Risk Factors Comparison 2024-03-14 to 2023-02-10 Form: 10-K

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

~~Investing in our common stock involves a high degree of risk.~~ You should carefully consider the risks ~~and uncertainties~~ described below ~~together with all of~~ **, as well as** the other information ~~contained~~ in this Annual Report on Form 10- K, including our **audited** consolidated financial statements and ~~the~~ related notes ~~appearing elsewhere in this Annual Report on Form 10- K~~ **and the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations, "** and in our other **public** filings ~~with~~ **in evaluating our business. The occurrence of any of** the ~~Securities~~ **events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such** ~~and~~ **an event** ~~Exchange Commission~~ , **the market price of** ~~before deciding to invest in~~ our common stock **could decline** . ~~The risks described below are not the only risks facing our company. The occurrence of any of the following risks, or of additional~~ **Additional** risks and uncertainties not presently known to us ~~, could cause~~ **or that we currently deem immaterial also may impair** our business ~~, prospects, operating~~ **operations** ~~results~~ and ~~financial condition to suffer materially. In such event,~~ the ~~trading~~ **market** price of our common stock **. Risk Factor Summary We are early in our development efforts, with a limited operating history, and we have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and future viability. • We have incurred significant net losses and we expect to continue to incur significant net losses for the foreseeable future. • We have never generated revenue from product sales and we may never achieve or maintain profitability. • We are substantially dependent on ELVN- 001 and ELVN- 002. If we are unable to advance ELVN- 001 or ELVN- 002 through clinical development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed. • The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities. • We have limited resources and are currently focusing our efforts on ELVN- 001 and ELVN- 002 for development in particular indications and advancing our other research programs. As a result, we may fail to capitalize on programs, product candidates or indications that may be more profitable or for which there is a greater likelihood of success. • Our prospects depend in large part upon developing and commercializing ELVN- 001 and ELVN- 002 and discovering, developing and commercializing product candidates from our other research programs, and failure to successfully identify, develop and commercialize additional product candidates** could ~~decline,~~ **impair our ability to grow. • If clinical trials of our product candidates fail to demonstrate safety** and ~~you might lose~~ **efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. • The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed. • Our success depends on our ability to protect our intellectual property and our proprietary technologies. • The market price of our common stock may be volatile and may drop. • We will need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital on favorable terms, on a timely basis or at** all **, we would be forced to delay, reduce** or **eliminate** ~~part of your~~ **our** ~~investment~~ **product development and clinical programs and may not have the capital required to otherwise operate our business. • We have incurred and will continue to incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies** . Risks Related to ~~the Proposed Merger~~ **Our Limited Operating History, Financial Position** and ~~Retention of Key Employees The Merger~~ **Need for Additional Capital We are a clinical stage biopharmaceutical company** with **a limited operating history upon which you can evaluate our business and prospects. Former** Enliven ~~may~~ **commenced operations in June 2019, has never completed a clinical trial, has** ~~not~~ **no** ~~be consummated~~ **products approved** ~~or~~ **for** ~~may not deliver the anticipated benefits we expect~~ **commercial sale and has never generated any revenue** . **Drug** ~~In April 2022, we announced that we were discontinuing the~~ development **is** ~~of tovinontrine and undertook~~ a **highly** ~~strategic review process, which was intended to result in an actionable plan that leverages our assets, capital and capabilities to maximize stockholder value. The strategic review process involved evaluating strategic alternatives and identifying and reviewing potential candidates for a strategic acquisition or other transaction. On October 13, 2022, we, Iguana Merger Sub, Inc., a Delaware corporation and our wholly- owned subsidiary, or the Merger Sub, and Enliven Therapeutics, Inc., a Delaware corporation, or Enliven, entered into an Agreement and Plan of Merger, or the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Enliven, with Enliven continuing as our wholly owned subsidiary and the surviving corporation of the merger, or Merger. The former Enliven securityholders immediately before the Merger, including those purchasing shares in the Enliven pre- closing financing, are expected to own approximately 84. 1 % of the aggregate number of shares of the combined company following the Merger, and our securityholders immediately before the Merger are expected to own approximately 15. 9 % of the aggregate number of shares of the combined company following the Merger, subject to certain** **uncertain** ~~assumptions~~ **undertaking and involves a substantial degree of risk.** We are devoting substantially all of our ~~time and~~ resources to **developing ELVN** ~~consummating the closing of the Merger; however, there can be no assurance that such activities will result in the consummation of the Merger or~~

