experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, manufacturing challenges, safety issues or other regulatory challenges. To become and remain profitable, we, our collaborators and any potential future collaborators must develop and eventually commercialize products with significant market potential.**

**This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, producing biologics with contract manufacturing development organizations (“ CDMOs ”) in the United States and in other countries, obtaining** marketing approval for ~~, AVROBIO' s~~ product candidates **, manufacturing, marketing** and **selling products for which we may obtain marketing approval** and ~~satisfy~~ **satisfying** any post- marketing requirements. **We** ~~Should AVROBIO resume development of its product candidates,AVROBIO~~ may never succeed in any or all of these activities and,even if ~~AVROBIO does~~ **we do** , ~~AVROBIO~~ **we** may never generate ~~revenues~~ **revenue** that ~~are~~ **is** significant or large enough to achieve profitability.If ~~AVROBIO does~~ **we do** achieve profitability, ~~AVROBIO~~ **we** may not be able to sustain or increase profitability on a quarterly or annual basis. **Our** ~~AVROBIO' s~~ failure to become and remain profitable would decrease the value of ~~AVROBIO~~ **the company** and could impair ~~their~~ **our** ability to raise capital,maintain ~~their~~ **our** research and development efforts,expand ~~their~~ **our** business **or** continue **our operations. Even if we succeed in commercializing one or more of our product candidates, we will continue** to ~~enhance~~ **incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have** ~~and~~ **an** ~~optimize AVROBIO~~ **adverse effect on our stockholders ' equity** ~~s vector technology~~ and ~~manufacturing processes~~ **working capital. To date** , ~~AVROBIO~~ **we have financed our operations primarily through the sale and issuance of common stock, convertible preferred stock, convertible promissory notes and the issuance of SAFEs. We** ~~expects~~ **expect** ~~its~~ **our** expenses ~~would~~ **to** increase in connection with ~~such~~ **our ongoing** activities ~~. In July 2023~~ , **particularly** ~~AVROBIO announced it was~~ **as we continue** ~~halting further development of its programs. Following such announcement, in September 2023 AVROBIO terminated its agreements with the University of Manchester, or~~ **our** ~~the MPSH License Agreement~~ **Phase 1b and Phase 2 clinical trials of TX45** , **pursue manufacturing activities** for ~~the license and development of a gene therapy for MPSH, or~~ **our** ~~Hunter syndrome~~ **HHT product candidate** , **TX2100,** and **initiate health authority and / or IND enabling safety studies and** ~~discontinued ---~~ **continue** ~~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~~ **research, develop and initiate clinical trials** of ~~three gene therapy~~ **any other future** 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~~ **if we successfully complete** development **through Phase 3** ~~of its product candidates~~ and ~~thereafter obtains~~ **obtain** ~~marketing~~ **regulatory** approval for any of **our** ~~AVROBIO' s~~ product candidates, ~~AVROBIO~~ **we** ~~expects~~ **expect** to incur significant **commercialization** expenses related to product **manufacturing, marketing,** 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, **we** ~~should AVROBIO resume development of its product candidates, AVROBIO~~ will need to obtain substantial additional funding in connection with **our** ~~AVROBIO' s~~ continuing operations. If ~~AVROBIO is~~ **we are** unable to raise capital when needed or on ~~reasonable~~ **attractive** terms, ~~and /~~ **we could be forced to delay, reduce or eliminate** ~~or~~ **our** ~~if a strategic transaction~~ **product development programs or any future commercialization efforts. As of December 31, 2024, we had $ 141. 2 million in cash and cash equivalents. Although we believe that our available cash and cash equivalents will be sufficient to fund our planned operations for at least 12 months following the date of our consolidated financial statements included in this Annual Report on Form 10- K, this belief** is ~~not completed, AVROBIO~~ **based on assumptions that** may ~~have~~ **prove** to ~~liquidate its assets~~ **be wrong, and we could use our available capital resources sooner than we currently expect** . ~~AVROBIO' s future~~ **Future** capital requirements **for TX45 or our preclinical programs** 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~~ **timing** and ~~costs~~ **completion** of ~~drug discovery, laboratory testing,~~ preclinical ~~development~~ **studies** and clinical trials for ~~AVROBIO' s~~ **our current or any future** product candidates, **as well as the associated costs,** including ~~the extent of~~ any ~~impacts from the COVID- 19~~ **unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to disease outbreaks, epidemics and** ~~pandemic~~ **pandemics** or **other causes** ~~similar public health crisis on these activities~~ ; • ~~should AVROBIO resume development~~ **the timing and amount** of ~~its~~ **milestone and royalty payments we are required to make or are eligible to receive under our license agreements with Harvard and other license agreements, as applicable; • the number of potential new** product candidates ~~,~~ **we identify and decide to develop; • the need for additional or expanded pre- clinical studies and clinical trials beyond** ~~the~~ **those** ~~costs, timing~~ **that we plan to conduct with respect to our current** and **future** ~~outcome of regulatory review of AVROBIO' s~~ product candidates; • the costs **involved in growing the organization to the size needed to allow for the research, development and potential commercialization** of **our current or any** future ~~activities, including, should AVROBIO resume development of its~~ product candidates **; • the costs involved in filing patent applications** , **maintaining and enforcing patents or defending against infringement or other claims raised by third parties; • the maintenance of our existing license and collaboration agreements and the entry into new license and collaboration agreements; • the time and costs involved in obtaining regulatory approval for our** product **candidates and**

**any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates; • the effect of competing technological and market developments; • the cost and timing of completion of commercial- scale outsourced manufacturing activities; • the cost of establishing** sales, ~~medical affairs,~~ marketing ~~, manufacturing~~ and distribution ~~,~~ **capabilities** for any ~~of AVROBIO's~~ product candidates for which ~~AVROBIO~~ **we may** ~~receives~~ **receive regulatory approval in regions where we choose to commercialize our products on our own; • the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and • market acceptance of any approved product candidates. We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt or royalty financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from geopolitical and economic instability, including the conflicts between Russia and Ukraine and in the Middle East or other factors could also adversely impact our ability to access capital as and when needed. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities. Raising additional capital will cause dilution to our stockholders, and may restrict our operations, or require us to relinquish rights to our product candidates. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity, debt or royalty financings, third- party funding, marketing, and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our current stockholders will be diluted, and the terms of these securities may include liquidation or other preferences. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights. If we raise additional capital through future collaborations, strategic alliances, or third- party licensing arrangements, we may have to relinquish certain valuable rights to our intellectual property, 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 capital when needed, we may be required to delay, limit, reduce or terminate our clinical development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves. Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates Notwithstanding the prior experience of individuals on our management team in drug discovery and development, we are still a relatively young organization that has not yet completed the full cycle of activities from discovery through regulatory approval for any of our portfolio projects. Our GEODe ™ discovery platform has been the focus of technology development efforts over the last four years and is in the early stages of being applied to novel therapeutic target opportunities. There is no guarantee the platform' s capabilities or its application to targets of interest will lead to therapeutic product candidates that can be successfully developed through different stages of clinical trials and registered for marketing as therapeutic drugs in the United States or any other territory. We are very early in our development efforts. If we are unable to advance TX45 or any of our other product candidates through clinical development, obtain regulatory approval and ultimately commercialize TX45 or any of our other product candidates, or experience significant delays in doing so, our business will be materially harmed. We have no products approved for sale and our lead product candidate, TX45, will require clinical development, regulatory review and approval in each jurisdiction in which we intend to market it, access to sufficient commercial manufacturing capacity, and significant sales and marketing efforts before we can generate any revenue from product sales. Before obtaining** marketing approval **from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. We are early in our product candidate development efforts, as TX45 is still in a Phase 1b clinical trial and recently initiated a Phase 2 clinical trial. Our ability to generate product revenues, which we do not expect will occur in the foreseeable future, if ever, will depend heavily on the successful development and eventual commercialization of TX45, TX2100, and any future product candidates we develop, which may never occur. TX45 and any future product candidates we develop will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions for specific indications for use, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales. The success of our current and future product candidates will depend on several factors, including the following: • successful and timely completion of preclinical studies and clinical trials for which the FDA, or any comparable foreign regulatory authority agree with the design, endpoints or implementation** ; • **sufficiency** ~~should AVROBIO resume development~~ of ~~AVROBIO~~ **our financial and other resources to complete the necessary preclinical studies and clinical trials; • receiving regulatory approvals or authorizations for conducting our planned clinical trials or future clinical trials; • initiation and successful patient enrollment in, and completion of, additional clinical trials on a timely basis; • our ability to demonstrate to the**

**satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe, pure, and potent for its targeted indications; • our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate** ' s **risk- benefit ratio for its proposed indication is acceptable; • timely receipt of marketing approvals for our** product candidates ~~,~~ **from applicable regulatory authorities; •** the ~~costs associated~~ **extent of any required post- marketing approval commitments to applicable regulatory authorities; • establishing and scaling up, either alone or** with ~~AVROBIO' s manufacturing process development and evaluation of~~ third- party manufacturers **, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved** ; • ~~revenue~~ **obtaining and maintaining patent and proprietary information protection or regulatory exclusivity for our product candidates, both in the United States and internationally; • successfully scaling a sales and marketing organization and launching commercial sales of our product candidates, if approved; • acceptance of our product candidates' benefits and uses, if approved, by patients, the medical community and third- party payors; • maintaining a continued acceptable safety profile of our product candidates following approval; • effectively competing with companies developing and commercializing other therapies in the indications which our product candidates target; • obtaining and maintaining healthcare coverage and adequate reimbursement from third- party payors; and • enforcing and defending intellectual property rights and claims. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize TX45 or any future product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for our current and future product candidates, we may not be able to continue our operations. All of our product candidates are in discovery, preclinical or Phase 1 and Phase 2 clinical trials. Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of TX45 or any future product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We cannot guarantee that any of our ongoing and planned clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, even if these trials are initiated or conducted on a timely basis, issues may arise that could result in the suspension or termination of such clinical trials. To date, we have completed only one clinical trial (Phase 1a trial in normal healthy volunteer with TX45) required for the approval of any of our product candidates. Enrollment in Part A of our TX45 Phase1b trial in patients with Group 2 PH and HFpEF is complete and we are currently conducting a Part B trial in Group 2 PH patients with HFrEF. We are enrolling a TX45 Phase 2 clinical trial in Group 2 PH patients with HFpEF, and we may experience delays in our ongoing clinical trials or preclinical studies. Additionally, we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time, have sufficient drug supply for our product candidates on a timely basis or be completed on schedule, if at all. Furthermore, our product candidate TX2100 is still in preclinical studies and the full results of such studies are not yet known. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. We also may experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize TX45 or any future product candidates, including: • delays in or failure to obtain regulatory authorizations to commence a trial; • delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical trials; • delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • delays in or failure to obtain institutional review board (" IRB ") approval at each site; • delays in or failure to recruit a sufficient number of suitable patients to participate in a trial; • failure to have patients complete a trial or return for post- treatment follow- up; • clinical sites deviating from trial protocol or dropping out of a trial; • delays in adding new clinical trial sites; • failure to manufacture sufficient quantities of our product candidates for use in clinical trials in a timely manner; • occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, such as complications with pharmacokinetic behaviors, or safety or tolerability concerns that could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks; • failure to perform clinical trials in accordance with the FDA' s or any other regulatory authority' s good clinical practices (" GCP ") requirements, or regulatory guidelines in other countries; • failure to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate' s risk- benefit ratio for its proposed indication is acceptable; • changes in regulatory requirements, policies and guidelines; • failure of our third- party research contractors to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • delays in establishing the appropriate dosage levels in clinical trials; • the quality or stability of our product candidates falling below acceptable standards; and • business interruptions resulting from natural disasters, political, geopolitical and economic instability, including political unrest or unstable economic conditions in China, the war between Russia and Ukraine, the conflict in the Middle East, terrorism, political turmoil, disease outbreaks, epidemics and pandemics. In addition, we could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or comparable foreign regulatory authorities, or recommended for suspension or termination by the Data Safety Monitoring Board for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety**

**issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any period during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly. To obtain the requisite regulatory approvals to market and sell any of our product candidates, including TX45 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our biologic products, including TX45, are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize TX45 and any future product candidates in the United States or abroad, we, our collaborators or our potential future collaborators must demonstrate with substantial evidence from adequate and well- controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications. Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses or may not provide a sufficient risk- benefit ratio, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do or find a risk- benefit ratio for a proposed indication acceptable, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in clinical trials. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of TX45 and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit our commercial potential. The results of preclinical studies and early- stage clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later- stage trials. The results of nonclinical, preclinical and early- stage clinical trials may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late- stage clinical trials after achieving positive results in early- stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. Any such setbacks in our clinical development could have a material adverse effect on our business, financial condition and results of operations. Our product candidates may be**

**associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval, we may suspend or abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval. Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. While our lead product candidate, TX45, has been generally well tolerated in its preclinical studies, the Phase 1a healthy volunteer trial and our Phase 1b study in patients with Group 2 PH to date, the results from future preclinical studies and clinical trials, including of our other product candidates, may identify safety concerns or other undesirable properties of our product candidates. The results of our ongoing Phase 1b clinical trial of TX45, the recently initiated Phase 2 clinical trial of TX45, and future clinical trials of these and other product candidates may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and results of operations significantly. Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective, which may limit the commercial expectations for the product candidate, if approved. Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or to change the requirements for approval of any of our product candidates. For example, immunogenicity is a concern for all protein therapeutics in human clinical trials, and immunogenic reactions in patients in our trials may lead to adverse effects and / or impact exposure, which in turn may lead to protocol amendments, clinical holds, or other actions that delay or significantly impact the prospects for our product candidates. Additionally** , if any ~~, should AVROBIO resume development~~ of **our** ~~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~~ **and we** ~~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 - **or** 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 **later** , events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which AVROBIO has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on AVROBIO's current and projected business operations and AVROBIO's financial condition and results of operations. These could include, but may not be limited to, the following: • Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; • Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and / or delays, inability or reductions in the company's ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources; • Potential or actual breach of contractual obligations that require AVROBIO to maintain letters of credit or other credit support arrangements; • Potential or actual breach of financial covenants in AVROBIO's credit agreements or credit arrangements; • Potential or actual cross- defaults in other credit agreements, credit arrangements or operating or financing agreements; or • Termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for AVROBIO to acquire financing on acceptable terms or at all. Any decline in available funding or access to AVROBIO's cash and liquidity resources could, among other risks, adversely impact AVROBIO's ability to meet AVROBIO's operating expenses, financial obligations or fulfill AVROBIO's other obligations, result in breaches of AVROBIO's financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on AVROBIO's liquidity and AVROBIO's current and / or projected business operations and financial condition and results of operations. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by AVROBIO's contract organizations, vendors, suppliers or other parties with whom AVROBIO conducts business, which in turn, could have a material adverse effect on AVROBIO's current and / or projected business operations and results of operations and financial condition. For example, contract organizations, vendors, suppliers or other parties with whom AVROBIO conducts business could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on AVROBIO's company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any bankruptcy or insolvency involving AVROBIO's contract organizations, vendors, suppliers or other parties with whom AVROBIO conducts business, or any breach or default by such parties, or the loss of any significant relationships with such parties, could result in a material

adverse impact on AVROBIO's business. Risks Related to AVROBIO's Business if Merger is Not Consummated AVROBIO may not be successful in completing the merger, and any strategic transactions that it may consummate in the future could have negative consequences. AVROBIO is exploring strategic transactions regarding any product candidates and related assets, including, without limitation, licensing transactions and asset sales. There can be no assurance that AVROBIO will be able to successfully consummate the merger or that the merger will be completed on attractive terms, within the anticipated timing, or at all. The process of continuing to evaluate these strategic options may be very costly, time- consuming and complex and AVROBIO has incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. AVROBIO may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in its business. In addition, any strategic business combination or other transactions that AVROBIO may consummate in the future could have a variety of negative consequences and it may implement a course of action or consummate a transaction that yields unexpected results that adversely affects its business and decreases the remaining cash available for use in its business or the execution of its strategic plan. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value or achieve the anticipated results. Any potential transaction would be dependent on a number of factors that may be beyond its control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with AVROBIO, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with AVROBIO on reasonable terms. Any failure of such a potential transaction to achieve the anticipated results could significantly impair its ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to its stockholders. If AVROBIO is not successful in setting forth a new strategic path for AVROBIO, or if its plans are not executed in a timely fashion, this may cause reputational harm with its stockholders and the value of its securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of AVROBIO could cause its stock price to fluctuate significantly. If AVROBIO is successful in completing the merger, it may be exposed to other operational and financial risks. Although there can be no assurance that the merger will be completed, the negotiation and consummation of the merger has required and will continue to require significant time on the part of its management, and the diversion of management' s attention may disrupt its business. The negotiation and consummation of the merger may also require more time or greater cash resources than AVROBIO anticipates and exposes AVROBIO to other operational and financial risks, including: • increased near- term and long- term expenditures; • exposure to unknown liabilities; • higher than expected acquisition or integration costs; • incurrence of substantial debt or dilutive issuances of equity securities to fund future operations; • write- downs of assets or goodwill or incurrence of non- recurring, impairment or other charges; • increased amortization expenses; • difficulty and cost in combining the operations and personnel of any acquired business with its operations and personnel; • impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership; • inability to retain key employees of AVROBIO or any acquired business; and • possibility of future litigation. Any of the foregoing risks could have a material adverse effect on its business, financial condition and prospects. AVROBIO' s corporate restructuring and the associated reduction in workforce may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt its business. In January 2022, and then between July 2023 and February 2024, AVROBIO implemented reductions in force that significantly reduced its workforce in order to conserve its capital expenditures. AVROBIO may not realize, in full or in part, the anticipated benefits, savings and improvements in its cost structure from its restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If AVROBIO is unable to realize the expected operational efficiencies and cost savings from the restructuring, its operating results and financial condition will be adversely affected. Furthermore, its restructuring plan may be disruptive to its operations. For example, its headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing its business strategy, including retention of its remaining employees. Employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business. Any future growth of AVROBIO' s business would impose significant added responsibilities on members of management, including the need to identify , recruit, maintain and integrate additional employees. Due to its limited resources, AVROBIO may not be able to effectively manage its operations or recruit and retain qualified personnel, which may result in weaknesses in its infrastructure and operations, risks that AVROBIO may not be able to comply with legal and regulatory requirements, loss of employees and reduced productivity among remaining employees. The impact and results of AVROBIO' s ongoing strategic process are uncertain and may not be successful. The AVROBIO Board remains dedicated to diligent deliberations and the making of informed decisions that the directors believe are in the best interests of the company and its stockholders. There can be no assurance, however, that the company' s current strategic direction, or the AVROBIO Board' s evaluation of strategic alternatives, will result in any initiatives, agreements, transactions or plans that will further enhance stockholder value. In addition, given the substantial restructuring of AVROBIO' s operations over the past several years, it may be difficult to evaluate its current business and future prospects on the basis of historical operating performance. Risks Related to the Discovery and Development of AVROBIO' s Product Candidates Business interruptions resulting from the COVID- 19 pandemic or similar public health crises have caused and may in the future cause a disruption of the development of AVROBIO' s product candidates and adversely impact AVROBIO' s business. Public health crises such as pandemics, epidemics, or any outbreak of an infectious disease or similar public health crises could adversely impact AVROBIO' s business. For example, the COVID- 19 pandemic disrupted normal business operations both in and outside of affected areas and has had significant negative impacts on businesses and financial markets worldwide. While AVROBIO currently has no ongoing clinical development activities following AVROBIO' s decision to halt its clinical development

programs while AVROBIO considers strategic alternatives, AVROBIO continues to monitor AVROBIO' s operations and follow applicable government recommendations, and the majority of AVROBIO' s employees have adopted a " hybrid " work schedule which generally limits the number of people in AVROBIO' s office at any particular time. Notwithstanding these measures, the COVID- 19 pandemic, including potential outbreaks of new variants, or any other public health crisis could affect the health and availability of AVROBIO' s workforce as well as those of the third parties on which AVROBIO relies. If members of AVROBIO' s management and other key personnel are unable to perform their duties or have limited availability due to any outbreak of an infectious disease or similar public health crises, AVROBIO may not be able to execute on AVROBIO' s business strategy and / or AVROBIO' s operations may be negatively impacted. In addition, clinical trial activities, should AVROBIO resume any such activities, including patient enrollment and data collection, are dependent upon global clinical trial sites which were adversely affected by the COVID- 19 pandemic. For example, as the global healthcare community responded to the fluctuations in COVID- 19 cases and hospitalizations, many hospitals, including AVROBIO' s clinical sites, temporarily paused elective procedures, which included dosing of new patients with AVROBIO' s investigational gene therapies. While AVROBIO substantially resumed data collection and dosing of new patients until halting AVROBIO' s development programs in July 2023, AVROBIO' s ability to continue clinical activities without further delay or interruption, should AVROBIO resume development of its programs, will depend on future developments that are highly uncertain and cannot be accurately predicted. Additional factors from any public health crisis that may delay or otherwise adversely affect enrollment in or the progress of the clinical trials of AVROBIO' s product candidates if AVROBIO resumes development of its programs, as well as AVROBIO' s business generally, include: • the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as AVROBIO' s clinical trial investigators, hospitals serving as AVROBIO' s clinical trial sites and hospital staff supporting the conduct of AVROBIO' s clinical trials; • limitations on travel that could interrupt key trial activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government- imposed travel restrictions or quarantines that may impact the ability or willingness of patients, employees or contractors to travel to AVROBIO' s clinical trial sites or secure visas or entry permissions, any of which could delay or adversely impact the conduct or progress of AVROBIO' s clinical trials; • interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in AVROBIO' s clinical trials; • business disruptions caused by workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact AVROBIO' s business operations or those of third party service providers, contractors, or suppliers on whom AVROBIO relies, impair the productivity of AVROBIO' s personnel, subject AVROBIO to additional cybersecurity risks, create data accessibility problems, cause AVROBIO to become more susceptible to communication disruptions, or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors; • business disruptions involving AVROBIO' s third parties on whom AVROBIO relies, including contract research organizations, or CROs, and other collaborators for the conduct of AVROBIO' s clinical trials or AVROBIO' s third party suppliers or manufacturers, which could impact their ability to perform adequately or disrupt AVROBIO' s supply chain; and • changes in hospital or research institution policies or government regulations, which could delay or adversely impact AVROBIO' s ability to conduct AVROBIO' s clinical trials. These and other factors arising from the public health crises could reemerge or worsen and adversely impact AVROBIO' s ability to conduct clinical trials and AVROBIO' s business generally, and could have a material adverse impact on AVROBIO' s operations and financial condition and results. The extent to which any public health crisis impacts AVROBIO' s operations or those of AVROBIO' s third party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the public health crisis, the efficacy and safety of vaccines, including against emerging variants, the ability of third parties to manufacture and distribute vaccines, among others. AVROBIO' s HSC lentiviral- based gene therapy product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development and of subsequently obtaining regulatory approval, should AVROBIO resume development of AVROBIO' s product candidates. AVROBIO has concentrated AVROBIO' s research and development efforts on AVROBIO' s HSC gene therapy approach, and should AVROBIO resume development of its product candidates AVROBIO' s future success would depend on AVROBIO' s successful development of viable gene therapy product candidates. There can be no assurance that AVROBIO will not experience problems or delays in developing new product candidates, should AVROBIO resume development of its product candidates, and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. For example, timely enrollment in AVROBIO' s clinical trials is dependent upon global clinical trial sites which were adversely affected by the COVID- 19 pandemic. In addition, AVROBIO may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial, additional or alternative partners, which should AVROBIO resume development of its product candidates may prevent AVROBIO from completing clinical studies or commercializing AVROBIO' s products on a timely or profitable basis, if at all. For example, as of July 12, 2023, the date on which AVROBIO announced that AVROBIO was halting all further development activities in AVROBIO' s programs, AVROBIO had dosed 11 patients using AVROBIO' s plato platform, including six patients in AVROBIO' s FAB- GT clinical trial (for which AVROBIO previously halted enrollment) and five patients in AVROBIO' s Guard1 clinical trial. AVROBIO' s implementation of the LV2 lentiviral vector or of AVROBIO' s cell processing to an industrialized, automated closed system using disposable supplies may not be successful or may experience unforeseen delays, should AVROBIO resume development of its product candidates, which may cause shortages or delays in the supply of AVROBIO' s products available for clinical trials and future commercial sales, if any, or impair AVROBIO' s research and development efforts, including those in any future clinical trials. In addition, there is no assurance that products using AVROBIO' s proprietary LV2 lentiviral vector

or manufactured using this automated system will ultimately achieve the same favorable preliminary results observed to date. Furthermore, the FDA generally prefers that clinical trials be double- blinded and potentially include sham controls. Such a trial design could be challenging to implement due to the nature of the treatment regimen of HSC gene therapy. In addition, the clinical trial requirements of the FDA and other foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as AVROBIO' s can be more expensive and take longer than for other, better known or more extensively studied product candidates. To date, only a limited number of HSC gene therapies have received marketing authorization from the FDA or foreign regulatory authorities. Should AVROBIO resume development of its product candidates, it is difficult to determine how long it would take or how much it would cost to obtain regulatory approvals for those product candidates in the United States, Canada, Europe, Japan or other major markets or how long it would take to commercialize those product candidates, if any were to be approved. Approvals by foreign regulatory authorities may not be indicative of what the FDA may require for approval, and vice versa. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the NIH also are subject to the NIH Guidelines, under which supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or the IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical trial can begin at any institution, its IRB and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of AVROBIO' s product candidates should AVROBIO resume their development. Similarly, foreign regulatory authorities may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that AVROBIO complies with these new guidelines. The FDA, NIH and the EMA have each expressed interest in further regulating biotechnology, including gene therapy and genetic testing. For example, the EMA advocates a risk-based approach to the development of a gene therapy product. Agencies at both the federal and state level in the United States, as well as the U. S. congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. For example, in 2016, the FDA established the Office of Tissues and Advanced Therapies, or the OTAT, within the CBER to consolidate the review of gene therapy and related products, and to advise the CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products, or the OTP, and elevation of OTP to a " Super Office " to meet its growing cell and gene therapy workload. Although FDA has indicated that this change of name and responsibilities is intended to, among other things, increase review capabilities and enhance expertise on new cell and gene therapies, AVROBIO cannot be certain that this approach will improve the time and cost associated with navigating gene therapy regulatory requirements, AVROBIO' s regulatory strategy or the potential success of AVROBIO' s product candidates. Such regulatory action and developments could, instead, delay, impede or even prevent commercialization of some or all of AVROBIO' s product candidates. These regulatory review committees and advisory groups and any new guidelines they promulgate may lengthen the regulatory review process, require AVROBIO to perform additional studies, increase AVROBIO' s development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post- approval limitations or restrictions. Should AVROBIO resume development of AVROBIO' s product candidates, AVROBIO will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. If AVROBIO fails to do so, AVROBIO may be required to delay or discontinue development of certain of those product candidates. These additional processes may result in a review and approval process that is longer than AVROBIO otherwise would have expected. Should AVROBIO resume development of its product candidates, the delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease AVROBIO' s ability to generate sufficient product revenue, and AVROBIO' s business, financial condition, results of operations and prospects would be materially and adversely affected. The FDA continues to develop its guidance for assessing gene and cell therapy products. For example, the agency has released a series of draft and final guidance documents relating to, among other topics, various aspects of gene therapy product development, review, and approval, including aspects relating to clinical and manufacturing issues related to gene therapy products. In January 2020, the FDA released a final guidance with recommendations for long- term follow- up studies of patients following human gene therapy administration due to the increased risk of undesirable and unpredictable outcomes with gene therapies that may present as delayed adverse events. Foreign regulatory agencies also may have requirements for **or** 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~~ **products** ~~candidates for any or all targeted indications. There have been cases of therapy- related myelodysplastic syndrome~~ , a ~~type~~ **number** of ~~blood disorder that is a potential precursor to acute myeloid leukemia, in patients with preexisting cancer where busulfan treatment was posited to be a contributing factor to this secondary malignancy. Even if AVROBIO is able to demonstrate that adverse events are not product- related, such occurrences could adversely affect patient recruitment (should AVROBIO resume development of its product candidates) or the ability of enrolled patients to complete the clinical trial, and lead to a decline in AVROBIO' s stock price. Additionally, if AVROBIO resume development of its programs and any of AVROBIO' s product candidates receives marketing approval, the FDA could require AVROBIO to adopt a REMS to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, and restrictions on how or where the product can be distributed, dispensed or used. Furthermore, if AVROBIO or others later identify undesirable side effects caused by AVROBIO' s product candidates, several~~ potentially significant negative consequences could result, including: • regulatory authorities may ~~suspend or~~ withdraw approvals of such product ~~candidate~~ **and require us to take such approved product off the market** ; • regulatory authorities may require **the** ~~additional~~ -- **addition** ~~or boxed~~ **of labeling statements, specific** warnings ~~on the label~~ **, a contraindication or field alerts to physicians and pharmacies** ; • ~~AVROBIO~~ **regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy (" REMS ") plan to ensure that the benefits of the product outweigh its risks; • we** may be required to change the way ~~a~~ **the** product ~~candidate~~ is ~~distributed, dispensed, or~~ administered ~~or~~ **,** conduct additional clinical trials **or change the labeling of the product** ; • ~~AVROBIO could~~ **we may** be **subject** ~~sued and held liable for harm caused~~ to ~~patients~~ **limitations on how we may promote the product** ; ~~and~~ • ~~AVROBIO' s~~ **sales of the product may decrease significantly; • we may be subject to litigation or product liability claims; and • our** reputation may suffer. Any of these events could prevent ~~AVROBIO~~ **us, our collaborators or our potential future partners** from achieving or maintaining market acceptance of ~~AVROBIO' s~~ **the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our** product candidates, **if** ~~lead to a decline in AVROBIO' s stock price, and significantly harm AVROBIO' s business, prospects, financial condition and results of operations. AVROBIO has never completed a pivotal or registrational clinical trial, and may be unable to do so for~~

any product candidates AVROBIO may develop, should AVROBIO resume development of its product candidates. AVROBIO is at an early stage of development for all of AVROBIO' s product candidates, and has currently halted further development of AVROBIO' s programs. Twenty- five patients were dosed in AVROBIO' s clinical trials, which includes 14 patients from AVROBIO' s Fabry program that AVROBIO deprioritized in January 2022, six patients in AVROBIO' s cystinosis program that AVROBIO sold to Novartis in June 2023, and five patients in AVROBIO' s Gaucher disease type 1 program. Should AVROBIO resume development of its product candidates, further clinical trials must be completed in order to obtain FDA or other regulatory approval to market these product candidates. AVROBIO has limited experience in preparing, submitting and prosecuting regulatory filings, and has not previously submitted a BLA for any product candidate. Carrying out later- stage clinical trials is a complicated and lengthy process, and AVROBIO does not expect that all data from patients participating in the clinical trials will be relevant or meaningful. In addition, across AVROBIO- sponsored clinical trials AVROBIO has dosed only four patients in the United States, and AVROBIO' s interactions with the FDA have generally been limited. AVROBIO cannot be certain how many additional clinical trials of any of AVROBIO' s product candidates would be required or how such trials should be designed, should AVROBIO resume development of its programs. In order to commence a clinical trial in the United States, AVROBIO is required to seek FDA acceptance of an IND for each of AVROBIO' s product candidates. AVROBIO cannot be sure any IND AVROBIO submits to the FDA, or any similar CTA AVROBIO submits in other countries, will be accepted. Should AVROBIO resume development of its product candidates, there can be no assurance that AVROBIO would be able to submit and secure similar clearances for any of AVROBIO' s other product candidates. AVROBIO may also be required to conduct additional preclinical testing prior to filing an IND for any of AVROBIO' s product candidates, and the results of any such testing may not be positive. Consequently, AVROBIO may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to a BLA submission and approval of any of AVROBIO' s product candidates. AVROBIO may require more time and incur greater costs than AVROBIO' s competitors and may not succeed in obtaining regulatory approvals of product candidates that AVROBIO develops. Failure to commence or complete, or delays in, the necessary clinical trials, could prevent AVROBIO from or delay AVROBIO in commercializing any of AVROBIO' s product candidates. Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials, should AVROBIO resume development of its product candidates. Results from preclinical studies or early clinical trials are not necessarily predictive of future clinical trial results and are not necessarily indicative of final results. There can be no assurance that prior results, such as signals of safety, activity or durability of effect, observed from preclinical studies or clinical trials will be replicated or will continue in ongoing or future studies or trials, should AVROBIO resume development of any of its programs. Furthermore, preliminary results may not be indicative of the final results of a trial after all data have been collected and analyzed. For example, in January 2022 AVROBIO announced the deprioritization of AVROBIO' s Fabry program due to several factors, including new clinical data showing variable engraftment patterns from the five most recently dosed Phase 2 FAB- GT patients. Although previously reported data from 13 patients treated across AVROBIO' s clinical- stage programs had shown durable engraftment out 9 to 54 months, the new data from the five most recently dosed Phase 2 FAB- GT patients were discordant with these other data and showed variable engraftment. Should AVROBIO resume development of its product candidates, there can be no assurance that similar engraftment or other issues will not occur in clinical trials of AVROBIO' s other product candidates, which are all based on AVROBIO' s technology and the same HSC approach utilized for AVR- RD- 01. There is a high failure rate for gene therapy and biologic product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in preclinical testing and earlier- stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, the design of a pivotal clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. AVROBIO has limited experience in designing and conducting clinical trials and AVROBIO may be unable to design and execute a clinical trial to support regulatory approval, should AVROBIO resume development of its product candidates. AVROBIO also may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy or the approval of competitive therapies during the period of AVROBIO' s product candidate development. Should AVROBIO resume development of any of AVROBIO' s product candidates, those product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies. Any such failure would cause AVROBIO to abandon the product candidate. Additionally, the clinical trials performed to date have been open- label studies and have been conducted at a limited number of clinical sites on a limited number of patients. An " open- label " clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. **We** 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 **our** AVROBIO'

~~s~~ clinical trials, which could delay or prevent ~~AVROBIO~~ **us** from proceeding with **, or otherwise adversely affect,** clinical trials of **our** ~~AVROBIO' s~~ product candidates. ~~Should AVROBIO resume development~~ **Identifying and qualifying patients to participate in clinical trials** of ~~its~~ **our** product candidates ~~, the timing and~~ **is critical to our** success **. The timely completion** of **our** ~~AVROBIO' s patient enrollment and~~ clinical **trials in accordance with our protocols depends, among other things, on our ability to recruit a sufficient number of eligible patients to participate and remain in the** trial **until its conclusion.** ~~activities would depend on AVROBIO' s ability to recruit patients~~ **Patients may be unwilling** to participate ~~as well as the completion of required follow- up periods. Patients may be unwilling to participate~~ in **our** ~~AVROBIO' s gene therapy~~ clinical trials because of negative publicity from adverse events related to **novel therapeutic approaches** ~~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. **Any delays related to** ~~In addition, the indications that AVROBIO has targeted and may in the future target are rare diseases, which may limit the pool of patients~~ **patient** ~~that may be enrolled~~ **enrollment could result** in **increased costs, delays in advancing our** ~~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 **our** ~~AVROBIO' s~~ product candidates or termination of the clinical trials altogether. **We** ~~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 **the** required or desired characteristics, to complete **our** ~~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 **many** factors **,** including the: • **location of trial sites in Moldova and Georgia for the Phase 1b trial and Phase II with its proximity to the conflict between Russia and the Ukraine; • delays in obtaining, or the inability to obtain, required approvals from institutional review boards (" IRBs ") and ethics committees or other governing entities at clinical trial sites selected for participation in our clinical trials; • delays in reaching agreement on acceptable terms with clinical trial sites on clinical budgets and / or clinical trial agreements; • deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements; •** size **and nature** of the patient population and process for identifying patients; • ~~design~~ **proximity and availability** of ~~the~~ **clinical** trial ~~protocol~~ **sites for prospective patients** ; • eligibility and exclusion criteria **for the trial** ; • ~~perceived risks and benefits~~ **design of the clinical trial; • safety profile, to date,** of the product candidate under study; • perceived risks and benefits of **the product candidate under study** ~~gene therapy- based approaches to treatment of diseases, including any required pretreatment conditioning regimens~~ ; • ~~availability~~ **perceived risks and benefits of our approach; • approval** of competing ~~therapies and~~ **product candidates currently under investigation for the treatment of similar diseases or conditions, or competing** clinical trials **for similar product candidates or targeting patient populations meeting our patient eligibility criteria** ; • severity of the disease under investigation; • ~~availability~~ **degree** of **progression of the** ~~genetic testing for potential patients~~ **patient** ~~; • proximity and availability~~ **' s disease at the time** of **enrollment** ~~clinical trial sites for prospective patients~~ ; • ability to obtain and maintain ~~subject~~ **patient** consent; • risk that enrolled patients will drop out before completion of the trial; • patient referral practices of physicians; and • ability to **adequately** monitor patients ~~adequately~~ during and after treatment. ~~AVROBIO historically expanded AVROBIO' s~~ **Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Delays in** patient enrollment **may result** ~~activities to include patients who reside~~ in ~~a country~~ **increased costs or may affect** ~~other~~ **the** ~~than the country where the applicable~~ **timing or outcome of our future** clinical **trials** ~~site is located~~ **, which could prevent completion of these trials** and ~~who~~ **adversely affect our ability to advance the development of our product candidates. Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and** are ~~required~~ **subject** to ~~travel~~ **audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim, topline** ~~for~~ **or** ~~some~~ **preliminary data from** ~~or~~ **our** ~~all of the~~ clinical ~~testing~~ **trials. Preliminary** and ~~procedures required for~~ **interim data from our clinical trials may change as more** ~~patients~~ **patient** ~~in~~ **data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to** the ~~applicable~~ **risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final** clinical trial **report** . **Interim** ~~AVROBIO has encountered and~~ **, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, topline and interim data** should ~~AVROBIO resume development~~ **be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance** of **data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, if any, and the company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial** ~~its~~ **is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate**