that such transaction will deliver the anticipated benefits or enhance stockholder value. Any delay in completing the proposed Merger may materially and adversely affect the timing and benefits that are expected to be achieved from the proposed Merger. Certain provisions of the Merger Agreement may discourage third parties from submitting alternative acquisition proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement. The terms of the Merger Agreement prohibit each party from soliciting or engaging in discussions with third parties regarding alternative acquisition proposals, except in limited circumstances when such party' s board of directors determines in good faith after consultation with outside legal counsel that an unsolicited acquisition proposal constitutes or could reasonably be expected to lead to a superior proposal and that failure to take such action would reasonably be expected to be inconsistent with its fiduciary duties under applicable law. In addition, if the Merger Agreement is terminated by us or Enliven under certain circumstances, including because of a decision of our board of directors to accept a superior proposal, we would be required to pay Enliven a termination fee of $ 3. 0 million. This termination fee may discourage third parties from submitting alternative takeover proposals to us or our stockholders, and may cause our board of directors to be less inclined to recommend an alternative proposal. The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects. The announcement and pendency of the Merger, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects. In the event that the Merger is not completed, the announcement of the termination of the Merger Agreement may also adversely affect the trading price of our common stock and our business prospects. Failure to consummate the Merger may result in us paying a termination fee to Enliven and could harm our common stock price and our future business and operations. The Merger will not be consummated if the conditions precedent to the consummation of the transaction are not satisfied or waived, or if the Merger Agreement is terminated in accordance with its terms. If the Merger is not consummated, we are subject to the following risks: • if the Merger Agreement is terminated under certain circumstances, we will be required to pay Enliven a termination fee of $ 3. 0 million; and • the price of our common stock may decline and remain volatile. If the Merger does not close for any reason, our board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of our various assets, dissolve or liquidate our assets or seek to continue to operate our business. If we seek another strategic transaction or attempt to sell or otherwise dispose of our remaining assets, there is no assurance that we will be able to do so, that the terms would be equal to or superior to the terms of the Merger or as to the timing of such transaction. If we decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves. If we were to seek to continue our business, we would need to determine whether to acquire one or more other product candidates. We would also need to raise funds to support continued operations and re- **001** assess our workforce requirements in consideration of our reduced workforce. The exchange ratio set forth in the Merger Agreement is not adjustable based on the market price of our common stock, so the merger consideration at the closing of the Merger may have a greater or lesser value than at the time the Merger Agreement was signed. The Merger Agreement has set the exchange ratio for Enliven capital stock being converted into our common stock, and **ELVN** the exchange ratio is based on the outstanding capital stock of Enliven and our outstanding common stock, in each case immediately prior to the closing of the Merger. Applying the exchange ratio formula in the Merger Agreement, our pre- **002** Merger stockholders will own approximately 15. 9 % of the combined company and pre- Merger Enliven stockholders (including those purchasing Enliven shares in the Financing Transaction) will own approximately 84. 1 % of the combined company on a pro forma basis, based on the number of shares of our common stock expected to be issued in connection with the Merger. Under certain circumstances further described in the Merger Agreement, however, these ownership percentages may be adjusted upward or downward based on our cash level at the closing of the Merger, and as a result, either our stockholders or the Enliven stockholders could own less of the combined company than expected. Any changes in the market price of our common stock before the completion of the Merger will not affect the number of shares of our common stock issuable to Enliven' s stockholders pursuant to the Merger Agreement. Therefore, if before the completion of the Merger the market price of our common stock declines from the market price on the date of the Merger Agreement, then Enliven' s stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date of the Merger Agreement. Similarly, if before the completion of the Merger the market price of our common stock increases from the market price of our common stock on the date of the Merger Agreement, then Enliven' s stockholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the Merger Agreement. The Merger Agreement does not include a price- based termination right. If the Merger is not consummated, we may be unable to retain the services of key remaining members of our management team and, as a result, may be unable to seek or consummate another strategic transaction, properly dissolve and liquidate our assets or continue our business. If we do not successfully consummate the transaction with Enliven, our board of directors may dissolve or liquidate our assets to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such transaction or liquidation. If the Merger does not close for any reason, our board of directors may elect to, among other things, dissolve or liquidate our assets, which may include seeking protection from creditors in a bankruptcy proceeding. If we decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves. In the event of a dissolution and liquidation, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations in preparation for the consummation of the Merger. Further, the Merger Agreement contains certain termination rights for each party, and provides that, upon termination under specified