**information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, if any, product candidate or our business. If the preliminary and interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our** product candidates ~~, in the future~~ may **be harmed** ~~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 **harm our business, operating results, prospects or financial condition. Preclinical development is uncertain. Our preclinical programs may experience** ~~delay~~ **delays or may never advance to** ~~AVROBIO' s progress and completion of planned~~ clinical trials ~~and~~ **, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all,** which would have an adverse effect on **our** ~~AVROBIO' s~~ business. **Before we can commence clinical trials for any product candidate, we must complete extensive preclinical studies that support any future Investigational New Drug (" IND ") applications in the United States, or similar applications in other jurisdictions.** In ~~addition~~ **July 2024** , **we received clearance from** ~~once these international patients return to their home country, they~~ - **the** ~~may need to travel back to the country where the applicable~~ **FDA for our IND application for our TX45 program. Conducting** ~~clinical~~ **preclinical** ~~site~~ **testing** is **a lengthy** ~~located. If these patients are unwilling or unable to return to the clinical site for testing and procedures~~ , **time- consuming and expensive** ~~progress~~ **process** and ~~completion of the clinical trial could be delayed~~ **delays associated with** ~~or prevented. AVROBIO' s~~ product candidates **for which we** ~~were being developed to treat rare~~ - **are** ~~conditions~~ **directly conducting preclinical testing and studies may cause us to incur additional operating expenses** . ~~Should AVROBIO resume development~~ **While we are currently conducting a Phase 1b and the recently initiated Phase 2 clinical trials for TX45, including some trials which may be outside** of ~~its~~ **the United States, we cannot be certain of the timely completion or outcome of our preclinical testing and studies for our other** product candidates ~~, AVROBIO would expect to seek initial marketing approvals in the United States, Europe~~ and ~~certain~~ **cannot predict if** ~~other~~ -- **the FDA will accept** ~~major markets, including Japan. However, AVROBIO may not be able to resume, initiate or~~ **our** ~~continue~~ **proposed clinical programs or if the outcome of our preclinical testing and foreign** clinical trials **will ultimately support the further development of our other product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect,** if ~~AVROBIO~~ **at all, and we** cannot ~~enroll a sufficient number~~ **be sure that submission** of ~~eligible patients to participate~~ **INDs or similar applications will result** in the ~~clinical trials required by~~ FDA or ~~other~~ **comparable** foreign regulatory authorities **allowing clinical trials to begin** . ~~AVROBIO~~ **The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, laws or regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate** ' s ~~ability to successfully resume, initiate, enroll and complete a~~ clinical ~~trial in~~ **development and may vary among jurisdictions. We have not obtained regulatory approval for** any ~~foreign country~~ **product candidate and it** is ~~subject~~ **possible that none of our existing product candidates or any product candidates we may seek** to **develop** ~~numerous risks unique to conducting business~~ in ~~foreign countries~~ **the future will ever obtain regulatory approval. Our product candidates could fail to receive regulatory approval for many reasons** , including **the following** : • **the FDA** ~~difficulty in establishing~~ or ~~managing relationships~~ **comparable foreign regulatory authorities may disagree** with **the design** ~~CROs clinical study sites and physicians; • different standards for~~ - **or implementation** ~~the conduct~~ of **our** clinical trials; • **we** ~~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 **be unable** ~~need to delay, limit or terminate the resumption or continuation of clinical trials, any of which would have an adverse effect on AVROBIO' s business, financial condition, results of operations and prospects. Should AVROBIO resume development of its product candidates, AVROBIO may encounter substantial delays in resuming its clinical trials or AVROBIO may fail~~ to demonstrate ~~safety and efficacy~~ to the satisfaction of ~~applicable regulatory authorities. Before obtaining marketing approval from regulatory authorities for the sale of AVROBIO' s product candidates, AVROBIO must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time- consuming and uncertain as to outcome. Should AVROBIO resume development of its product candidates, AVROBIO cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development, should AVROBIO resume any clinical development programs, include: • delays in reaching a consensus with regulatory agencies on study design; • delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites; • delays in obtaining required IRB approval at each clinical study site; • delays in recruiting suitable patients to participate in AVROBIO' s clinical studies; • imposition of a clinical hold by regulatory agencies, after an inspection of AVROBIO' s clinical study operations or study sites; • failure by AVROBIO' s CROs, other third parties or AVROBIO to adhere to clinical study requirements; • failure to perform in accordance with~~ the FDA ~~' s GCP or~~

applicable regulatory guidelines in other countries; • delays in the testing, validation, manufacturing and delivery of AVROBIO's product candidates to the clinical sites; • delays in having patients complete participation in a study or return for **or** 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 - **candidate is safe** are granted such designations , AVROBIO **pure and potent for its proposed indication; • the population studied** may not be able **sufficiently broad or representative** to realize **assure safety or efficacy in** the intended benefits **population for which we seek approval; • the results** of such designations. The **clinical trials may not meet the level of clinical significance required by the** FDA and **or** comparable foreign regulatory authorities offer certain designations for **approval; • we may be unable to demonstrate that a** product candidates - **candidate** 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 **clinical and** 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 - **other** can be no assurance that AVROBIO will realize their intended benefits **outweigh** . AVROBIO may seek a Breakthrough Therapy Designation for some of AVROBIO' s product candidates should AVROBIO resume development of its **safety risks; •** 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 **disagree with** grant accelerated approval to a therapeutic candidate designed to treat a serious or **our interpretation of data from preclinical studies** 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 **trials; •** 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~~ **may require additional preclinical studies or clinical trials beyond those that we currently anticipate; • the data collected from clinical trials of our product candidates may not be sufficient** to ~~seek and receive such accelerated~~ **support the submission of a Biologics License Application (" BLA ") as applicable, to the FDA or other submission or to obtain regulatory** approval **in** ~~. There can be no assurance that after AVROBIO' s evaluation of the feedback and other~~ -- **the United States** ~~factors AVROBIO would decide to pursue or submit a BLA for~~ - **or elsewhere; •** ~~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 **may find deficiencies with** ~~, AVROBIO would continue to pursue~~ or ~~apply~~ **fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract** for ~~accelerated~~ **clinical and commercial supplies; and • the** approval **policies or regulations of the FDA** 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 **or the laws they enforce may significantly change in a manner rendering our clinical data insufficient for approval. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, financial condition and results of operations. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, if any, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. The FDA and any comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction. We are presently conducting clinical development in the United States, Eastern Europe, the European Union, Australia, and New Zealand and will likely choose to conduct additional international clinical trials in the future. The acceptance of study data by the FDA or any comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice, (ii) the trials are performed by clinical investigators of recognized competence and pursuant to compliance with current GCP requirements and (iii) the FDA is able to validate the data through an on- site inspection or other appropriate mean. Additionally, the FDA' s clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time- consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction. Even if we receive regulatory approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with such product candidate. If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies and submission of safety, efficacy and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with CGMPs and GCP requirements for any clinical trials that we conduct post- approval. 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. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with CGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we receive for our product candidates may be subject to 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 safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long- term patient follow- up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post- marketing information and reports and registration. The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; • fines, warning letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals; • product seizure or detention or refusal to permit the import or export of our product candidates; and • injunctions or the imposition of civil or criminal penalties. The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses and a company that is found to have improperly promoted off- label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product' s labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off- label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer' s communications on the subject of off- label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined companies from engaging in off- label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product' s FDA approved labeling. The holder of a BLA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We** could also ~~require AVROBIO~~ **be asked** to conduct ~~further studies prior~~ **post- marketing clinical trials** to ~~considering AVROBIO~~ **verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post- marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post- marketing study or failure to complete such a study could result in the withdrawal of marketing approval. The policies of the FDA and of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. If approved, our investigational products may face competition from biosimilars approved through an abbreviated regulatory pathway. We are developing TX45 initially for the treatment of Group 2 Pulmonary Hypertension (" PH ") in HFpEF, which we anticipate will be regulated as a biological product. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the " ACA ") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (" BPCIA "), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor** ' s ~~application or granting approval of any type~~ **own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety** , ~~including~~ **purity** , ~~for example, if~~ **and potency of the** other **company** ~~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~~ **. The law is complex and is still being interpreted and implemented by the FDA. As a** result ~~in~~ **, its ultimate impact, implementation, and meaning are subject to uncertainty. We believe that any of our product candidates approved as** a ~~longer time~~ **biological product under a BLA should qualify for the 12- year** period **of exclusivity. However, there is a risk that this exclusivity could be shortened due** to **congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated.**

**Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biotechnology products. Currently, we have no products that have been approved for commercial sale; however, the current and future use of product candidates by us and our collaborators in clinical trials, and the potential sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, our collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for** commercialization of ~~such~~ **our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the** product candidate, ~~could increase the cost of development of such~~ **we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our** product ~~candidate~~ **candidates** ~~and could harm AVROBIO~~ **. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our products due to negative public perception; • injury to our reputation; • withdrawal of clinical trial participants or difficulties in recruiting new trial participants; • initiation of investigations by regulators; • costs to defend or settle the related litigation; • a diversion of management** ' s ~~competitive position in the marketplace. Moreover~~ **time and our resources; • substantial monetary awards to trial participants or patients; • product recalls** , ~~even~~ **withdrawals or labeling, marketing or promotional restrictions; • loss of revenues from product sales; and • the inability to commercialize any of our product candidates,** if ~~AVROBIO~~ **approved. Although we believe we maintain adequate product liability insurance for our product candidates, it** is **possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the** ~~able~~ **sale** ~~to~~ **of commercial products if we** obtain ~~accelerated~~ **marketing** approval for any of **our** ~~AVROBIO's~~ product candidates **. However** , ~~there~~ **we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims** is **brought against us for uninsured liabilities or in excess of insured liabilities, our assets may** ~~no~~ **not** ~~guarantee that~~ **be sufficient to cover such claims and our business operations could be impaired. Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations. Due to our limited resources and access to capital, we must, and have in the** ~~post~~ **past decided** ~~approval studies will be able~~ to ~~confirm~~ **, prioritize development of certain product candidates over** ~~the~~ **other** ~~clinical benefit~~ **potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs** , **our attractiveness as a commercial partner and may ultimately have an impact on our commercial success. Because we have limited resources and access to capital to fund our operations, we must decide** which **product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular proprietary molecules in our library, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and** could cause ~~FDA~~ **us** to **miss valuable opportunities** ~~withdraw AVROBIO's approval~~ . ~~Should AVROBIO resume development~~ **If we make incorrect determinations regarding the market potential** of ~~its~~ **our** product candidates ~~, AVROBIO may also pursue programs~~ or **misread trends** ~~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~~ -- **the biotechnology industry** ~~is a significant patient or public health need in the UK. To access the ILAP~~ , **in particular** ~~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~~ **our lead** ~~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~~ , **TX45** ~~there can be no assurance that the FDA would decide to grant it. Even if AVROBIO does receive Fast Track designation~~ , **TX2100** ~~AVROBIO may not experience a faster development process~~ , ~~review or~~ **our business** ~~approval compared to conventional FDA procedures~~ , **financial condition** and **results** ~~receiving a Fast Track designation does not provide assurance~~ of ~~ultimate FDA approval~~ **operations could be materially adversely affected** . **We** ~~In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from AVROBIO's clinical development program. In addition, should AVROBIO resume development of AVROBIO's product candidates, AVROBIO~~ may seek ~~a RMAT designation for some of AVROBIO's product candidates. An RMAT is defined as cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Gene therapies, including genetically modified cells that lead to a durable modification of cells or tissues may meet the definition of a regenerative medicine therapy. The RMAT program is intended to facilitate efficient development and expedite review of RMATs, which are intended to treat, modify, reverse, or cure a serious or life- threatening disease or condition. A new drug application or a BLA for an RMAT may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long- term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy that is granted accelerated approval and is subject to post- approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real- world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post- approval monitoring of all patients treated with such therapy prior to its approval. RMAT designation is within the discretion of the FDA. Accordingly, even if AVROBIO believes one of AVROBIO's product candidates meets the criteria for designation as a regenerative medicine advanced therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of AVROBIO's product candidates qualify for RMAT designation, the FDA may later decide that the biological products no longer meet the conditions for qualification. Should AVROBIO resume development of its product candidates, AVROBIO may be unable to obtain~~ orphan drug designation for ~~AVROBIO's~~ product candidates ~~and~~ **we develop** , ~~even if AVROBIO obtains such~~ **and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug** designation, **including** ~~AVROBIO may not be able to realize~~ the ~~benefits~~ **potential for market exclusivity. As part** of ~~such~~ **our business strategy, we may seek orphan drug** designation **for any** ~~, including potential marketing exclusivity of AVROBIO's~~ product candidates **we develop** , ~~if approved~~ **and we may be unsuccessful. While we have not made a determination on whether we intend to seek orphan drug designation for any of our product candidates at this time, we may do so in the future** . Regulatory authorities in some jurisdictions, including the United States ~~and other major markets~~ , may designate drugs ~~intended to treat conditions or~~ **for** ~~diseases affecting~~ relatively small patient populations as orphan drugs. Under the Orphan Drug Act ~~of 1983~~ **in the United States** , the FDA may designate a **drug** ~~product candidate~~ as an orphan drug if it is **a drug** intended to treat a rare disease or condition, which is generally defined as ~~having~~ a patient population of fewer than 200, 000 individuals **annually** 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~~ **United States** , ~~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)~~ **entitles a party to financial incentives such as opportunities** for ~~any other product candidates, there can be no assurances that the FDA or applicable foreign regulatory authorities will~~ grant ~~such designation. Additionally~~ **funding towards certain clinical trial costs** , **tax advantages** ~~the designation of any of AVROBIO's product candidates as an~~ **and user- fee waivers. Generally** ~~orphan product does not mean that any regulatory agency will accelerate regulatory review of~~ , **in** ~~or ultimately approve, that product candidate, nor does it limit~~ the **United States, if a** ~~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 **subsequently** receives the first marketing approval for the indication for which it has such designation, the ~~product~~ **drug** 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 **seven years** ~~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 **we** obtains - **obtain** orphan drug exclusivity for a **any of our** product candidate **candidates**, that exclusivity may not effectively protect the product candidate from competition because different drugs **therapies** can be approved for the same condition in **and** the United States **same therapies can be approved for different conditions but used off- label**. Even after an orphan drug is approved, the FDA may **can** subsequently approve another **the same** drug for the same condition if the FDA concludes that the latter - **later** 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 **addition** the European Union, a **designated** marketing authorization may be granted to a similar medicinal product for the same orphan indication at any time **drug may not receive orphan drug exclusivity** if : • the second applicant can establish in its - **it** application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior; • the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or • the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product. A marketing application for a product candidate with rare pediatric disease designation, or RPDD, if approved, may not meet the eligibility criteria for a Priority Review Voucher, or PRV, or the RPDD program may sunset before the FDA is able to consider eligibility for a voucher. Designation of a drug or biologic as a product for a rare pediatric disease does not guarantee that a BLA for such drug or biologic will meet the eligibility criteria for a rare pediatric disease PRV at the time the application is approved. Under the FD & C Act, should AVROBIO resume development of AVROBIO' s product candidates, AVROBIO would need to request a rare pediatric disease PRV in AVROBIO' s original BLA for any of AVROBIO' s product candidates that previously received RPDD. The FDA may determine that any such BLA, if approved, does not meet the eligibility criteria for a PRV, including for the following reasons: • The disease indication no longer meets the definition of a rare pediatric disease; • the BLA contains an active ingredient that has been previously approved in a BLA; • the BLA is not deemed eligible for priority review; • the BLA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population (that is, if the BLA does not contain sufficient clinical data to allow for adequate labeling for use by the full range of affected pediatric patients); or • the BLA is approved for a different adult **use that is broader than the** indication than the rare pediatric disease for which **it received orphan designation. Moreover, orphan drug exclusive marketing rights in** the product candidate **United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer** is **unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug** designated **designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process**. The authority **While we may seek orphan drug designation** for **applicable indications** the FDA to award rare pediatric disease PRVs for **our** drugs that have received rare pediatric disease designation prior to September 30, 2024 currently -- **current and** expires on September 30, 2026. If the BLA for any **future** of AVROBIO' s product candidates with RPDD **, we may never receive such designations. Even if we do receive such designations, there** is not - **no guarantee that we** approved prior to September 30, 2026 for any reason, regardless of whether it meets the criteria for a rare pediatric disease PRV, it will **enjoy the benefits of** not be eligible for a PRV. However, it is also possible the **those designations** authority for FDA to award rare pediatric disease PRVs will be further extended through federal lawmaking. Should AVROBIO resume development **Risks Related to Commercialization** of its **Our** product **Product** candidates **Candidates**, even if AVROBIO **If we are successful in** obtains **obtaining** regulatory **marketing** approval **from** 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 **TX45 or any** compliance with cGMP requirements and adherence to commitments made in the **other** 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 **candidate** tracking and tracing requirements. If AVROBIO , or **our ability to generate revenues from any** 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 **products** is manufactured **will depend on** or **our success in** 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~~ : • **launching commercial sales** ~~issue a warning letter asserting that AVROBIO is in violation~~ of ~~the law~~ **such products, whether alone or in collaboration with others** ; • ~~seek an injunction~~ **receiving approved labels with claims that are necessary or desirable** ~~or~~ **for** ~~impose administrative~~ **successful marketing** , ~~civil~~ **and that do not contain safety or other limitations that would impede** ~~or~~ **our** ~~criminal penalties or monetary fines~~ **ability to market such products** ; • ~~suspend~~ **creating market demand** ~~or~~ **for** ~~withdraw regulatory~~ **such products through marketing, sales and promotion activities; • hiring, training, and deploying a sales force or contracting with third parties to commercialize such products in the United States; • creating strategic collaborations with, or offering licenses to, third parties to promote and sell such products in foreign markets where we receive marketing** approval; • ~~suspend any ongoing~~ **manufacturing such products (i) in sufficient quantities, (ii) at acceptable quality and cost and (iii) in a presentation that is practical and compatible with the intended** clinical ~~trials~~ **use to meet commercial demand at launch and thereafter** ; • ~~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 **wholesalers** 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 , **distributors** 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 **and group purchasing organizations** 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~~ **maintaining patent** and **trade secret protection** ~~cost associated with locating~~ and **regulatory exclusivity** ~~qualifying alternative suppliers~~ for **such products** ~~AVROBIO' s components in a timely manner~~ ; • **achieving market acceptance** ~~production delays related to the evaluation and testing~~ of **such** products **by patients** ~~from alternative suppliers~~ , **the medical community,** and ~~corresponding regulatory qualifications~~ **third- party payors** ; • **achieving coverage and adequate reimbursement from third- party payors for such products** ~~a delay in delivery due to AVROBIO' s suppliers prioritizing other customer orders over AVROBIO' s~~ ; • **patients** ~~damage to AVROBIO~~ ' ~~s reputation caused by defective components produced by AVROBIO' s suppliers~~ **willingness to pay out- of- pocket in the absence of such coverage and adequate reimbursement from third- party payors** ; • ~~increased cost~~ **effectively competing with other therapies; and • maintaining a continued acceptable safety profile** of **such** ~~AVROBIO' s warranty program due to product~~ **products** ~~repair~~ **following launch. To the extent we are not able to do any of the foregoing, or our** ~~replacement based upon defects in components produced~~ **business, financial condition, results of operations, stock price and prospects will be materially harmed. The biotechnology industry is characterized** by **intense competition** ~~AVROBIO' s suppliers;~~ and **rapid innovation. Our competitors may be able** ~~• fluctuation in delivery by AVROBIO' s suppliers due~~ to **develop** ~~changes in demand from AVROBIO or their~~ other ~~customers~~ **compounds or drugs that are able to achieve similar or better results** . ~~If~~ **Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions.** ~~any~~ **Many** of ~~these risks materialize~~ **our competitors have substantially greater financial** , ~~AVROBIO' s costs could~~ **technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well- established sales forces. Smaller or early- stage companies may also prove to be** ~~significantly~~ ~~--~~ **significant competitors** ~~increase and AVROBIO' s ability to conduct AVROBIO' s clinical trials and~~ , ~~if AVROBIO' s~~ **particularly as they develop novel approaches to treating disease indications that our** product candidates are ~~approved,~~ **also focused on treating. Established pharmaceutical companies may also invest heavily** to ~~meet demand~~ **accelerate discovery and development of novel therapeutics** ~~for~~ - **or** ~~AVROBIO' s products~~ **to in- license novel therapeutics that** could **make** ~~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 -- **the** 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 **we develop obsolete** may not be detectable in final product testing . AVROBIO **Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in** or **our competitors. Competition may increase further as** AVROBIO' s contract manufacturers must supply all necessary documentation in support of a BLA **result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing** on a timely **an exclusive** basis **drug or biologic** and must adhere to the FDA' s GLP and cGMP regulations enforced by the FDA through its facilities inspection program. Some of AVROBIO' s contract manufacturers have not produced a commercially- approved product **products that are more effective, safer, more easily commercialized** 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 - **or less costly than our** compliance with the applicable regulations as a condition of regulatory approval of AVROBIO' s product candidates or any **may develop proprietary technologies or secure patent protection that we may need for the development** of AVROBIO' s **our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement. We compete in the segments of the biotechnology, pharmaceutical and** other potential **related industries that develop and market therapies for the treatment of Group 2 PH with HFpEF and Hereditary Hemorrhagic Telangiectasia (" HHT ") disorders. Although there are no other companies who have commercialized therapies for the same therapeutic areas that our** products - **product candidates target, there are many other companies, including large biotechnology and pharmaceutical companies, that are developing therapies for the same therapeutic areas. For example, AstraZeneca and Tenax Therapeutics for the treatment of Group 2 PH and Diagonal Therapeutics and Vaderis Therapeutics for the treatment of HHT** . In addition, **in January 2025** the regulatory authorities may , at any time **Eli Lilly terminated its Phase 2 trial of volenrelaxin , which has affected investor** audit or inspect a manufacturing facility involved with the preparation --- **perception** of **relaxin** AVROBIO' s product candidates **in general. We anticipate that we will continue to face intense and increasing competition as new treatments enter the market and advanced technologies become available. There can be no assurance that** or **our** AVROBIO' s **competitors are not currently developing, or will not in** other -- **the** potential **future develop,** products **that are equally** or the associated quality systems for - **or** compliance with the regulations applicable to the activities **more effective or are more economically attractive than any of our current or future product candidates. Competing products may gain faster or greater market acceptance than our products, if any, and medical advances or rapid technological development by competitors may result in our product candidates** being **becoming** conducted **non- competitive or obsolete before we are able to recover our research and development and commercialization expenses** . If these facilities **we or our product candidates** 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 - **compete effectively** 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 - **it** 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 **our** ~~AVROBIO' s~~ business ~~. In addition~~ , **financial condition** ~~these agreements typically restrict the ability of AVROBIO' s collaborators, advisors, employees~~ and **results** ~~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 **operations. We do** ~~these agreements, independent development or publication of information including AVROBIO' s trade secrets in cases where AVROBIO does~~ not have ~~proprietary~~ **a sales** or **marketing infrastructure** ~~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 **no experience in the sale or marketing of biotechnology products. To achieve commercial success for** ~~an~~ **any approved** ~~adverse impact on AVROBIO' s business. Risks Related to Commercialization of AVROBIO' s Product~~ **product , we must** ~~Candidates Should AVROBIO resume development~~ ---- **develop** ~~of its~~ **or acquire a sales and marketing organization, outsource these functions to third parties or enter into strategic collaborations. We may decide to establish our own sales and marketing capabilities and promote our** product candidates **if** and ~~obtain~~ **when regulatory** approval ~~of any of AVROBIO' s product candidates, and AVROBIO is unable~~ **has been obtained in the United States or in other jurisdictions. There are risks involved if we decide** to establish **our own** sales ~~, distribution~~ and marketing capabilities or enter into ~~agreements~~ **arrangements** with third parties to **perform these services. Even if we establish sales and marketing capabilities, we may fail to launch our products effectively or to** market **our** ~~and sell AVROBIO' s product~~ **products** ~~candidates, AVROBIO will be unable to generate any~~ **effectively since we have no experience in the sales and marketing of biotechnology** ~~product~~ **products** ~~revenue~~ . **In addition** ~~To successfully commercialize any of AVROBIO' s product candidates~~ , **recruiting** ~~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 **training** ~~development of AVROBIO' s own commercial team or the establishment of~~ a ~~contract~~ sales force **is** ~~to market any product candidate AVROBIO may develop will be~~ expensive and time ~~-~~consuming and could delay any product launch. ~~Moreover~~ **In the event that any such launch is delayed or does not occur for any reason** , ~~AVROBIO~~ **we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we** cannot ~~be certain~~ - **retain or reposition our sales and marketing personnel. Factors** that ~~AVROBIO will be able to successfully develop this capability. AVROBIO~~ may **inhibit our efforts to commercialize our products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to or educate adequate numbers of physicians on the benefits of our products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; • unforeseen costs and expenses associated with creating an independent sales and marketing organization; and • costs of marketing and promotion above those anticipated by us. If we** enter into ~~collaborations regarding~~ **arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues to us could be lower than if we were to market and sell** any ~~approved product~~ **products** ~~candidates~~ **that we develop ourselves. Such collaborative arrangements** with **partners may place** ~~other~~ -- **the** ~~entities to utilize their established marketing~~ **commercialization of our products outside of our control** and **would make us subject** ~~distribution capabilities, but AVROBIO may be unable~~ to **a number of risks including that we may** ~~enter into such agreements on favorable terms, if at all. If any future collaborators do~~ not ~~commit sufficient~~ **be able to control the amount or timing of** resources **that our collaborative partner devotes** to ~~commercialize AVROBIO~~ **our products or that our collaborator** ' s **willingness** ~~product candidates,~~ or ~~AVROBIO~~ **ability to complete** ~~is~~ **its obligations** ~~unable to develop the necessary capabilities on AVROBIO' s own~~ , ~~AVROBIO will~~ **and our obligations under our arrangements may** be ~~unable to generate sufficient product revenue to sustain AVROBIO~~ **adversely affected by business combinations or significant changes in our collaborator** ' s business **strategy** . ~~AVROBIO competes~~ **In addition, we may not be successful in entering into arrangements** 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~~ **sell and market our products or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration** with ~~the sales and marketing efforts of AVROBIO' s~~ **third parties, we may not be successful in commercializing our** ~~product~~ **products** ~~candidates~~ , if ~~approved. Without an~~ **any** ~~internal team or the support of a third- party~~

~~to perform marketing and sales functions~~ , **which in turn would have a material** ~~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~~ -- **adverse effect** ~~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~~ **our** ~~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 ~~,~~ **and** results of operations ~~and prospects~~ . **Even if a** ~~Should AVROBIO resume development of its product candidates, the commercial success of any current or future~~ product candidate ~~will depend upon~~ **we develop receives marketing approval, it may fail to achieve** the degree of market acceptance by physicians, patients, third- party payors and others in the medical community **necessary for commercial success** . ~~Should AVROBIO resume development of its~~ **The revenues that we generate from our sales may be limited, and we may never become profitable. We have never commercialized a product candidate for any indication. Even if our** product candidates **are approved by the appropriate** ~~, and thereafter if AVROBIO obtains any~~ regulatory ~~approval~~ **authorities** for **marketing and sale** ~~AVROBIO' s product candidates~~ , ~~the~~ **they may not gain acceptance among physicians** ~~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~~ **others in the medical community. If any** product candidates **for which we obtain regulatory approval does** ~~in particular, as effective, safe and cost- effective. Any product that AVROBIO brings to the market may~~ not gain **an adequate level of** market acceptance **, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates** by ~~physicians~~ **the medical community** , patients ~~,~~ **and** 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: •~~ **some of which are beyond our control. For example, physicians are often reluctant to switch** ~~the~~ **their patients and patients may be reluctant to switch from existing therapies even when new and** ~~potential~~ **potentially more effective or safer** ~~efficacy and potential advantages over alternative~~ treatments **enter** ~~, 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~~ -- **the** ~~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~~ **Efforts** to educate the medical community and third- party payors on the benefits of **our** ~~AVROBIO' s~~ product candidates may require significant resources and may ~~never~~ **not** be successful. **If any of our product candidates** ~~Such efforts to educate the marketplace may require more resources than~~ are **approved but** ~~required by the conventional technologies marketed by AVROBIO' s competitors. If these products~~ do not achieve an adequate level of **market** acceptance, ~~AVROBIO may not generate~~ **we could be prevented from or** ~~significant~~ **significantly delayed in achieving profitability. The degree of market acceptance of any** product **for which we receive marketing** ~~revenue and may not become profitable. Should AVROBIO resume development of its product candidates, if AVROBIO obtains~~ approval **will depend on** ~~to commercialize AVROBIO' s product candidates outside of the United States,~~ a ~~variety~~ **number** of **factors, including: • the** ~~risks associated with international operations could materially adversely affect AVROBIO' s business. AVROBIO had been conducting~~ clinical ~~trials~~ **indications** for **which our** ~~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 **; • physicians, hospitals and patients considering our product candidates as a safe and effective treatment; • the potential and perceived advantages of our product candidates over alternative treatments; • the prevalence and severity of any side effects; • product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities; • limitations or warnings contained in the labeling approved by the FDA or comparable foreign**

**regulatory authorities; • the timing of market introduction of our product candidates in relation to other potentially competitive products; • the cost of our product candidates in relation to alternative treatments; • the amount of upfront costs or training required** for ~~commercialization~~ **physicians to administer our product candidates; • the availability of coverage and adequate reimbursement from third- party payors and government authorities; • the willingness of patients to pay out- of- pocket in the absence of comprehensive coverage and reimbursement by third- party payors and government authorities; • the relative convenience and ease of administration** , ~~AVROBIO~~ **including as compared to alternative treatments and competitive therapies; • the effectiveness of our sales and marketing efforts and distribution support; and • the presence or perceived risk of potential product liability claims. Healthcare reform may negatively impact our ability to profitably sell TX45 and any potential future product candidates, if approved. Third- party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The United States and** ~~may~~ **many** ~~enter~~ **foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of TX45 or any potential future product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges and amendments to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act (the " IRA "), was signed** into ~~agreements~~ **law, which among other things, (1) directs the Department of Health and Human Services (the " HHS "), to negotiate the price of certain high expenditure, single- source biologics that have been on the market for 11 years covered under Medicare (the " Medicare Drug Price Negotiation Program ") and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA includes certain exemptions to the price negotiation program, including a limited exemption for products with orphan drug designation. This exemption applies only to products with one orphan drug designation that is (i) for a rare disease or condition and (ii) is approved for indication (s) for such rare disease or condition. By limiting price negotiation exemption to products with only one orphan drug designation, the IRA may decrease our interest in pursuing orphan drug designation for our product candidates in multiple indications. The IRA also, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost through a newly established manufacturer discount program. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed- upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is possible that the ACA and IRA may be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures of the second Trump administration may impact the ACA or IRA, increase the pressure on drug pricing or limit the availability of coverage and adequate reimbursement for TX45 and any potential future product candidates, which would adversely affect our business. There has also been increasing executive, legislative and enforcement interest in the United States with respect to drug pricing practices. There have been U. S. congressional inquiries, presidential executive orders and proposed and enacted 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. For example, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation (" CMMI ") to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration' s executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo (" Loper Bright "), the U. S. Supreme Court overturned the longstanding Chevron doctrine,**

**under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA Such reforms could have an adverse effect on anticipated revenue from TX45 and any potential future product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. In many countries outside the United States, government- sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and / or difficulty in understanding the value of medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure and we expect that legislators, policy makers and healthcare insurance funds in the EU Member States will continue to propose and implement cost cutting measures. These measures include mandatory price controls, price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage, government- mandated price cuts, limitations on coverage of target population and introduction of volume caps. Many countries implement health technology assessment (" HTA "), procedures that use formal economic metrics such as cost- effectiveness to determine prices, coverage and reimbursement of new therapies. These assessments are increasingly implemented in established and emerging markets. In the EU, Regulation (EU) 2021 / 2282 on Health Technology Assessment, which will become effective on January 12, 2025, will allow EU member states to use common HTA tools, methodologies and procedures to conduct joint clinical assessments and joint scientific consultations whereby HTA authorities may provide advice to health technology developers. Each EU member state will, however, remain exclusively competent for assessing the relative effectiveness of health technologies and making pricing and reimbursement decisions. Given that the extent to which pricing and reimbursement decisions are influenced by the HTA process currently varies between EU member states, it is possible that our products may be subject to favorable pricing and reimbursement status only in certain EU countries. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, including following periodic review, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. Moreover, in order to obtain reimbursement for our products in some EU member states, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. Efforts to generate additional data for the HTA process will involve additional expenses which may substantially increase the cost of commercializing and marketing our products in certain EU member states. We cannot predict the likelihood, nature or extent of healthcare reform initiatives that may arise from future legislation or administrative action. However, it is possible that countries will continue taking aggressive actions to seek to reduce expenditures on drugs. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and / or allow access to new technologies. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Inadequate funding for the FDA and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the 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 the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies (including layoffs) may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, many staff members from the FDA and other agencies have recently been laid off. If a prolonged government shutdown or disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns and / or disruptions could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operation. Our relationships with healthcare providers, customers and third- party payors will be subject to applicable anti- kickback, fraud and abuse, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers, including physicians, and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we or our partner obtains marketing approval. Our arrangements with healthcare providers, third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products for which we or our partner obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following: • the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an**

**individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (the " FCA ") or federal civil monetary penalties; • the FCA imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims. The FCA also permits a private individual acting as a " whistleblower " to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery; • The Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (" HITECH "), also imposes obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses, and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, processing and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non- U. S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; • the federal Sunshine Act, as amended, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the HHS information related to " payments or other transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and local laws requiring the registration of pharmaceutical sales representatives; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing; federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and state and foreign laws that govern the privacy and security and other processing of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements** with third parties **will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found** to ~~market~~ **be in violation of any of these laws or any other governmental regulations that may apply to it, we may be subject to significant civil, criminal and administrative penalties, damages, fines, additional regulatory oversight, litigation, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and** ~~them~~ **the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect 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. Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti- bribery laws of EU member states, national sunshine rules, regulations, industry self- regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Our business could be materially and adversely affected in the future by political unrest in China, as well as the effects of disease outbreaks, epidemics and pandemics. Disease outbreaks, epidemics and**

**pandemics in regions where we may have clinical trial sites or other business operations could adversely affect our business, including by causing significant disruptions in our operations and / or in the operations of third- party manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics have negative impacts** on ~~a worldwide basis or~~ **our ability to initiate new clinical trial sites, to enroll new patients and to maintain existing patients who are participating** in ~~more limited geographical regions~~ **our clinical trials, which may include increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of TX45, TX2100 and any potential future product candidates, if at all** . ~~AVROBIO expects~~ **Disease outbreaks, epidemics and pandemics also could adversely impact clinical trial results for TX45 or other future potential product candidates, such as by diminishing or eliminating their efficacy or by producing a safety concern, either through direct biological effects or through confounding of the data collection and analysis. This adverse impact could terminate further development of TX45, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and / or increase the cost) of a product approval by the FDA or other regulatory authorities, lead to a restrictive product label** that ~~AVROBIO~~ **significantly limits prescribing of an approved product, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TX45. In addition, because our key manufacturer and supplier for TX45 is located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies, laws, rules and regulations of the United States or Chinese governments, as** ~~will~~ **well as political unrest or unstable economic conditions in China. For example, trade tensions between the United States and China have been escalating in recent years. The U. S. government has indicated its intent to adopt a new approach to trade policy and in some cases to renegotiate, or potentially terminate, certain existing bilateral or multi- lateral trade agreements. For example, on February 1, 2025, President Donald Trump signed executive orders imposing a 25 % tariff on certain imports from Mexico and Canada, and a 10 % tariff on certain imports from China, which were to take effect on February 4, 2025. A 30- day pause was granted to Canada and Mexico. However, these newly proposed and imposed tariffs have resulted in threatened and actual retaliatory tariffs against U. S. goods. Our components may in the future** be subject to **these tariffs, which could increase our manufacturing costs and could make our products, if successfully developed and approved, less competitive than those of our competitors whose inputs are not subject to these tariffs. We may otherwise experience supply disruptions or delays, and although we carefully manage our inventory and lead- times, our supplier may not continue to provide us with battery components in our required quantities, to our required specifications and quality levels or at attractive prices. In addition, certain Chinese biotechnology companies and CDMOs may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U. S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the House of Representatives of the prior Congress (the 118thCongress) passed the BIOSECURE Act, which proposed targeting U. S. government contracts, grants, and loans for entities that use biotechnology equipment or services from certain named Chinese biotechnology companies, and potentially** additional ~~risks related to~~ **Chinese biotechnology companies designated in the future. The language of the proposed BIOSECURE Act would, among other things, prohibit U. S. federal agencies from** entering into ~~international~~ **or renewing any contract with any entity that uses biotechnology equipment or services produced or provided by a " biotechnology company of concern. " The version of the bill passed by the prior House of Representatives included a grandfathering provision allowing biotechnology equipment and services provided or produced by named biotechnology companies of concern under a contract or agreement entered into before the effective date until January 1, 2032. The BIOSECURE Act did not become law in the 118th Congress. It is unclear whether the current Congress (the 119th Congress) will introduce the BIOSECURE Act or similar legislation in this congressional session and, if so, how the scope, prohibitions, or designated biotechnology companies of concern may differ from the version of the BIOSECURE Act passed by the House in the prior 118th Congress. If these bills become law, or similar laws are passed, they could severely restrict the ability of companies to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U. S. government. Such disruption could have adverse effects on the development of our product candidates and our** business ~~relationships~~ **operations. General supply chain issues may be exacerbated during disease outbreaks** , ~~including: • different~~ **epidemics and pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. If our contract development and manufacturing organizations (" CDMOs ") are required to obtain an alternative source of certain raw materials and components, for example, additional testing, validation activities and** regulatory ~~requirements~~ **approvals may be required which can also have a negative impact on timelines. Any associated delays in the manufacturing and supply of drug substance and drug product** for ~~approval of drugs~~ **our clinical trials could adversely affect our ability to conduct ongoing** and ~~biologics in~~ **future clinical trials of TX45 or TX2100 on our anticipated development timelines. Likewise, the operations of our third- party manufacturers may be requisitioned, diverted or allocated by U. S. or** foreign **government orders. If any of** ~~countries; • reduced protection for intellectual property rights; • unexpected changes in tariffs, trade barriers and regulatory requirements; • economic weakness, including inflation, fluctuating interest rates, or~~ **our** ~~political instability in particular~~ **CDMOs or raw materials or components suppliers become subject to acts or orders of U. S. or** foreign **government entities to allocate** ~~economies and markets; • compliance with tax, employment, immigration and labor laws for~~ **or** ~~employees living~~ **prioritize manufacturing capacity, raw materials or components to the manufacture or distribution of vaccines or medical supplies needed to test or treat patients in a disease outbreak, epidemic or pandemic, this could delay** ~~or~~ **our clinical trials, perhaps substantially** ~~traveling abroad; • foreign currency fluctuations~~ , which could **materially** ~~result in increased operating expenses~~ and ~~reduced~~ **adversely affect our business. Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the**