circumstances, we may be required to pay Enliven a termination fee of $ 3. 0 million, which would further decrease our available cash resources. If our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under our clinical trials; (ii) obligations under our employment, separation and retention agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of us; and (iii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of us. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of our liquidation, dissolution or winding up. Lawsuits may be filed against us and the members of our board of directors arising out of the proposed Merger, which may delay or prevent the proposed Merger. Putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against us, our board of directors, Enliven, Enliven' s board of directors and others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, and we may not be successful in defending against any such future claims. Lawsuits that may be filed against us, our board of directors, Enliven, or Enliven' s board of directors could delay or prevent the Merger, divert the attention of our management and employees from our day- to- day business and otherwise adversely affect our financial condition. Certain of our officers and directors may have interests in the proposed Merger that are different from, or in conflict with or in addition to, those of our stockholders generally. Certain officers and directors of ours may have interests in the proposed Merger that are different from the interests of our stockholders generally, including potentially, among others, the continued service as a director of the combined company, the acceleration of stock option vesting, and continued indemnification. The closing of the Merger may also result in the acceleration of vesting of options to purchase shares of our common stock held by our executive officers and directors, whether or not there is a covered termination of such officer' s employment. In addition, certain of our current directors and executive officers are expected to become directors of the surviving company upon the closing of the Merger, and all of our directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. These interests, among others, may influence our officers and directors and cause them to view the Merger differently from how our stockholders generally may view it. As a result of our decision to discontinue further investment in tovinontrine and the reductions in our workforce, we have only six full- time employees remaining as of the date of this filing. If we are unable to retain certain of our remaining employees, our ability to consummate the planned Merger may be delayed or seriously jeopardized. In April 2022, we announced workforce reductions, and current headcount has been reduced to six full- time employees as of the date of this filing. Our cash conservation activities may yield unintended consequences, such as attrition beyond the planned workforce reductions and reduced employee morale, which may cause the remaining employees to seek alternate employment. Competition among biotechnology companies for qualified employees is intense, and the ability to retain the remaining employees is critical to our ability to effectively manage our business and to consummate the planned Merger. Additional attrition could have a material adverse effect on our business and ability to consummate the Merger. In addition, as a result of the reduction in our workforce, we face an increased risk of employment litigation. Our stockholders potentially may not receive any payment on the contingent value rights and the contingent value rights may otherwise expire valueless. The Merger Agreement contemplates that, at or prior to the effective time of the Merger, we will enter into a Contingent Value Rights Agreement, or the CVR Agreement, with a rights agent pursuant to which each of our stockholders of record immediately prior to the Merger will receive one contingent value right, or a CVR, for each outstanding share of our common stock held by such stockholder on such date. Each CVR will represent the contractual right to receive payments upon the occurrence of certain events related to the Asset Sale, subject to and in accordance with the terms and conditions of, the CVR Agreement. The right of our stockholders to derive any value from the CVRs will be contingent solely upon the disposition of such assets within the time periods specified in the CVR Agreement. We may not be able to achieve successful results from the disposition of such assets as described above. If this is not achieved for any reason within the time periods specified in the CVR Agreement, no payments will be made under the CVRs, and the CVRs will expire valueless. Risks Related to Our Business Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant losses since our inception. We expect to incur operating losses for the foreseeable future and may never achieve or maintain profitability. Our net income was $ 1. 5 million for the year ended December 31, 2022 and our net loss was $ 51. 4 million for the year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of $ 146. 0 million. To date, we have financed our operations primarily through the sale of common stock and the sale of convertible preferred stock. We have historically devoted substantially all of our financial resources and efforts to research and development, including clinical trials and preclinical studies of tovinontrine. In April 2022, we made the decision to discontinue development of tovinontrine and are not currently developing product candidates. We may never generate revenues that are significant enough to achieve profitability. We are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment. If the Merger is not completed, we will reconsider our strategic alternatives, including dissolving and liquidating our assets, pursuing another

strategic transaction, or operating our business. Our future capital requirements depend on many factors, and adequate additional financing may not be available to us on acceptable terms, or at all. We expect to devote significant time and resources to the completion of the Merger. However, there can be no assurances that such activities will result in the completion of the Merger. If the Merger is not completed, we will reconsider our strategic alternatives. We consider one of the following courses of action to be the most likely alternatives if the Merger is not completed: • Dissolve and liquidate our assets. If, for any reason, the Merger does not close, our board of directors may conclude that it is in the best interest of stockholders to dissolve the company and liquidate our assets. In that event, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims. There would be no assurances as to the amount or timing of available cash remaining to distribute to stockholders after paying our obligations and setting aside funds for reserves. • Pursue another strategic transaction. We may resume the process of evaluating a potential strategic transaction in order to attempt another strategic transaction like the Merger. • Operate our business. Our board of directors may elect to seek new product candidates for development. If our board of directors elects to seek new product candidates for development, we expect that we would incur significant research and development expenses. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate any such future research and development programs or commercialization efforts and / or we could be forced to revise or abandon our current business strategy. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, any product candidates, if approved, may not achieve commercial success. Commercial revenues, if any, will not be derived unless and until we can achieve sales of products, which we do not anticipate for several years, if at all. Accordingly, if we decide to pursue any future product development efforts, we will need to obtain substantial additional funding in connection with our continuing operations. In April 2021, we entered into a sales agreement, or the Sales Agreement, with Cantor Fitzgerald & Co, LLC, as sales agent, providing for the offering, issuance and sale by us of up to an aggregate $ 75. 0 million of our common stock from time to time in " at- the- market " offerings under a shelf registration statement on Form S- 3. As of December 31, 2022, we have issued and sold 231, 291 shares of common stock under the Sales Agreement, resulting in net proceeds of $ 1. 4 million after deducting commissions and offering expenses. The extent to which we utilize the Sales Agreement as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, general market conditions and the extent to which we are able to secure funds from other sources. Accordingly, we may not be able to sell shares under the Sales Agreement at prices or amounts that we deem acceptable, and there can be no assurance that we will sell any further common stock pursuant to the Sales Agreement. As of December 31, 2022, we had cash and cash equivalents of $ 88. 2 million. Our future capital requirements will depend on many factors, including: • whether we complete the Merger with Enliven and, if the Merger is completed, the capital requirements of the combined company; • whether we realize the anticipated cost savings in connection with our April 2022 workforce reduction; • if we decide to pursue any future product development efforts, our ability to bring any such product candidate through preclinical and clinical development, and the timing and scope of these research and development activities **,** ; • the costs of obtaining clinical **trial activities** and commercial supplies of any product candidates we may develop; • our ability to successfully commercialize any product candidates we may develop; • the manufacturing , **business planning** selling and marketing costs associated with any product candidates we may develop , including the cost and timing of establishing our sales and marketing capabilities; • the amount and timing of sales and other revenues from any product candidates we may develop, including the sales price and the availability of coverage and adequate third- party reimbursement; • the time and cost necessary to respond to technological and market developments; • the extent to which we may acquire or in- license product candidates and technologies; • the impact of the COVID- 19 pandemic and our response to it; • the costs of maintaining , expanding and protecting our intellectual property portfolio ; **, hiring personnel, raising capital,** and • **providing general and administrative support for** the **these** costs associated **operations. We are currently evaluating ELVN- 001 in a Phase 1 clinical trial in adults** with **CML,** operating as a public company and maintaining compliance **we are evaluating ELVN- 002 in a Phase 1 clinical trial in adults** with exchange listing and SEC requirements **solid tumors with HER2 alterations** . We may seek **filed an IND and received FDA clearance in the first quarter of 2024 for an** additional financing to achieve **Phase 1 trial evaluating ELVN- 002 in combination with trastuzumab with and without chemotherapy in MBC and CRC with overexpressed** our **or** business objectives **amplified HER2** . Adequate additional financing may **We have nominated a development candidate for our third program and have completed IND- enabling studies for that product candidate. We have** not **initiated** be available to us on acceptable terms, or at all. In addition, we may seek additional capital when market conditions are favorable, or for strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis or on terms acceptable to us, we may be required to delay, limit, reduce or terminate any preclinical studies, clinical trials or other activities for any **other** product candidates **candidate** under development at such time, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize any product candidates. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of the sale of one or more of our product candidates or other assets, equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our