**forecasted growth, our business may not grow at similar rates, or at all. Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meets our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties. Our** ~~revenues~~ **revenue will be dependent** , **in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage** and **reimbursement, the ability to gain market share and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than our expects or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we obtain approval to market TX45 or** other ~~obligations incident~~ **potential future product candidates, these products may become subject** to **unfavorable pricing regulations, reimbursement practices from third- party payors or healthcare reform initiatives** ~~doing business in another country; • workforce uncertainty in countries where labor unrest is more common than~~ in the United States **and** ~~; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities~~ abroad ~~; and •~~ **, which could harm our** 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~~ **drug products** vary widely from country to country. **Current and future** ~~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. **In many regions, including the EU, Japan and Canada, the pricing of prescription drugs is controlled by the government and** ~~Some~~ **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~~ **regulatory approval** ~~or~~ **for the** product ~~licensing approval~~ is granted **. Regulatory agencies in those countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country** . 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 **our** ~~AVROBIO' s~~ ability to recoup **our** ~~AVROBIO' s~~ investment in one or more product candidates, even if ~~any~~ **our** product candidates ~~AVROBIO may develop obtain~~ **obtains** marketing approval. **Our commercial success also depends on** ~~Please see the section titled " Business – Government Regulation – Coverage~~ **coverage** and **adequate** ~~Reimbursement~~ **reimbursement** ~~. " Should AVROBIO resume development~~ of ~~its~~ **our** product candidates **by** ~~, 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~~ **including government payors,** private health insurers ~~and~~ **,** health maintenance organizations **and other organizations** , ~~decide~~ which ~~medications~~ **may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. In the United States and markets in other countries, governments and private insurers closely examine medical products to determine whether** they **should be covered by reimbursement and, if so, the level of reimbursement that** will **apply** ~~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 **the** CMS an agency within the HHS ~~as~~ **.** CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare ~~.~~ **and** ~~Private~~ **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~~ **drugs** . ~~Outside~~ **Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drug products. We cannot be sure that coverage and reimbursement will be available for any product that we or our partners commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our partners obtain regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our partners may not be able to successfully commercialize any product candidate for which marketing approval is obtained. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign health authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including costs of research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in** the United States **. In addition , many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Our inability to promptly obtain coverage and profitable reimbursement rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize products and overall financial condition. Risks Related to Our Intellectual Property Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, and methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third- party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected. The patenting process is expensive and time- consuming, and we may not be able to file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue, obtain or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. In addition, we cannot guarantee that patent applications or patents that we initially believe to be owned by the company will not be encumbered by third party ownership or other third party rights that may not have been evident to us at the time of preparation or filing. For instance, such rights could arise from the intellectual contributions of company employees who were previously employed by third parties, such as universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors, or from the intellectual contributions of company consultants, advisors, or independent contractors with current or previous relationships with such third parties. Therefore, these patents and applications may not be prepared, filed, prosecuted or enforced in a manner consistent with the best interests of our business. Furthermore, licenses from such third parties may be required or desirable but may not be available on reasonable terms, or at all. The strength of patents in the biotechnology field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in- license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents are successfully issued, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around its claims. If the breadth or strength of protection provided by the patent applications, we hold with respect to our product candidates is threatened, we could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent**

**application related to our product candidates. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim, and we may be subject to a third- party preissuance submission of prior art to the USPTO. There also may be prior art of which we are aware, but which we believe does not affect the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor' s technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights or will design around the claims of patents that we have had issued that cover our products. The United States has enacted and implemented wide- ranging patent reform legislation. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will / will not be viewed in future and whether patent expiration dates may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (" UPC "). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as ~~international~~ national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: • others may be able to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by the claims of our patents; • the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use; • we or our licensors, as the case may be, may fail to meet our obligations to the U. S. government in regards to any in- licensed patents and patent applications funded by U. S. government grants, leading to the loss of patent rights; • we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies; • it is possible that our pending patent applications will not result in issued patents; • it is possible that there are prior public disclosures that could invalidate us or our licensors' patents, as the case may be, or parts of ours or their patents; • it is possible that others may circumvent our owned or in- licensed patents; • it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to our own; • the laws of foreign countries may not protect ours or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States; • the claims of our owned or in- licensed issued patents or patent applications, if and when issued, may not cover our product candidates; • our owned or in- licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties; • the inventors of our owned or in- licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors; • it is possible that our owned or in- licensed patents or patent applications omit individual (s) that should be listed as inventor (s) or include individual (s) that should not be listed as inventor (s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable; • we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents; • we may not develop additional proprietary technologies for which we can obtain patent protection. • it is possible that product candidates we develop may be covered by third parties' patents or other exclusive rights; or • the patents of others may have an adverse effect on our business. We are dependent on patents, know- how and proprietary technology, both our own and licensed from others including Harvard. Any**

**termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and • the inventorship or ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners. In addition, intellectual property license agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of** operations **and prospects. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We** are generally **also** subject to ~~extensive governmental price controls~~ **all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which is described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer. If we fail to comply with our obligations under our patent license with a third party, we could lose license rights that are important to our business. We are a party to a license agreement pursuant to which we in- license key patent and patent applications for our product candidates. These existing licenses impose various diligence, milestone payment, royalty, insurance** and other **obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or** market **the products covered by such licensed intellectual property. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. We may have limited control over the maintenance and prosecution of these in- licensed patents and patent applications, activities or any other intellectual property that may be related to our in- licensed intellectual property. For example, we cannot be certain that such activities by our licensor have been or will be conducted in compliance with applicable laws and** regulations ~~,~~ **or will result in valid** and ~~AVROBIO believes~~ **enforceable patents and** ~~the~~ **other** ~~increasing emphasis on cost~~ **intellectual property rights. If we are unable to protect the confidentiality of our proprietary information, our business and competitive position would be harmed. In addition to patent protection, we rely upon know** ~~-~~ ~~containment initiatives~~ **how, as well as non- disclosure agreements and invention assignment agreements with our employees, consultants and third- parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example,** in ~~Europe~~ **the case of misappropriation by** ~~and~~ ~~-~~ **an** ~~certain~~ **employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our proprietary information and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated proprietary information can be difficult, expensive, and time- consuming, and the outcome is unpredictable. In addition, proprietary information may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed. In addition, courts outside the United States are sometimes less willing to protect proprietary information. If we choose to go to court to stop a third party from using any of our proprietary information, we may incur substantial costs. These lawsuits may consume our time and** other ~~major markets where AVROBIO plans~~ **resources even if we are successful. Although we take steps** to ~~commercialize~~ **protect our proprietary information and proprietary information, including through contractual means with our employees and consultants, third parties** may ~~put pressure on~~ **independently develop substantially equivalent proprietary information and techniques or otherwise gain access to, or disclose, our technology. Thus, we may not be able to meaningfully protect our proprietary information. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and** ~~the~~ **other** ~~pricing and usage~~ **advisors to execute confidentiality agreements upon the commencement** of ~~AVROBIO~~ **employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party** ’ s **relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our proprietary information. Third- party claims of intellectual property infringement**

may prevent or delay our product discovery and development efforts. Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and / or proprietary technologies infringe their intellectual property rights. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to our product candidates and programs. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. If a third- party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to: • infringement and other intellectual property claims which, regardless of merit, may be expensive and time- consuming to litigate and may divert our management' s attention from our core business; • substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party' s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner' s attorneys' fees; • a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do; • if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and / or grant cross- licenses to intellectual property rights for its products; and • redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. • Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources . In addition, ~~many~~ any ~~countries,~~ uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Third ~~prices~~ parties ~~of medical products~~ may assert that we are ~~subject to varying price control mechanisms~~ employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is protected under the Safe Harbor exemption as ~~part of national health systems,~~ set forth in 35 U. S. C. § 271. If and ~~pricing negotiations~~ when TX45 or another one of our product candidates is approved by the FDA, certain third parties may seek to enforce their patents by filing a patent infringement lawsuit against us. While we do not believe that any claims of such patent that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with ~~governmental authorities~~ evidence that is " clear and convincing, " a heightened standard of proof. There may be third- party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take ~~considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, AVROBIO may~~ many years ~~be required~~ to ~~conduct a clinical trial~~ issue, there may be currently pending patent applications which may later result in issued patents that our ~~compares the cost effectiveness of AVROBIO' s~~ product candidates may infringe ~~to other available therapies~~ . In ~~general~~ addition , ~~the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their~~ third ~~own prices~~ parties may obtain patents in ~~for medicines, but monitor and control company profits. Additional foreign price controls or other~~ the future and claim ~~changes in pricing regulation could restrict the amount~~ that ~~AVROBIO is able~~ use of our technologies infringes upon these patents. If any third- party patents were held by a court of competent jurisdiction to ~~charge for AVROBIO' s~~ cover the manufacturing process of our product candidates ~~. Accordingly~~ , constructs or molecules used in ~~markets outside~~ or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or ~~the~~ they ~~United States~~ are finally determined to be held invalid or unenforceable. Similarly , ~~the reimbursement~~ if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for ~~AVROBIO' s~~ manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the ~~products~~ product ~~may be reduced compared with the United States and may be insufficient~~ candidate unless we obtained a license or until such patent expires or is finally determined to ~~generate~~ be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable ~~revenues and profits~~ terms or at all . ~~Moreover~~ If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms , ~~efforts~~ or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies

**licensed to us. In addition, if the breadth or strength of protection provided** by ~~governmental~~ **our patents** and **patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our 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 our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Even if such a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Lastly, we may need to indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our product candidates, including TX45. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the product candidates or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services. Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated proprietary information. As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. In addition, we have used and continue to use consultants, advisors, and / or independent contractors with relationships with third parties, including institutions and / or other companies. We try to ensure that our employees, consultants, advisors, and / or independent contractors have the right to assign to us intellectual property generated during their engagement with us, and that they do not use the proprietary information or know- how of others in their work for us. Although no claims against us are currently pending, there is no guarantee that in the future we may not be subject to claims that we or our employees, consultants, advisors, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties, or improperly assign intellectual property rights to us. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace. We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in- license or use these proprietary rights. Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing pre- existing pharmaceutical compounds. We may be unable to acquire or in- license any compositions, methods of use, processes or** other third- party ~~payors~~ **intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms , if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to it. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability**

**to pursue our program. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. We may be involved in lawsuits related to our patents or the patents of our licensors, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that its patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In addition, because some patent applications** in the United States ~~and abroad~~ **may be maintained in secrecy until the patents are issued** , ~~to cap~~ **patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications** ~~or~~ **for** ~~reduce healthcare~~ **technology covered by our owned and in- licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering products or technology similar to ours. Any such patent application may have priority over our owned and in- licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to those owned by or in- licensed to us, we or, in the case of in- licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U. S. patent application on inventions owned by or in- licensed to us, we may incur substantial** costs ~~may cause such organizations to limit both coverage and level of reimbursement for new products approved and~~ , **divert management** ~~as a result, they may not cover or provide adequate payment for AVROBIO~~ ' s ~~product candidates~~ **time and expend other resources, even if we are successful** . ~~Should AVROBIO resume development~~ **Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority** of **inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to** ~~its~~ **it** ~~product candidates, AVROBIO expects~~ **from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all. Litigation or interference proceedings may result in a decision adverse** to ~~experience pricing pressures~~ **our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required** in connection with **intellectual property litigation,** ~~the~~ **there** ~~sale~~ **is a risk that some** of **our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees on** any **issued patent are** ~~of AVROBIO' s product candidates,~~ due to **be paid to** the **USPTO** ~~trend toward managed healthcare, the increasing influence of health maintenance organizations~~ and ~~additional legislative changes~~ **foreign patent agencies in several stages over the lifetime of the patent** . The **USPTO** ~~downward pressure on healthcare costs in general, particularly prescription drugs~~ and ~~surgical~~ **various foreign governmental patent agencies require compliance with a number of** ~~procedures~~ **procedural , documentary, fee payment** and other ~~treatments, has become very intense. As~~ **provisions during the patent application process and following the issuance of** a **patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can** result **in abandonment or lapse of the patent or patent application** , ~~increasingly high barriers~~ **resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but** are ~~being erected~~ **not limited** to **, failure** ~~the entry of new products. Due~~ to ~~the novel nature~~ **respond to official actions within prescribed time limits, non- payment** of ~~AVROBIO' s technology~~ **fees and failure to properly legalize and submit formal documents. In such** ~~and~~ **an event** ~~the potential for AVROBIO' s product candidates to offer therapeutic benefit in a single administration~~ , ~~AVROBIO faces uncertainty related~~ **our competitors might be able** to **enter** ~~pricing and reimbursement for these~~ **the market** ~~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 **would** ~~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~~ **equivalent** ~~., opposition~~ proceedings ~~)~~ **in foreign jurisdictions** .Such proceedings could result in **the** revocation **or cancellation of** or amendment to ~~our~~ **AVROBIO' s** patents in such a way that they no longer cover ~~our~~ **AVROBIO' s** product candidates.The outcome following legal assertions of invalidity and unenforceability is unpredictable.With respect to the validity question,for example, ~~we~~ **AVROBIO** cannot be certain that there is no invalidating prior art,of which ~~we,our patent counsel and~~ 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 ~~and /~~ or unenforceability, **AVROBIO** ~~or if we are otherwise unable to adequately protect our rights,we would~~ **could** lose at least part,and perhaps all,of the patent protection on **one** ~~our~~ **or more of AVROBIO' s** product candidates.Such a loss of patent protection could have a material ~~adverse impact~~ ' s **activities do not infringe our owned or in- licensed patents. In addition, the Supreme Court has recently changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in- licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria which could also make it more difficult to obtain patents. We, or our licensors, may not be able to detect infringement against our owned or in- licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in- licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors, later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in- licensed patents, as the case may be, against such third party. If another party questions the patentability of any of our claims in our owned or in- licensed U. S. patents, the third- party can request that the USPTO review the patent claims such as in an inter partes review, ex parte re- exam or post- grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in foreign patent offices, where either our owned or in- licensed foreign patents are challenged. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our** business **. In the future, we may be involved in similar proceedings challenging the patent rights of others, and the outcome of such proceedings is highly uncertain. We may choose to challenge the patentability of claims in a third party' s U. S. patent by requesting that the USPTO review the patent claims in ~~and~~ an ~~results of operations~~ ex- parte re- exam, inter partes review or post- grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party' s patent in patent opposition proceedings in the foreign patent offices** . The **costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the** United States **, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions such as patent term adjustments** and **/ or extensions,** ~~many~~ **may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 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. However, we 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 we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO, of a petition for patent term extension under the Hatch- Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch- Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trade names or trademarks that incorporate variations of our unregistered trade names or trademarks. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. Risks Related to Our Reliance on Third Parties We currently rely and expect to rely in the future on the use of manufacturing suites in third- party facilities or on third parties to manufacture TX45, TX2100 and any other product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third- party manufacturing suites or if the third- party manufacturers encounter difficulties in production. We do not currently lease or own any facility that may be used as our clinical- scale manufacturing and processing facility and currently rely on contract development and manufacturing organizations (" CDMO "), including WuXi Biologics (Hong Kong) Limited (" WuXi Biologics "), to manufacture TX45 for use in our Phase 1a, Phase 1b and the recently initiated Phase 2 clinical trials. We currently have a sole source relationship with WuXi Biologics for our supply of TX45. If there should be any disruption in such supply arrangement or the supply arrangement with our CDMO for TX2100, including any adverse events affecting our sole supplier for TX45, Wuxi Biologics, it could have a negative effect on the clinical development of our product candidates and other operations while we work to identify and qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with CGMP requirements and any other regulatory requirements of the FDA or comparable** foreign ~~jurisdictions~~ **regulatory authorities for the manufacture of a product candidate. We perform periodic audits of each CDMO facility that supports our supply of TX45 and TX 2100 and reviews and approves all TX45 and TX2100 CGMP- related documentation. We also** have ~~enacted~~ **quality agreements with** ~~or~~ **our CDMOs that document our mutual agreement on compliance with CGMPs and expectations on quality- required communications to us. Beyond this, we have no control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities and the associated Quality Management System for the manufacture of a product candidate or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect our ability to develop, obtain regulatory approval for or market such product candidate, if approved. Similarly, our failure, or the failure of our CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of a product candidate or drug and harm our business and results of operations. In addition, we have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. Moreover, our CDMOs may experience manufacturing difficulties due to resource constraints, governmental restrictions or as a result of labor disputes or unstable political environments. Supply chain issues, including those resulting from the a health pandemic and the ongoing military conflict between Russia and Ukraine, may affect our third- party vendors and cause delays. Furthermore, since we have engaged WuXi Biologics, a manufacturer located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments or political unrest or unstable economic conditions in China. For example, the U. S. House of Representatives of the prior Congress (the 118th Congress) passed the BIOSECURE Act, which** proposed **targeting U. S. government contracts, loans, and grants to entities that use biotechnology equipment or services from certain Chinese biotechnology companies, including Wuxi Biologics, and would authorize the U. S. government to name other Chinese biotechnology companies of concern. The version of the BIOSECURE Act passed by the prior House of Representatives included a grandfathering provision allowing biotechnology equipment and services provided or produced by WuXi**

**Biologics and other named biotechnology companies of concern under a contract or agreement entered into before the effective date until January 1, 2032. The BIOSECURE Act did not become law in the 118th Congress. It is unclear whether the current Congress (the 119th Congress) will introduce the BIOSECURE Act or similar legislation in this congressional session and, if so, how the scope, prohibitions, or designated biotechnology companies of concern may differ from the version of the BIOSECURE Act passed by the House in the prior 118th Congress. In addition to the BIOSECURE Act, any additional U. S. executive action,** legislative **action, or potential sanctions with China could materially impact our work with WuXi Biologics. U. S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. For example, in the event that we need to transfer from WuXi Biologics, which is our sole manufacturing source for TX45, we anticipate that the complexity of the manufacturing process may materially impact the amount of time it would take to secure a replacement manufacturer. The delays associated with the verification of a new manufacturer, if we are able to identify** ~~and~~ **an alternative source, could negatively affect our ability to supply product candidates, including TX45, in a timely manner or within budget. If any CDMO on which we will rely fails to manufacture quantities of a product candidate at quality levels necessary to meet** regulatory ~~changes affecting~~ **requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition, cash flows, and prospects could be materially and adversely affected. In addition, our CDMO and / or distribution partners are responsible for transporting temperature- controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and our CDMO may also face product seizure or detention or refusal to permit** the ~~healthcare system~~ **import or export of products. Our business could be materially adversely affected by business disruptions to our third- party providers** that could **materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or** prevent **the completion of** ~~or~~ **our** ~~delay marketing~~ **preclinical studies and clinical trials or the** approval of ~~AVROBIO' s~~ **any of our** product candidates **by the FDA, result in higher costs or adversely impact commercialization of our products. We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third- party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements, to validate our assays and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third- party contractors and CROs are required to comply with good laboratory practices (" GLPs "), as applicable, and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these GLPs and GCPs through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLPs and GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or clinical trials comply with applicable GLP or GCP regulations. In addition, our clinical trials must be conducted with product, including biologic product, produced in compliance with applicable CGMP regulations. Our failure to comply with these regulations may require us to repeat preclinical studies or clinical trials, which would delay the regulatory approval process. Further, these laboratories, investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third- party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. There is a limited number of third- party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third- party laboratories,**

**CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. Switching or adding additional laboratories or CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our contracted laboratories and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and results of operations. In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical- stage product candidate** or any future product candidates ~~, restrict~~ **. Our future collaborations will be important to** ~~or~~ **our** ~~regulate post~~ **business. If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected. A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional strategic collaborations in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our product could change and our costs of development and commercialization could increase. Furthermore, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in** ~~- approval activities and affect AVROBIO' s ability~~ **license these intellectual property rights. Any future collaborations we enter into may pose a number of risks, including, but not limited** to ~~profitably sell~~ **, the following: • collaborators have significant discretion in determining the efforts and resources that they will apply; • collaborators may not perform their obligations as expected; • collaborators may not pursue development and commercialization of** any product **candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities; • collaborators may delay clinical trials, provide insufficient funding** for ~~which AVROBIO obtains marketing approval. In the United States, the pharmaceutical industry has been~~ a **clinical trial program** ~~particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been~~ , ~~and likely will continue to be~~ **stop a clinical trial or abandon a product candidate , repeat or conduct new clinical trials or require a new formulation** ~~legislative and regulatory proposals at the federal and state levels directed at broadening the availability~~ of ~~healthcare and containing~~ **a product candidate** ~~or~~ **for clinical testing; • collaborators could independently** ~~lowering the cost of healthcare. Please see the section titled " Business — Government Regulation — Healthcare Reform. " Should AVROBIO resume development ---~~ **develop** ~~of its~~ **, or develop with third parties, products that compete directly or indirectly with our products and** product candidates ~~,~~ **if** the ~~continuing efforts of~~ **collaborators believe that** the **competitive products** ~~government, insurance companies, managed care -~~ **are more likely** ~~organizations and other payers of healthcare services~~ to ~~contain~~ **be successfully developed** or ~~reduce costs of healthcare may adversely affect:~~ **can be commercialized under terms that are more economically attractive than ours;** • ~~the demand for any of AVROBIO' s~~ product candidates **discovered in collaboration with ours may be viewed by our collaborators as competitive with their own product candidates or products** , ~~if approved~~ **which may cause collaborators to cease to devote resources to the commercialization of our product candidates** ; • **collaborators may** ~~the ability to set a price that AVROBIO believes is fair~~ **fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution** ~~for -~~ **or** ~~any~~ **marketing** of ~~AVROBIO' s~~ **a product candidate or product; • collaborators with marketing and distribution rights to one or more of our** product candidates ~~, if~~ **that achieve regulatory** ~~approved~~ **approval may not commit sufficient resources to the marketing and distribution of such product or products** ; • ~~AVROBIO' s ability~~ **disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead** to **additional responsibilities** ~~generate revenues and achieve or~~ **for** ~~maintain profitability~~ **us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive** ; • ~~the level of taxes~~ **collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation** that ~~AVROBIO~~ **could jeopardize or invalidate our intellectual property or**

**proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • if a collaborator of ours** is **involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and • collaborations may be terminated by the collaborator, and, if terminated, we could be** required to **raise additional** ~~pay; and • the availability of~~ capital ~~. Legislative and regulatory proposals have been made~~ to **pursue further development** ~~expand post- approval requirements and restrict sales and promotional activities for~~ **or commercialization** ~~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 **applicable** ~~marketing approvals of AVROBIO' s~~ product candidates ~~, if any, may be~~ . **If** ~~In addition, increased scrutiny by Congress of the FDA' s approval process may significantly delay or~~ **our collaborations do not** ~~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 ~~,~~ **in** ~~they~~ **the successful discovery, development and commercialization of** ~~may not cover or provide adequate payment for AVROBIO' s~~ product candidates **or if one of our collaborators terminates its agreement** ~~. There has been increasing legislative and enforcement interest in the United States~~ with **us** ~~respect to specialty drug pricing practices. Specifically~~ , **we may not receive any future research funding or milestone or royalty payments under such collaboration. All of** ~~there~~ **the risks relating** ~~have been several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed~~ to **product development, regulatory approval and commercialization described in this Quarterly Report also apply to the activities of our therapeutic collaborators. Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected. We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a collaboration will depend** , among other things, **upon** ~~bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and~~ **an assessment of** ~~manufacturer patient programs, and reform government program reimbursement methodologies for drugs. It is expected that~~ the **collaborator** ~~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 **resources and expertise,** ~~future revenues. Any reduction in reimbursement from Medicare or other~~ **the** ~~government programs~~ **terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. These factors** may **include the design or** ~~result~~ **results** ~~in a similar reduction in~~ **of preclinical studies or clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to** ~~payments~~ **patients , the potential** ~~from private payors. Should AVROBIO resume development~~ of **competing products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there** ~~its~~ **is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The collaborator may also consider alternative** product candidates **or technologies** ~~, the implementation of cost containment measures or~~ **for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our** other ~~healthcare reforms~~ **development programs, delay our potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we** may ~~prevent AVROBIO from being~~ **need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be** able to **further develop** ~~generate revenue, attain profitability or commercialize AVROBIO' s~~ product candidates ~~. Inadequate funding for~~ **or bring** ~~the~~ **them** ~~FDA and other government agencies could hinder their ability~~ to ~~hire~~ **market** and **generate** ~~retain key leadership and other personnel, prevent new products~~ **product revenue. Nonclinical research requires** ~~and services from being developed or commercialized in a timely manner or otherwise prevent those~~ **the use of** ~~agencies from performing normal business functions on~~ **Non - Human Primates (" NHP ")** ~~which the operation of AVROBIO' s business may rely~~ , **the supply of** which could ~~negatively impact AVROBIO' s business~~ **delay or prevent development of product candidates** . ~~The~~ **Consistent with various rules, regulations and CGMP requirements, our** ability ~~of the FDA~~ to ~~review~~ **advance our pre- clinical programs** and ~~approve new~~ **successfully develop our** ~~products~~ **product candidates requires access** ~~can be affected by a variety of factors, including government budget and funding levels, ability~~ to ~~hire~~ **animal research models sufficient to assess safety** and ~~retain key personnel and accept~~ **in some cases to establish** the ~~payment of~~ **rationale for therapeutic** ~~user~~ **use** ~~fees, and statutory,~~ **. Failure to access or a significant delay in accessing animal research models that meet our needs or that fulfil** regulatory **requirements** ~~, 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 **materially** ~~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 **our ability** ~~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 **advance our** ~~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- **clinical programs** pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre- approval inspections. Should the FDA determine that an **and successfully develop** 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 **our product candidates** defer action on the application until an **and** inspection can be completed **this could result in significant harm to our business** . 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 **, researchers** or any other public health crisis and may **CROs** experience **experienced** delays **significant limitations** in their regulatory activities **access to animal research models, specifically including a sharp reduction in the availability of NHPs originating from breeding farms in Southeast Asia and limited access to the generation of genetically- modified rodent models used in efficacy evaluations** . If **we are unable to obtain NHPs in sufficient quantities and in** a prolonged government shutdown occurs **timely manner to meet the needs of our pre- clinical research programs** , it could **if the price of NHPs that are available increases** significantly impact **, or if our suppliers are unable to ship the NHPs in their possession that are reserved for** the **them , our** ability of the FDA to timely review **advance our pre- clinical programs** and **successfully** process AVROBIO' s regulatory submissions, should AVROBIO resume development ---- **develop** of its product **our pre- clinical** candidates , which could have a material adverse effect on AVROBIO' s business. Further, future shutdowns of other government agencies, such as the SEC, may **be** 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 **affected** 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 **significantly delayed** 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 **Our** AVROBIO' s Business Operations AVROBIO' s gene therapy approach utilizes lentiviral vectors derived from viruses , **Employee Matters** which may be perceived as unsafe or may result in unforeseen adverse events. Negative public opinion and **Managing Growth Our** 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 **our** AVROBIO' s ability to retain key **executives** employees, consultants and advisors and to attract, retain and motivate qualified personnel. AVROBIO is **We are** highly dependent on **our management** principal members of AVROBIO' s executive team and key employees , **including Alise Reicin, M. D., our President and Chief Executive Officer, Daniel Lochner, our Chief Financial Officer, Peter McNamara, Ph. D., our Chief Scientific Officer and Marcella K. Ruddy, M. D., our Chief Medical Officer. Each of** the **them** loss of whose services may adversely impact **currently terminate** the **their** achievement of AVROBIO' s objectives. While AVROBIO has entered into employment agreements with **us** 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 . **The loss** Following the resignation of **the** AVROBIO' s former President and Chief Executive Officer, Geoff MacKay, on May 1, 2023, AVROBIO appointed its Chief Financial Officer, Erik Ostrowski, to serve **services** in **of any of** the **these persons could impede** 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 **achievement of our research,** development of AVROBIO' s programs and to conduct a comprehensive exploration of strategic

~~alternatives~~ , **and commercialization objectives** ~~AVROBIO paused AVROBIO' s search for a permanent Chief Executive Officer~~ . **We do** ~~Accordingly, no assurance can be made as to when or whether AVROBIO will hire a permanent Chief Executive Officer. AVROBIO does~~ not **currently** maintain " key person " **life** insurance ~~policies~~ on the lives of ~~these individuals or~~ **our executives or** ~~the lives of~~ any of **our** ~~AVROBIO' s other~~ employees **. Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success** . The loss of the services of ~~one or~~ **our** ~~more of AVROBIO' s current~~ executive **officers** or **other** key employees ~~might~~ **could** impede the achievement of ~~AVROBIO' s ongoing~~ **our research, development and commercialization objectives and seriously harm our ability to successfully implement our** business ~~commitments and strategic~~ **strategy** ~~objectives~~ . ~~Retaining other qualified~~ **Furthermore, replacing executive officers and key** employees ~~, consultants~~ **may be difficult and may take** ~~and~~ **an extended period of time because of the limited number of individuals** ~~advisors for AVROBIO' s business, including scientific and technical personnel, remains critical to AVROBIO' s success. AVROBIO implemented a reduction~~ in **our industry** ~~force in January 2022 in connection~~ with the ~~deprioritization~~ **breadth** of **skills** ~~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~~ **and experience required** ~~adverse impact on employee morale. While AVROBIO believes AVROBIO' s relations with AVROBIO' s continuing employees~~ to ~~be good~~ **successfully develop** , **gain regulatory approval** ~~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 **commercialize our product candidates** ~~other personnel in AVROBIO' s industry, which is likely to continue~~ . ~~As a result, competition~~ **Competition to hire from this limited pool** ~~for skilled personnel, including in gene therapy research and vector manufacturing,~~ is intense **,** and **we** ~~the turnover rate can be high. AVROBIO~~ may ~~not~~ be ~~able~~ **unable** to **hire, train,** retain **or motivate these key** personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for ~~individuals with~~ similar ~~skill sets~~ **personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions** . In addition, ~~AVROBIO' s~~ **we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high- quality personnel, our** ability to ~~retain qualified personnel~~ **pursue our growth strategy will be limited. Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties. Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. We may become exposed to costly and damaging liability claims, either when testing a product candidate in the clinical or at the commercial stage, and our product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the current and future use of a product candidate in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit,** could be **difficult and costly to defend and could materially and adversely affect the market for our products or any prospects for commercialization of our products. Although we believe we currently maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be** ~~impacted~~ **impaired . Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, CDMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third- party manufacturers to produce our product**

**candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected** by **a man- made or natural disaster or** other ~~factors~~ **business interruption. Failure to comply with health- related data protection laws and regulations could lead to government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business. We and any current and future collaborators are subject to federal, state / provincial, municipal and foreign data protection laws and regulations** , such as ~~remote~~ **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, including 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** ~~or~~ **our** ~~hybrid working arrangements~~ **operations or the operations of our collaborators. In addition** , **we may obtain health information from third parties,including research institutions from which we obtain clinical trial data,that** are subject to privacy and security requirements under HIPAA,as amended by HITECH.Depending on the facts and circumstances, ~~AVROBIO~~ **we** could be subject to civil,criminal,and administrative penalties if **we violate** ~~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~~ **us** to take on more onerous obligations in **our** ~~AVROBIO' s~~ contracts,restrict **our** ~~AVROBIO' s~~ ability to collect,use and disclose data,or in some cases,impact **our** ~~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** ~~impact employees' productivity and morale. In addition~~ , **criminal** ~~in recent months~~ , **and administrative penalties)** ~~the market price of AVROBIO' s common stock has experienced significant downward pressure~~ , **private litigation, and /** ~~resulting in " underwater " or " out- of- the- money " stock options for~~ - **or adverse publicity and could negatively** ~~many of AVROBIO' s employees, thereby limiting the desired retentive effect~~ **affect** ~~that AVROBIO' s equity incentive program was intended to achieve. The inability to recruit, if necessary, or~~ **our** ~~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 **business** ~~financial condition would be adversely affected~~ . ~~AVROBIO~~ **Moreover, clinical trial subjects, employees, and other individuals about whom we or our current or future collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals ' privacy rights** ~~s restructuring plan may also be disruptive to AVROBIO' s operations~~ , **failed to comply with data protection laws,** ~~for~~ - **or** ~~example~~ **breached our contractual obligations** , ~~AVROBIO' s reductions in force~~ **even if we are not found liable,** could **be expensive** ~~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~~ **time- consuming** to **defend and** ~~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 **adverse publicity** ~~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 **harm our** ~~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~~ . **Our** ~~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~~ **We are** exposed to the risk of fraud or other misconduct by **our** ~~AVROBIO' s~~ employees, principal investigators, consultants **,** and commercial partners. Misconduct by these parties could include intentional failures to comply with ~~the~~ **FDA** regulations ~~of the FDA~~ or ~~of~~ **the regulations applicable in** other **jurisdictions** ~~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~~ **us** . In particular, sales, marketing and business ~~conduct~~ **arrangements** 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 **also** could ~~also~~ involve the improper use of information obtained in the course of clinical ~~studies~~ **trials or interactions with the FDA or other regulatory authorities** , which could result in regulatory sanctions and cause serious harm to **our** ~~AVROBIO' s~~ reputation. **It** ~~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~~ **we** ~~takes~~ **take** to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting ~~AVROBIO~~ **us** from ~~governmental~~ **government** investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against **us** ~~AVROBIO,~~ and ~~AVROBIO is~~ **we are** not successful in defending ~~itself~~ **ourselves** or asserting **our** ~~AVROBIO' s~~ rights, those actions could ~~have a significant impact on AVROBIO' s business, including the imposition of significant fines or other sanctions. AVROBIO is subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. AVROBIO can face serious consequences for violations. Among other matters, U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. AVROBIO has direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. AVROBIO also expects, should AVROBIO resume development of its product candidates, that AVROBIO' s non- U. S. activities would increase in time. Should AVROBIO resume development of its product candidates, AVROBIO would also expect to engage third parties for clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and AVROBIO can be held liable for the corrupt or other illegal activities of AVROBIO' s personnel, agents, or partners, even if AVROBIO does not explicitly authorize or have prior knowledge of such activities. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the United States Foreign Corrupt Practices Act' s accounting provisions. AVROBIO is subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws health information privacy and security laws, and other health care laws and regulations. If AVROBIO is unable to comply, or have not fully complied, with such laws, AVROBIO could face substantial penalties. AVROBIO is subject, and may be increasingly subject if AVROBIO obtains FDA approval for any of AVROBIO' s product candidates, to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti- Kickback Statute, the federal civil and criminal FCA and Physician Payments Sunshine Act and regulations. Please see the section titled " Business — Government Regulation — Other Healthcare Laws and Compliance Requirements. " These laws will impact, among other things, AVROBIO' s clinical trial programs, healthcare professional interactions, grant making activities, and AVROBIO' s anticipated sales, marketing and medical educational programs. In addition, AVROBIO may be subject to patient privacy laws by both the federal government and the states in which AVROBIO conducts AVROBIO' s business. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company' s attention from the business. The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can~~ result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, ~~individual~~ imprisonment, exclusion from ~~participation~~ **participating** in **government** ~~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~~ **requirements** and oversight if ~~AVROBIO~~ **we** ~~becomes~~ **become** subject to a corporate integrity agreement or ~~other~~ **similar** agreement to resolve allegations of non- compliance with these laws ~~. Any action~~ **, contractual damages, reputational harm and the curtailment** ~~for~~ **or** ~~violation~~ **restructuring** of ~~these laws~~ **our operations** , **any of which** ~~even if successfully defended,~~ could ~~cause~~ **have** a **negative impact on our** ~~pharmaceutical manufacturer to incur significant legal expenses and divert management' s attention from the operation of the~~ business **, financial condition, results of operations and prospects** . If ~~any of~~ **our information**

**technology systems, or** the ~~physicians~~ **information technology systems of our CROs, our CDMOs, service providers, our current and potential future partners** or other **third parties** ~~healthcare providers or entities~~ with whom ~~AVROBIO expects~~ **we work fail or suffer security breaches, we could experience adverse consequences, including but not limited** to ~~do~~ **material disruptions to our** business **operations and product development** ~~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~~ **regulatory investigations** or ~~case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such~~ actions ~~are instituted against AVROBIO~~ , **litigation** ~~and AVROBIO is not successful in defending itself or asserting AVROBIO' s rights~~ , **fines** ~~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~~ **loss of revenue or** profits ~~and future earnings~~ , **or** ~~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~~ **adverse consequences** . ~~Failure to comply with health and data~~ **We collect, store, receive, process, generate, use, transfer, disclose, make accessible,** ~~protection~~ --- **protect** ~~laws~~ **, secure, dispose of, share,** and **transmit** ~~regulations could lead to government enforcement actions~~ ( **collectively, process** ~~which could include civil or criminal penalties~~ ) **proprietary** , **confidential** ~~private litigation,~~ and **sensitive information** ~~/ 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..... relating to the processing of sensitive data (such as health **- related** data **of clinical trial participants and employee information** ), ~~providing~~ **in the course of our business. Similarly, third- parties with whom we work process certain of that** information **on our behalf. Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable** to ~~individuals regarding~~ **damage from cyber- attacks, malicious internet- based activity, online and offline fraud, and other similar activities that threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are constantly evolving and growing in frequency, sophistication, and intensity. For example, these threats may include (without limitation) malware, viruses, software vulnerabilities and bugs, software or hardware failure, hacking, denial of service attacks, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), ransomware, insider threats (such as theft of misuse by personnel), credential stuffing, telecommunications failures, loss or theft of devices,** data ~~processing activities~~ **or other information technology assets** , ~~where necessary obtaining consent~~ **attacks enhanced or facilitated by AI, earthquakes, fires, floods and similar threats. Threats such as ransomware attacks, for example, are becoming increasingly prevalent and severe, and attackers are increasingly leveraging multiple attack methods to extort payment** from ~~individuals~~ **victims, such as data theft and disabling systems and can lead** to **significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Security incidents may result from the actions of a wide variety of actors with a wide range of motives and expertise, including traditional hackers, our personnel or the personnel of the third parties with** whom **we work, organized criminal threat actors, hacktivists, sophisticated nation- states and nation- state- supported actors. During times of war and** ~~the~~ **other major conflicts** ~~data processing relates~~ , ~~responding~~ **we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to conduct our clinical trials. Future or past business transactions (such as acquisitions or integrations) could expose us** to additional ~~data subject requests~~ **cybersecurity risks and vulnerabilities** , **as our systems could be negatively affected by vulnerabilities present** ~~imposing notification of personal data breaches to the competent national data protection authorities, implementing safeguards~~ in ~~connection with the~~ **acquired or integrated entities' systems and technologies. Furthermore, we may discover** security ~~and confidentiality~~ **issues that were not found during due diligence** of ~~the personal data~~ **such acquired or integrated entities** , ~~accountability requirements~~ and ~~taking certain measures when engaging~~ **it may be difficult to integrate companies into our information technology environment and security program. In addition, our reliance on** third- party **service providers could introduce new cybersecurity risks and vulnerabilities, and other threats to our business operations. For example, we rely on third parties to operate critical business systems and** ~~processors~~ --- **process sensitive data in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions** . ~~The GDPR informs AVROBIO~~ **We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to collect, store, and transmit sensitive data as part of our research activities. Our ability to monitor these third parties is limited, and these third parties may not have adequate information security measures in place. If our**