assets, making capital expenditures or declaring dividends. If we raise additional funds through the sale of one or more of our product candidates or other assets, collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed or on terms acceptable to us, we may be required to delay, limit, reduce or terminate any product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability. We commenced activities in 2016 and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, and undertaking preclinical studies and clinical trials of our product candidates . We have not yet demonstrated our ability to **complete** successfully develop any product candidate **clinical trials** , obtain regulatory **marketing** approvals, manufacture a commercial - scale product or arrange for a third - party to do so on our behalf **, develop a companion diagnostic** , or conduct sales and marketing activities necessary for successful product commercialization. Consequently **As a result** , any **it may be more difficult for investors to accurately** predictions ---- **predict** about our future **likelihood of** success or **and** viability **than it** may not be as accurate as they could be if we had a longer operating history **. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early- stage biopharmaceutical companies in rapidly evolving fields. We also expect that, as we advance** or **our product candidates, we will need to transition from** a history **company with a research and development focus to a company capable** of **supporting commercial activities. We have not yet demonstrated an ability to** successfully **overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer. We have incurred significant net losses, have not generated any revenue to date and have financed our operations principally through private placements of our preferred stock. Our net loss was $ 71. 6 million for the year ended December 31, 2023. As of December 31, 2023, we had an accumulated deficit of $ 154. 4 million. We are still in the very early stages of** developing **development of our product candidates and have not yet completed any clinical trials. As a result, we expect that it will be many years, if ever, before we have commercialized a product and can generate revenue from product sales. Even if we succeed in receiving marketing approval for** and commercializing **one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential** products. We expect our financial condition **to continue to incur significant expenses** and **increasing** operating results to **losses for the foreseeable future. The net losses we incur may** fluctuate significantly from quarter **to quarter such that a period** - to- quarter **period comparison of our results of operations may not be a good indication of our future performance. 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** year **adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock. We have never generated revenue from product sales and may never achieve or maintain profitability. We have never generated any revenue from commercial product sales. To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities can include completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products that are approved and satisfying any post** - to- year due to a variety of factors, **marketing requirements. We do not anticipate generating any revenue from product sales for** many **years** of which are beyond our control. Each of our announcements regarding the termination of development of tovinontrine and the related workforce reduction , **if ever** the Asset Sale, and the signing of the Merger Agreement are likely to further increase the variability of our operating results in the coming quarters as compared to prior quarters. Accordingly, our stockholders should not rely upon the results of any quarterly or annual periods as indications of future operating performance . Our ability to use our net operating losses, **generate revenue and achieve profitability depends significantly on** or **our** NOLs **ability to achieve several objectives** , **including: • successful** and **timely completion of clinical development of ELVN- 001, ELVN- 002, including development of any combination drug products, and any other product candidates, preclinical and clinical development of other** research **programs** and **any other future programs, and / or** development tax credit carryforwards to offset future taxable income may be subject to certain limitations. We have a history of **a companion diagnostic, if required for regulatory approval** cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future ; thus, we do not know whether **• establishing and maintaining relationships with CROs and clinical sites** or **for the clinical** when we will generate taxable income necessary to utilize our NOLs or research and development tax credit carryforwards. As of **ELVN** December 31, 2022, we had federal NOLs of $ 123. 5 million and state NOLs of $ 113. 8 million. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three year period, is subject to limitations on its ability to utilize its pre - change NOLs **001, ELVN- 002** and research and development tax credit carryforwards to offset future taxable income. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the **other programs; • timely receipt** past, including as a result of **marketing approvals from applicable** our public offering of shares of common stock in July 2021, and the Merger, if completed, will result in such an ownership change. We may experience additional ownership changes in the future as a result of subsequent changes in our stock ownership (which may be outside our control). As a result, if, and to the extent that, we earn

net taxable income, our ability to use our pre- change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations. There is also a risk that due to regulatory **authorities** changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. As described below in " Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition, " the Tax Cuts and Jobs Act, or the TCJA, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, includes changes to U. S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. Additionally, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes. Our business and operations have been and may continue to be adversely affected by the COVID- 19 pandemic, as may the operations of our third- party service providers. The COVID- 19 pandemic and government measures taken in response to it have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen. The future progression of the pandemic and its effects on our business and operations are uncertain. The COVID- 19 pandemic has affected our operations to date, including by causing delays in the conduct of clinical trials. While we have not experienced any significant disruptions with the third parties on which we rely, the COVID- 19 pandemic, or the spread of another infectious disease, could also negatively affect the operations of our third- party manufacturers, which could result in disruptions in the supply of any product candidates **for which** we may **successfully complete clinical** develop **development ; •** . In addition, many of our employees are currently working remotely. The COVID- 19 pandemic continues to rapidly evolve and could more significantly impact our operations in the future. Although we are not currently developing any - **an efficient and scalable manufacturing process for our** product candidates, if we decide to pursue any future product development efforts, the COVID- 19 pandemic may adversely affect our development activities, including **obtaining finished products that are appropriately packaged for sale** our ability to recruit and retain patients in clinical trials, as a result of many factors, including: • diversion of healthcare resources away from the conduct of our clinical trials in order to focus on pandemic concerns, including the availability of necessary materials, the attention of physicians serving as clinical trial investigators, access to hospitals serving as clinical trial sites, availability of hospital staff supporting the conduct of clinical trials and the reluctance of patients enrolled in clinical trials to visit clinical trial sites ; • potential interruptions **establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate products and services,** in global shipping affecting the transport of **both amount and quality, to support our combination studies,** clinical trial materials, such as investigational drug **development and meet the market demand for our** product **candidates** , **if approved** patient samples and other supplies used in clinical trials ; • **successful commercial launch following** the impact of further limitations on travel that could interrupt key clinical trial activities, such as clinical trial site initiations and monitoring activities, travel by our employees, contractors or patients to clinical trial sites, or the ability of employees at any **marketing approval, including the development** of **a commercial infrastructure, whether in- house** our - **or** contract manufacturers **with one** or **more collaborators** contract research organizations, or CROs, to report to work, any of which could delay or adversely impact the conduct or progress of clinical trials, and limit the amount of clinical data we will be able to report ; • **a continued acceptable safety profile following** any future interruption of, or delays in receiving, supplies of clinical trial material from our contract manufacturing organizations, or CMOs, due to staffing shortages, production slowdowns or stoppages or disruptions in delivery systems; and • availability of future capacity at contract manufacturers to produce sufficient drug substance and drug product to meet forecasted clinical trial demand if any of these manufacturers elect or are required to divert attention or resources to the manufacture of other pharmaceutical products. Additionally, while the potential economic impact and the duration of the COVID- 19 pandemic is difficult to assess or predict, any impact of the COVID- 19 pandemic on the global financial markets **marketing approval** may reduce our ability to access capital, which could negatively impact our short- term and long- term liquidity. While we expect the impacts of COVID- 19 will continue to have some adverse effect on our business, the extent to which COVID- 19 impacts our operations will depend on future developments, which remain uncertain and cannot be predicted with confidence, including the duration of the pandemic, new information which may emerge concerning the severity of COVID- 19 and variants of COVID- 19, the actions to contain COVID- 19 or treat its impact and changes in government spending or priorities, among others. The COVID- 19 pandemic is a widespread health crisis that continues to adversely affect the global economy and financial markets of many countries, and any economic downturn could also affect our operations, our ability to raise additional funds through public offerings and the volatility of our stock price and trading in our stock. Even after the COVID- 19 pandemic has subsided, we may continue to experience adverse impacts to our business as a result of any economic recession or depression that has occurred or may occur in the future. Risks Related to the Discovery, Development and Commercialization of Our Product Candidates We do not currently have any product candidates in active development. Future clinical trials of our product candidates, if any, may not be successful. If we are unable to successfully develop or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed. As discussed above, if the Merger is not completed, we will reconsider our strategic alternatives, including dissolving and liquidating our assets, pursuing another strategic transaction, or operating our business. If our board of directors elects to seek new product candidates for development, we will face the risks related to discovery, development and commercialization of our product candidates set forth in this section, in addition to other risks described in this Risk Factors section. Although we have invested a significant portion of our efforts and financial resources in the development of our product candidates, we are not currently actively developing any of our product candidates. If we decide to pursue any future product development efforts, our ability to generate meaningful product revenues will depend heavily on the successful development of our product candidates. To the extent that we pursue any