**third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover damages, or we may be unable to recover such awards. Supply- chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. Certain functional areas of our workforce work remotely on a full- or part- time basis or otherwise utilize network connections, computers and devices outside of our premises or network, which imposes additional risks to our business. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. In the future we may be required to or choose to, expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents, particularly where required by applicable data privacy and security laws or regulations or industry standards. Certain data privacy and security obligations require us to implement and maintain certain security measures or industry- standard or reasonable security measures to protect our information technology systems and sensitive information. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past and expect such attempts will continue in the future. If our information systems or data, or that of the third parties on which we rely, are compromised, it could interrupt our operations, disrupt our development programs and have a material adverse effect on our business, financial condition and results of operations, whether due to a loss of our trade secrets or other proprietary information or similar disruptions. For example, the loss or corruption of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, cause us not to comply with applicable federal and / or state breach notification laws and foreign law equivalents and otherwise subject us to liability under applicable laws and regulations that protect the privacy and security of personal information. Likewise, we rely on third parties for the manufacture of TX45, to analyze clinical trial samples and to conduct clinical trials, and security incidents experienced by these third parties could have a material adverse effect on our business. Security incidents affecting us or the third parties we rely on or partners with could also result in substantial remediation costs and expose us to litigation (including class claims), regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and / or oversight, fines, penalties, indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, interruptions in our operations (including availability of data), financial loss and other liabilities and harms. Additionally, such incidents may trigger data privacy and security obligations requiring us to notify relevant stockholders, including affected individuals, customers, regulators, and investors. Such disclosures may be costly, and related requirements or the failure to comply with them could lead to adverse consequences. Even a perceived security incident or failure in compliance by us or a third- party partner may result in negative publicity, harm to our reputation, or other adverse effects. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveal competitively sensitive details about the company and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of ours could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel ' s , or vendors' use of generative AI technologies. We, and the third parties with whom we work, are subject to rapidly changing and increasingly stringent U. S. and foreign laws, regulations, and rules, contractual obligations , industry standards, policies and other obligations relating to privacy, data protection and information security. Our actual or perceived failure to comply with ~~respect to any clinical trials conducted in the~~ these ~~EEA~~ obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and otherwise harm ~~or~~ our business. We, and the third parties with whom we work process proprietary, confidential and sensitive information, including personal information (including health- related data), which subjects us to numerous evolving and complex data privacy and security obligations, including various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and ~~the~~ other obligations that govern the processing of such information in connection with our business. Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union' s General Data Protection Regulation, (" EU GDPR ") and the United Kingdom' s GDPR (" UK ~~. Its definition of~~ GDPR ") and the Swiss Federal Data Protection Act (collectively, "**

**European Data Protection Laws ") impose strict requirements for processing** personal **information, including relating to transfer of personal information to countries like the United States. European Data Protection Laws and other relevant laws govern patient confidentiality and storage of personal health** data ~~includes coded data~~ , **including personal information from** ~~requires changes to informed consent practices and detailed notices for~~ clinical trial ~~subjects~~ **participants** and ~~investigators. In addition, the~~ **other individuals located in the EEA, the United Kingdom (the " UK "), or Switzerland Companies that violate the EU or UK** GDPR ~~imposes strict rules~~ **can face private litigation, regulatory investigations and enforcement actions, prohibitions** on ~~the transfer of personal~~ data ~~out of~~ **processing,** ~~the~~ **other administrative measures** ~~EEA or the UK~~ , **reputational damage** ~~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~~ **the greater** of ~~global revenues or~~ 20 million Euros **/** ~~(£~~ 17. 5 million **pounds sterling** ~~for~~ - **or 4 % of** ~~the~~ **their** ~~UK)~~ **worldwide annual revenue, in either case** , whichever is greater ~~,~~ **. Certain jurisdictions have enacted data localization restrictions or laws** and ~~confers a private right~~ **regulations restricting cross- border transfers** of ~~action~~ **personal information, except in limited circumstances where adequate safeguards are in place. In particular, regulators and courts in the EEA, the UK, and Switzerland have significantly restricted the transfer of personal information to the United States and other countries whose privacy laws they generally believe are inadequate. Other jurisdictions have in the past and may continue to adopt similarly stringent data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal information from the EEA, the UK, or Switzerland to the United States, such as the EEA standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework (the " Framework ") and the UK extension thereto (which allows for transfers for to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges and there is no assurance that we can satisfy or rely** 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~~ **these measures to lawfully transfer** ~~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 **to the United States. If we are unable to implement a valid compliance solution for cross- border transfers of personal information, or if the requirements for a legally- compliant transfer are too onerous, we may face increased exposure to significant adverse consequences** , including ~~genetic~~ **substantial fines** , ~~biometric~~ **regulatory actions** , **as well as injunctions against the export and processing of personal information from the EEA, UK, Switzerland,** or ~~health~~ **other countries that implement cross- border** data **transfer restrictions** . ~~The GDPR~~ **Our inability to import personal information from the EEA, UK or Switzerland or other countries may also restrict or** ~~prohibits~~ - **prohibit our clinical trial activities in those countries; limit our ability to collaborate with CROs, service providers, contractors and other companies subject to laws restricting** cross- border data transfers ~~of personal~~ **; require us to increase our** data ~~to countries outside the EEA or the UK that are not considered by the European Commission and UK government as providing " adequate " protection to personal data, or third countries, including the United States in certain circumstances, unless a valid GDPR transfer mechanism (for example, the European Commission approved the SCCs and the UK IDTA) has been put in place. Where relying on the SCCs / UK IDTA for data transfers, AVROBIO may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. Further, the EU and United States have adopted its adequacy decision for the Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost, and may result in AVROBIO needing to make strategic considerations around where EEA and UK personal data is located and which service providers AVROBIO can utilize for the processing of EEA and UK personal data. AVROBIO has yet to adopt and implement comprehensive processes, systems and other relevant measures within AVROBIO' s organization, and / or with AVROBIO' s relevant collaborators, service providers, contractors or consultants, which are appropriate to address relevant requirements relating to international transfers of personal data from Europe, and to minimize the potential impacts and risks resulting from those requirements, across AVROBIO' s organization. Failure to implement valid mechanisms for personal data transfers from Europe may result in AVROBIO' s facing increased exposure to regulatory actions, substantial fines and injunctions against processing personal data from Europe. Inability to export personal data may also: restrict AVROBIO' s activities outside Europe; limit AVROBIO' s ability to collaborate with partners as well as other service providers, contractors and other companies outside of Europe; and / or require AVROBIO to increase AVROBIO' s~~ processing capabilities ~~within Europe~~ **in other countries** at significant expense ~~or~~ **and may** otherwise **negatively impact** ~~cause AVROBIO to change the geographical location or~~ **our business** ~~segregation of AVROBIO' s relevant systems and~~ operations ~~— any~~ **. Depending on how these laws are interpreted, we may have to make changes to** ~~or~~ **our business practices and products to comply with such obligations** ~~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 **our** ~~AVROBIO' s~~ services and operating **our** ~~AVROBIO' s~~ business. **Privacy and data security laws** ~~The type of challenges AVROBIO faces~~ in ~~Europe will likely also arise in other~~ -- **the** ~~jurisdictions~~ **United States at the federal, state and local level are increasingly complex and changing rapidly. For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, at the state level, the privacy and data protection landscape is changing rapidly. Many states**

**have enacted comprehensive privacy laws** that **impose certain obligations on covered businesses** ~~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~~ , **including** ~~the European Commission has issued an adequacy decision recognizing the UK as~~ providing ~~adequate protection under~~ **specific disclosures in privacy notices and affording residents with certain rights concerning** ~~the~~ **their** ~~EU GDPR and, therefore, transfers of~~ personal data ~~originating in the EU to the UK remain unrestricted~~ . **As applicable** ~~Like the EU GDPR~~ , **such rights may include** the ~~UK GDPR restricts~~ **right to access, correct, or delete certain** personal data ~~transfers outside~~ **, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of** ~~the~~ **these** ~~UK~~ **rights may impact our business and ability** to ~~countries not regarded~~ **provide our products and services if we become subject to these laws. For example, the California Consumer Rights Act (" CCPA "), as amended** by the ~~UK as~~ **California Privacy Rights Act of 2020 (" CPRA ") applies to personal information data of consumers, business representatives, and employees who are California residents and requires businesses to** ~~providing~~ **provide** ~~adequate protection. The UK government has confirmed that~~ **specific disclosures in privacy notices and honor requests of such individuals to exercise certain rights concerning their** personal data ~~transfers from the UK to the EU remain free flowing~~ . The **CCPA provides fines** ~~UK Government has also now introduced a Data Protection and Digital Information Bill, or~~ **for noncompliance and a limited private right** ~~the UK Bill, into the UK legislative process. The aim~~ of **action in connection with certain** ~~the UK Bill is to reform the UK' s~~ data **breaches** ~~protection regime following Brexit~~ . ~~If passed,~~ **While the CCPA and** ~~the~~ **other** ~~final version of~~ **state privacy laws contains an exemption for certain personal information processed in connection with clinical trials,,** ~~the~~ **these developments** ~~UK Bill may have the effect of~~ further **complicate compliance efforts,** ~~altering the similarities between the UK~~ and **increase** ~~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 **costs** ~~programs and could require AVROBIO to implement different compliance measures~~ for **us** ~~the UK~~ and the **third parties** ~~EEA. Given the breadth and depth of its obligations, complying~~ with **whom we work. Similar laws have been passed or are being considered in several** ~~the~~ **other states** ~~GDPR' s requirements is rigorous and time intensive and requires significant resources and assessment of AVROBIO' s technologies, systems and practices~~ , as well as **at the federal and local levels. The evolving patchwork of differing state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third party litigation and regulatory investigations, enforcement, fines, and penalties. We are bound by contractual obligations and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self- regulatory principles, regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Our obligations related to data privacy and security (and consumers' data privacy obligations) are quickly changing in an increasingly stringent fashion and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Monitoring, preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time- related resources). These obligations have in the past and may in the future necessitate changes to our information technologies, systems and practices and to** those of any **third parties that process personal information on our behalf. In addition, these obligations may require us to change aspects of our business model. Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could impact whether or not we are in compliance. If we (or third parties with whom we work) fail, or are perceived to have failed, to address or comply with data privacy, protection and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (e. g., investigations, fines, penalties, audits, inspections and similar); litigation (including class- related claims) and mass arbitration demands; additional reporting requirements and / or oversight; bans on processing personal information; orders to destroy or not use personal information; and / or imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. We are subject to U. S. and certain foreign anti- corruption laws and regulations, export and import controls, sanctions and embargoes. We could face liability and other serious consequences for violations which can harm our business. We are subject to anti- corruption laws and regulations, including the FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act and other state and national anti- bribery laws in the countries in which we may conduct activities in the future. Anti- corruption laws are interpreted broadly and generally prohibit companies and their employees, agents, contractors and other** third- party collaborators **from offering** , ~~service providers~~ **promising, giving, or authorizing others to give anything of**

**value, either directly or indirectly through third parties, to any person in the public or private sector to obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We may engage third parties to sell our products or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals outside the United States. We can be held liable for the corrupt or other illegal activities of our employees, agents** , contractors, **and** ~~or consultants that process or transfer personal data collected in the~~ **other** ~~EEA~~ **partners, even if we do not explicitly authorize** or **have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and** ~~the~~ **other** ~~UK~~ **consequences. We are also subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations and various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls** . Compliance with **applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U. S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U. S. sanctions. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors or collaborators, or** ~~the~~ **those** ~~GDPR~~ **of our affiliates,** will ~~be a rigorous~~ **comply with all applicable anti- corruption, export and import control, and sanctions laws and regulations. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our** ~~and~~ **brand , our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition. We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. If earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevent us from using all or a significant portion of our headquarters or other facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of** time **. We do not have a disaster recovery or** ~~- intensive process that may increase AVROBIO' s cost of doing~~ business **continuity plan** ~~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 **place** ~~connection with European activities. AVROBIO faces potential product liability,~~ and ~~, if successful claims are brought against AVROBIO, AVROBIO~~ may incur substantial **expenses as a result** ~~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 **absence** ~~development of its product candidates, the future sale of any products for -~~ **or limited nature of our internal or third- party service provider disaster recovery and business continuity plans,** 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 **our** ~~AVROBIO' s~~ business **. In addition** , **the long- term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including raw materials and other natural resources, necessary to run our business. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business. Legislation or other changes in U. S. tax law could adversely affect our 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 Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in ~~or~~ our tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. Our ability to use our U. S. net operating loss carryforwards and certain other U. S. tax attributes may be limited. As of December 31, 2024, we had U. S. federal net operating loss carryforwards of $ 399. 3 million. The amount of net operating loss carryforwards that we are permitted to deduct is limited to 80 % of taxable income in each such taxable year to which the net operating loss carryforwards are applied. In addition, our U. S. federal net operating losses and tax credits may be subject to limitations under Sections 382 and 383 of the Code, if we have undergone or undergo an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a rolling three- year period. We may have experienced such ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law. Our ability to utilize our net operating loss carryforwards could be limited by an " ownership change " as described above, which could result in increased tax liability to us. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. The global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, any necessary debt or equity financing that we undertake may be more difficult, more costly and more dilutive than it would be otherwise. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy and financial performance and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget. Geopolitical developments, such as the Russian invasion of Ukraine, the conflict in the Middle East or deterioration in the bilateral relationship between the United States and China, may impact government spending, international trade and market stability, and cause weaker macro- economic conditions. Certain political developments may also lead to regulatory uncertainty and to rules that may adversely affect our business. Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported** results of operations. **Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred frequently in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.** If ~~AVROBIO~~ **we or any CDMOs and suppliers we engage** ~~fails~~ **fail** to comply with environmental, health and safety laws and regulations, ~~AVROBIO~~ **we** could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of **our** ~~AVROBIO' s~~ business. ~~AVROBIO is~~ **We and any CDMOs and suppliers we engage are** subject to numerous **federal, state and local** environmental, health and safety laws ~~and~~ **,** regulations **and permitting requirements** , including those governing laboratory procedures ~~and~~ **;** the **generation,** handling, use, storage, treatment and disposal **of hazardous and regulated materials and wastes; the emission and discharge** of hazardous materials **into the ground, air** and ~~wastes~~ **water; and employee health and safety** . **Our** ~~AVROBIO' s~~ operations involve the use of hazardous and flammable materials, including chemicals and biological

**and radioactive** materials. **Our** ~~AVROBIO' s~~ operations also produce hazardous waste ~~products~~. ~~AVROBIO~~ **We** generally ~~contracts~~ **contract** with third parties for the disposal of these materials and wastes. ~~AVROBIO~~ **We** cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from **our** ~~AVROBIO' s~~ use of hazardous materials, ~~AVROBIO~~ **we** could be held liable for any resulting damages, and any liability could exceed **our** ~~AVROBIO' s~~ resources. ~~AVROBIO~~ **Under certain environmental laws, we could be held responsible for costs relating to any contamination at third- party facilities. We could** also ~~could~~ incur significant costs associated with civil or criminal fines and penalties. ~~Furthermore,~~ **Compliance with applicable** environmental laws and regulations **may** ~~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~~ **expensive, and current or** future ~~compliance~~ **environmental laws and regulations may impair our research and product development efforts**. In addition, **we cannot entirely eliminate the risk of accidental injury** ~~AVROBIO may incur substantial costs in order to comply with current~~ or **contamination from** ~~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 **materials** ~~laws and regulations also may result in substantial fines, penalties~~ or **wastes** ~~other sanctions~~. Although ~~AVROBIO~~ **we** ~~maintains~~ **maintain** workers' compensation insurance to cover ~~AVROBIO~~ **us** for costs and expenses ~~AVROBIO~~ **we** may incur due to injuries to **our** ~~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~~ **We do not carry specific biological or hazardous waste insurance coverage**, ~~AVROBIO may incur substantial costs~~ **and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly,** in ~~order to comply~~ **the event of contamination or injury, we could be held liable for damages or be penalized** with **fines in** ~~current or future environmental, health and~~ **an amount exceeding** ~~safety laws and regulations. These current or future laws and regulations may impair AVROBIO' s research~~, ~~development~~ **and** ~~or~~ **our** ~~production efforts~~ **our resources clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and prospects**. Failure to comply with these laws ~~and~~ **,** regulations **and permitting requirements** also may result in substantial fines, penalties or other sanctions or ~~liabilities, which could materially adversely affect AVROBIO' s~~ business **disruption** ~~, financial condition, results of operations and prospects. AVROBIO might not be able to utilize a significant portion of AVROBIO' s net operating loss carryforwards and research and development tax credit carryforwards. As of December 31, 2023 and 2022, AVROBIO had federal and state net operating loss carryforwards of $ 575. 9 million and $ 657. 0 million, respectively, and federal research and development tax credit carryforwards of approximately $ 6. 4 million and $ 6. 8 million, respectively. If not utilized, the net operating loss carryforwards and research and development credits will generally expire at various dates through 2041 (other than federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017, which are not subject to expiration and generally may not be carried back to prior taxable years except that net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years). These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code, or Code and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership over a three- year period, the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income may be limited. AVROBIO may have experienced ownership changes in the past. AVROBIO may also experience ownership changes in the future as a result of subsequent shifts in AVROBIO' s stock ownership, some of which may be outside of AVROBIO' s control. In addition, the merger, if consummated, may also constitute an ownership change (within the meaning of Section 382 of the Code) which could eliminate or otherwise substantially limit AVROBIO' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes. If an ownership change occurred or occurs and AVROBIO' s ability to use AVROBIO' s historical net operating loss and tax credit carryforwards is materially limited (or entirely eliminated), or if AVROBIO' s research and development carryforwards are adjusted, it would harm AVROBIO' s future operating results by effectively increasing AVROBIO' s future tax obligations. For taxable years beginning after December 31, 2020, deductions for federal net operating losses arising in taxable years beginning after December 31, 2017 may only offset 80 % of taxable income. Risks Related to AVROBIO' s Intellectual Property Should AVROBIO resume development of its product candidates, third- party claims of intellectual property infringement may prevent or delay AVROBIO' s development and commercialization efforts. AVROBIO' s commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter parties reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which AVROBIO is pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that AVROBIO' s product candidates may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that AVROBIO or AVROBIO' s licensors are employing their proprietary technology without authorization. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of AVROBIO' s product candidates. In particular, AVROBIO is aware of issued patents in the United States that cover the lentiviral vectors used in the manufacture of AVROBIO' s product candidates. While AVROBIO believes that AVROBIO has reasonable defenses against a claim of infringement, potentially including that certain of these patents are expected to expire prior to commercializing AVROBIO' s product candidates, if approved, in the United States, there can be no assurance that AVROBIO will prevail in any such action~~

by the holder of these patents. In the event that the holder of these patents seeks to enforce its patent rights and AVROBIO' s defenses against a claim of infringement are unsuccessful, AVROBIO may not be able to commercialize AVROBIO' s product candidates in the United States, if approved, without first obtaining a license to some or all of these patents, which may not be available on commercially reasonable terms or at all. In addition, the defense of any claim of infringement, even if successful, is time- consuming, expensive and diverts the attention of AVROBIO' s management from AVROBIO' s ongoing business operations. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that AVROBIO' s product candidates may infringe or be alleged to infringe. In addition, third parties may obtain patents in the future and claim that use of AVROBIO' s or AVROBIO' s licensors' technologies infringes upon these patents. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of AVROBIO' s product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block AVROBIO' s ability to commercialize such product candidate unless AVROBIO obtained a license under the applicable patents, or until such patents expire. Similarly, if any third- party patents were held by a court of competent jurisdiction to cover aspects of AVROBIO' s formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block AVROBIO' s ability to develop and commercialize the applicable product candidate unless AVROBIO obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. Parties making claims against AVROBIO may obtain injunctive or other equitable relief, which could effectively block AVROBIO' s ability to further develop and commercialize one or more of AVROBIO' s product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from AVROBIO' s business. In the event of a successful claim of infringement against AVROBIO, AVROBIO may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign AVROBIO' s infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Even in the absence of a finding of infringement, AVROBIO may choose to obtain a license, if such a license is available. A successful claim of patent or other intellectual property infringement against AVROBIO could materially adversely affect AVROBIO' s business, results of operations and financial condition. AVROBIO' s rights to develop and commercialize its product candidates, should AVROBIO resume development of its product candidates, are subject, in part, to the terms and conditions of licenses granted to AVROBIO by others. AVROBIO depends upon the intellectual property rights granted to AVROBIO under licenses from third parties that are important or necessary to the development of AVROBIO' s technology and products, including technology related to AVROBIO' s manufacturing process and AVROBIO' s gene therapy product candidates. In particular, AVROBIO had in- licensed certain intellectual property rights and know- how from the University Health Network, or UHN (relevant to AVR- RD- 01 and AVROBIO' s Fabry program, which AVROBIO deprioritized in January 2022) and affiliates of Lund University (relevant to AVR- RD- 02 and AVROBIO' s Gaucher type 1 and type 3 programs). The Fabry license agreement with UHN was terminated as of January 4, 2024. In addition, AVROBIO has in- licensed patents and patent applications from BioMarin (relevant to AVR- RD- 03 and AVROBIO' s Pompe program) directed to compositions and methods related to the manufacture and use of AVR- RD- 03. AVROBIO also previously had in place in- licensed patent applications from The University of Manchester relevant to AVR- RD- 05 and AVROBIO' s Hunter program, which license agreement was terminated as of September 8, 2023. Any termination of AVROBIO' s remaining licenses could result in the loss of significant rights and could harm or prevent AVROBIO' s ability to commercialize AVROBIO' s product candidates, should AVROBIO resume development of such product candidates. Each of AVROBIO' s existing licenses with affiliates of Lund University and BioMarin are exclusive but are limited to particular fields, such as Gaucher disease type 1, or Pompe disease, and are subject to certain retained rights. Absent an amendment or additional agreement, AVROBIO may not have the right to use intellectual property in- licensed for one of AVROBIO' s programs for another program. In addition, licenses that AVROBIO may enter into in the future may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which AVROBIO may wish to develop or commercialize AVROBIO' s technology and products in the future. As a result, AVROBIO may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of AVROBIO' s licenses. Licenses to additional third- party technology that may be required for AVROBIO' s development programs may not be available in the future or may not be available on commercially reasonable terms, or at all , which could have a material adverse effect on **our** AVROBIO' s business **and ,** financial condition . In some circumstances , **results of** AVROBIO may not have the right to control the preparation --- **operations** , filing and **prospects. Any** prosecution of patent applications, or to maintain the patents, covering technology that AVROBIO licenses from third parties. For example **- party CDMOs and suppliers we engage will also be subject to these and other environmental** , **health and safety laws and regulations. Liabilities they incur** 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 **laws** and **regulations** 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 **result in significant costs or** be adversely affected. AVROBIO' s current license agreements impose, and - **an interruption in operations** AVROBIO expects that future license agreements that AVROBIO may enter into will impose , **which** 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 **our business, financial condition, results of operations and prospects. We incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. As a public company, we incur significant legal, accounting and other expenses that Legacy Tectonic did not incur as a private company. In addition, the Sarbanes- Oxley Act of 2002 (the " Sarbanes- Oxley Act "), as well as rules subsequently implemented by the SEC, and Nasdaq have imposed various requirements on public companies. In July 2010, the Dodd- Frank Wall Street Reform and Consumer Protection Act (the " Dodd- Frank Act ") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act that require the SEC to adopt additional rules and regulations in these areas such as " say on pay " and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costlier. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage. Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. We currently qualify as a " smaller reporting company, " as such term is defined in Rule 12b- 2 under the Exchange Act, which allows the us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in this Quarterly Report and in our periodic reports and proxy statements. Once we are no longer a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies. As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes- Oxley Act, the regulations of Nasdaq, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. The Sarbanes- Oxley Act requires us to, among other things, establish corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Commencing with our fiscal year ending the year after the Merger is completed, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10- K filing for that year, as required by Section 404 of the Sarbanes- Oxley Act. Prior to the closing of the Merger, we were never required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Stockholders**

**previously filed lawsuits, which were subsequently dismissed, relating to the Merger; however, additional lawsuits could be filed. Prior to the Merger, three actions were filed by purported stockholders of AVROBIO in connection with the 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). Two actions have been filed in the Supreme Court of New York, captioned Price v. Avrobio, Inc., et al., No. 652555 / 2024 (filed May 17, 2024) and Keller v. Avrobio, Inc., et al., No. 652597 / 2024 (filed May 21, 2024). The foregoing actions are referred to as the " Merger Actions. " The Merger Actions generally allege that the Registration Statement misrepresents and / or omits certain purportedly material information in connection with the Merger, potential conflicts of interest of** AVROBIO' s ~~business. If AVROBIO cannot maintain a necessary license~~ **officers and directors, and the events that led to the signing of the Merger** ~~agreement~~ **Agreement . The Price and Keller actions assert claims** ~~or~~ **for breach of fiduciary duty against all defendants. The Merger Actions seek, among other things, an injunction enjoining the consummation of the Merger, rescission of the Merger** if **consummated** ~~the agreement is terminated~~ , **costs of** ~~AVROBIO may be unable to successfully develop and commercialize~~ the **action, including plaintiff** ~~affected product candidates. If AVROBIO is unable to obtain and maintain patent protection for AVROBIO~~ ' s ~~product candidates,~~ **attorneys' fees and experts' fees and other relief the court may deem just and proper. AVROBIO also received demand letters from eleven purported AVROBIO stockholders (the " Demands "). The Demands generally assert that the Registration Statement misrepresents and /** or **omits certain purportedly material information relating to the Merger. AVROBIO believed that the disclosures set forth in the Registration Statement complied fully with all applicable law, that no supplemental disclosures were required under applicable law, and that the allegations in the Merger Actions and Demands were without merit. However, in order to moot the claims in the Merger Actions and Demands, avoid nuisance and possible expense and business delays, and provide additional information to its stockholders, and without admitting any liability or wrongdoing, AVROBIO decided voluntarily to supplement certain disclosures in the Registration Statement (the " Supplemental Disclosures "). On June 4, 2024, AVROBIO made certain Supplemental Disclosures on Form 8- K filed with the Securities and Exchange Commission. Following the issuance of the Supplemental Disclosures, each of the Merger Actions was voluntarily dismissed and each of the Demands were withdrawn. Additional potential plaintiffs may file lawsuits challenging the Merger. The outcome of any current or future litigation is uncertain. Such litigation,** if ~~the scope of the patent protection obtained is~~ not **resolved** ~~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 **us, including** assert claims against AVROBIO. AVROBIO may not prevail in any **costs associated with** lawsuits that AVROBIO initiate and the damages or other -- **the indemnification of directors and officers** 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 **plaintiff were successful in obtaining an injunction obtaining** a **rescission** patent covering one of **the Merger** AVROBIO' s product candidates, should **then** such **injunction may rescind** a patent issue, the **Merger after** defendant could counterclaim that the patent covering AVROBIO' s product candidate is **its consummation** invalid or unenforceable. In patent **Regardless of the outcome,** litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an **can have a** 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..... of patent protection could have a material adverse impact on **us because of defense** AVROBIO' s business. In addition to the protection afforded by patents, AVROBIO relies on trade secret protection and **settlement costs** confidentiality agreements to protect proprietary know- how that is not patentable or that AVROBIO elects not to patent, **diversion of management resources** processes for which patents are difficult to enforce and any other **factors** 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~~ **Our** Common Stock The market price of ~~AVROBIO common stock may be highly volatile, and you may not be able to resell your~~ **our** ~~shares at or above the price at which you purchased AVROBIO' s shares. AVROBIO' s stock price is likely to be volatile. Since AVROBIO' s IPO in June 2018, through March 7, 2024, the trading price of AVROBIO~~ common stock has **been and is likely** ~~ranged from $ 53. 70~~ to ~~$ 0. 56~~ **continue to be volatile and fluctuate substantially** . The **trading price of our common stock has been and is likely to continue to be highly volatile. Furthermore, the** stock market in general ~~,~~ and the market for biopharmaceutical **and pharmaceutical** companies in particular **have** ~~, has~~ experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, ~~you~~ **our stockholders** may not be

able to sell **their shares** ~~your common stock~~ at or above the price ~~at which you purchased~~ **they paid for their** shares. The market price ~~for AVROBIO~~ **of our** common stock may be influenced by many factors, including: • ~~the outcome of AVROBIO' s exploration of strategic alternatives; • adverse~~ results ~~or delays in~~ **of clinical trials and** preclinical studies **of or our** ~~clinical trials; • reports of adverse events in other gene therapy products~~ **product candidates, or those of or our competitors or existing or future collaborators** ~~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 **and development** projections ~~AVROBIO we~~ may provide to the public; • failure ~~by AVROBIO~~ to meet or exceed the financial **and development** projections of the investment community; • **if we do not achieve** the ~~perception~~ **perceived benefits** of the ~~pharmaceutical~~ **Merger as rapidly or to the extent anticipated by financial or** industry **analysts** ~~by the public, legislatures, regulators and the investment community~~ ; • announcements of significant acquisitions, strategic ~~partnerships~~ **collaborations** , joint ventures or capital commitments by **us or** ~~AVROBIO, AVROBIO' s strategic partners or~~ **our** ~~AVROBIO' s~~ competitors; • **actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms; •** disputes or other developments relating to proprietary rights, including patents, litigation matters **,** and **our** ~~AVROBIO' s~~ ability to obtain patent protection for **our** ~~AVROBIO' s~~ technologies; • additions or departures of key ~~scientific or management personnel, or other skilled~~ personnel; • significant lawsuits, including patent or stockholder litigation; • **if** ~~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 **reports about our business, or if they issue adverse or misleading opinions regarding our business and stock; • changes in the market valuations of similar companies; • general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors; • sales of securities by us, the selling stockholders or other securityholders in the future; • if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates; • trading volume of our common stock; • announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments; • adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets; • the introduction of technological innovations or new therapies that compete with our product candidates; • period- to- period fluctuations in our financial results; and • the other factors described in this " Risk Factors " section. Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time- consuming, and could divert our management' s attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock. Sales of our common stock or the perception of such sales, by us or selling stockholders, in the public market or otherwise, could cause the market price for our securities to decline, even though selling stockholders would still realize a profit on sales at lower prices. Resales of the securities offered may cause the market price of such securities to drop significantly, even if our business is doing well. The sale of our common stock in the public market or otherwise, or the perception that such sales could occur, could harm the prevailing market price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of our common stock may cause the market price of our securities to drop significantly, even if our business is doing well. Certain selling stockholders acquired securities at prices that are significantly less than the current trading price of our common stock. Accordingly, certain selling stockholders could still realize a profit on sales at lower prices. Even if the trading price of our common stock falls to or significantly below the current trading price, selling stockholders may still have an incentive to sell and profit**

**due to the nominal purchase prices paid by such selling stockholders, which are significantly lower than the purchase prices paid by the public stockholders. Pursuant to the Subscription Agreement, we filed a resale shelf registration statement covering the resale of up to an aggregate of 2, 969, 583 shares of our common stock, which was declared effective on July 30, 2024. In addition, in connection with the private placement we completed in February 2025 (the " February 2025 PIPE "), we intend to file a resale shelf registration statement covering the resale of up to an aggregate of 3, 689, 465 shares of our common stock. Given the substantial number of shares available for resale, the sale of shares by such stockholders, or the perception in the market that the stockholders of a large number of shares intend to sell shares, could increase the volatility of the market price of our common stock or result in a significant decline in the public trading price of our common stock. In addition, certain of our shares are subject to lock- up agreements in connection with the February 2025 PIPE. Following the expiration of these lock- up agreements, the relevant stockholders will not be restricted from selling shares our common stock held by them, other than by applicable securities laws. Stockholders not subject to these lock- up agreements will not be restricted from selling shares of our common stock held by them, other than by applicable securities laws. Common stock that is issued in connection with stock options and restricted stock units will also become eligible for sale in the public market, to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after any legal or contractual restrictions on resale lapse, the trading price of our common stock could decline. Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval. Based on the number of shares outstanding as of December 31, 2024, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 72 % of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. If equity research analysts do not** publish ~~inaccurate~~ **research** or **reports, or publish** unfavorable research **or reports,** about ~~AVROBIO' s~~ **us, our** business **or our market** , **our stock** ~~AVROBIO' s share~~ price and trading volume could decline. The trading market for ~~AVROBIO~~ **our** common stock will **be influenced by** ~~likely depend in part on~~ the research and reports that **equity research** ~~securities or industry~~ analysts publish about ~~AVROBIO~~ **us and** ~~or~~ **our** ~~AVROBIO' s~~ business. ~~AVROBIO does~~ **Equity research analysts may elect to not provide research coverage of our common stock and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will** not have any control over ~~these~~ -- **the** analysts **or the content and opinions included in their reports** . ~~Although AVROBIO has obtained~~ **The price of our common stock could decline if one or more equity** research ~~coverage from certain~~ analysts **downgrade** ~~, there can be no assurance, including during such time period that AVROBIO pursues potential strategic alternatives, that analysts will continue to cover AVROBIO or~~ **our** ~~provide~~ **stock or issue other** ~~favorable~~ **unfavorable** ~~coverage~~ **commentary or research** . If one or more **equity research** 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~~ **ceases** coverage of **us** ~~AVROBIO' s company~~ or ~~fail~~ **fails** to ~~regularly~~ publish reports on ~~AVROBIO~~ **us regularly** , ~~AVROBIO~~ **demand for our common stock** could **decrease** ~~lose visibility in the financial markets~~ , which **in turn** could cause **our stock** ~~AVROBIO' s share~~ price or trading volume to decline. ~~Concentration~~ **We have broad discretion in the use** of **our cash** ~~ownership of AVROBIO common stock among AVROBIO' s existing executive officers, directors~~ and ~~principal stockholders~~ **cash equivalents and** may ~~prevent new investors~~ --- **invest** ~~from influencing~~ **or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment. We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a** significant ~~corporate decisions. Based~~ **return, if any,** on **our investment** ~~shares outstanding as~~ of ~~March 7, 2024, AVROBIO' s executive officers, directors, five percent stockholders and their affiliates beneficially owned approximately 37. 8 % of AVROBIO' s voting stock. As a result, if~~ these **net** ~~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 - **proceeds** to document and evaluate AVROBIO' s internal control over financial reporting, which is both costly and challenging . **You** 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 **have** 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 **opportunity** financial markets due to **influence our decisions on how** a loss of confidence in the reliability of AVROBIO' s financial statements. If AVROBIO fails to **our cash resources. Because we do** maintain an effective system of internal control over financial reporting, AVROBIO may not **anticipate paying** 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~~ **our share capital in the foreseeable future, capital appreciation, if any, will be your sole source of gain** . ~~AVROBIO~~ **You should not rely on an investment in our shares to provide dividend income. We have never declared or paid cash dividends on our share capital. We** currently **intend to** ~~anticipates that AVROBIO will~~ retain **all of our** future earnings **, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements or preferred equity may preclude us from paying dividends. As a result, capital appreciation, if any, of our common shares will be your sole source of gain** for the **foreseeable future. Investors seeking** ~~development, operation and expansion of AVROBIO' s business and do not anticipate declaring or paying any~~ cash dividends **should not purchase our shares** ~~for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock~~ . Provisions in **our** ~~AVROBIO' s~~ charter and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire ~~AVROBIO~~ **us** or increase the cost of acquiring ~~AVROBIO~~ **us** , even if doing so would benefit ~~AVROBIO~~ **our** stockholders or remove **our** ~~AVROBIO' s~~ current management. **Our** ~~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~~ **the Company** or changes in **our** ~~AVROBIO' s~~ management. **Our** ~~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~~ **our** common stock; • create a classified board of directors whose members serve staggered three- year terms; • specify that special meetings of ~~AVROBIO~~ **our** stockholders can be called only by the ~~AVROBIO~~ Board, the chairperson of the ~~AVROBIO~~ Board, **our** ~~AVROBIO' s~~ Chief Executive Officer or **our** ~~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~~ **our** stockholders, including proposed nominations of persons for election to the ~~AVROBIO~~ Board; • provide that **our** ~~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 **our** ~~AVROBIO' s~~ amended and restated by- laws; and • require supermajority votes of the holders of ~~AVROBIO~~ **our** common stock to amend specified provisions of **our** ~~AVROBIO' s~~ charter and bylaws. These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in **our** ~~AVROBIO' s~~ management. In addition, because ~~AVROBIO is~~ **we are** incorporated in Delaware, ~~AVROBIO is~~ **we are** 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 **our** ~~AVROBIO' s~~ outstanding voting stock to merge or combine with ~~AVROBIO~~ **us** . Any provision of ~~AVROBIO' s amended and restated certificate of incorporation or~~ **our charter,** ~~amended and restated by- laws~~ **bylaws** or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for ~~AVROBIO~~ **our** stockholders to receive a premium for their shares of ~~AVROBIO~~ **our** common stock, and could also affect the price that some investors are willing to pay for ~~AVROBIO~~ **our** common stock. **Our** ~~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. **Our** ~~AVROBIO' s~~ amended and restated bylaws provide that, unless ~~AVROBIO~~ **we** ~~consents~~ **consent** 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 **our** ~~AVROBIO' s~~ behalf; (2) any action asserting a claim of breach of or based on a fiduciary duty owed by any of **our** ~~AVROBIO' s~~ current or former directors, officers or other employees to ~~AVROBIO~~ **us or** ~~or~~ **our** ~~AVROBIO~~ stockholders; (3) any action asserting a claim against ~~AVROBIO~~ **us** or any of **our** ~~AVROBIO' s~~ current or former directors, officers, employees or stockholders arising pursuant to any provision of the DGCL, **our** ~~AVROBIO' s~~ amended and restated certificate of incorporation or **our** ~~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. **Our** ~~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 **our** ~~AVROBIO' s~~ principal executive offices are located in ~~Cambridge~~ **Watertown** , Massachusetts. In addition, **our** ~~AVROBIO' s~~ amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of **our** ~~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 **our** ~~AVROBIO' s~~ compliance with the U. S. federal securities laws and the rules and regulations thereunder. ~~AVROBIO~~ **We** ~~recognizes~~ **recognize** 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 **our** ~~AVROBIO' s~~ amended and restated bylaws may limit ~~AVROBIO~~ **our** stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with ~~AVROBIO~~ **us or** ~~or~~ **our** ~~AVROBIO' s~~ directors, officers or employees, which may discourage such lawsuits against ~~AVROBIO~~ **us** and **our** ~~AVROBIO' s~~ directors, officers and employees even though an action, if successful, might benefit ~~AVROBIO~~ **our** 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 **our** ~~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~~ **we** 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~~ **us** than ~~AVROBIO~~ **our** 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. 76