development efforts in the future, our success will depend on several factors, including the following: • successfully completing clinical trials; • acceptance by the FDA or other regulatory agencies of regulatory filings; • expanding and maintaining a workforce of experienced clinical- stage drug development professionals and others to continue to develop our product candidates; • **commercial acceptance of** obtaining and maintaining intellectual property protection and regulatory exclusivity for our product candidates ; • making arrangements with third- party manufacturers for, or establishing, commercial manufacturing capabilities; • establishing sales, marketing and distribution capabilities and successfully launching commercial sales, if and when approved, whether alone or in collaboration with others; • acceptance of our product candidates, if and when approved, by patients, the medical community and third- party payors; • effectively competing with **satisfying any required post- marketing approval commitments to applicable regulatory authorities; • identifying, assessing and developing new product candidates; • obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in** other -- **the** existing therapies **United States and internationally; • defending against third- party interference or infringement claims** , if any; • **entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates; •** obtaining and maintaining coverage , adequate pricing and adequate reimbursement from **by** third- party payors , including government payors **for our product candidates** ; • patients' willingness to pay out- of- pocket **addressing any competing therapies and technological and market developments; and • attracting, hiring and retaining qualified personnel. We may never be successful in achieving our objectives and, even if we do, we may never generate revenue that is significant** for -- **or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations. Any changes in the manufacturing process, suppliers, or facilities will require further comparability analysis and approval by the FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy. If we pursue alternative tablet formulations or other changes to any of** our product candidates **in , the FDA and** the **other** absence of coverage and / or adequate reimbursement from third- party payors; and • maintaining a continued acceptable safety profile following receipt of any regulatory **authorities may require additional studies** approvals. Many of these factors are beyond our control , including **bridging studies, which may significantly delay our** clinical outcomes, the **trial timelines and** regulatory review process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive marketing approval for **. We have not submitted** and **an NDA** successfully commercialize any product candidates we seek to develop, or if we experience delays as a result of any of these factors or otherwise, we may need to spend significant additional time and resources to identify additional product candidates, advance them **the FDA** through preclinical and clinical development and apply for **or similar approval filings to a comparable foreign** regulatory **authority** approvals, which would adversely affect our business, prospects, financial condition and results of operations. Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates. The risk of failure for any product candidates **candidate** we may develop **. An NDA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the product candidate** is **safe and effective** high. It is impossible to predict when or **for** if any **each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product candidate. We cannot be certain that our current or future** product candidates we may develop will **be successful** prove effective or safe in humans **clinical trials** or will receive regulatory approval. **If we do not receive regulatory approvals for current or future product candidates or companion diagnostics, as applicable, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we receive regulatory approval and have commercial rights, the availability of competitive therapies and whether there are sufficient levels of reimbursement and adoption by physicians. Risks Related to the Discovery, Development and Commercialization of Our Product Candidates We are very early in our development efforts. In addition, we are substantially dependent on ELVN- 001 and ELVN- 002. If we are unable to advance ELVN- 001 or ELVN- 002 through clinical development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed. We are very early in our development efforts. We are currently evaluating ELVN- 001 in a Phase 1 clinical trial in adults with CML, and we are evaluating ELVN- 002 in a Phase 1 clinical trial in adults with solid tumors with HER2 alterations. We filed an IND and received FDA clearance in the first quarter of 2024 for an additional Phase 1 trial evaluating ELVN- 002 in combination with trastuzumab with and without chemotherapy in MBC and CRC with overexpressed or amplified HER2. We have nominated a development candidate for our third program and have completed IND- enabling studies for that product candidate. We have not initiated clinical trials for any other product candidate and we may experience unexpected or adverse results in the future. We will be required to demonstrate thorough, adequate and well- controlled clinical trials that our product candidates are safe and effective, with a favorable benefit- risk profile, for use in their target indications** Before **before** obtaining **we can seek regulatory approvals for their commercial sale. Our initial clinical trials will begin with relatively small cohorts before expanding in size in subsequent cohorts. If safety issues arise in an early cohort, we may be delayed or prevented from subsequently expanding into larger trial cohorts. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical**

development and eventual commercialization of ELVN- 001 and ELVN- 002, including the development of any combination drug products or companion diagnostics. We are not permitted to market or promote any product candidate before it receives marketing approval from **the FDA, EMA or any comparable foreign** regulatory authorities ~~for the sale of any product candidate~~ ~~, we must complete preclinical development~~ and ~~then conduct extensive~~ **we may never receive such marketing approvals. We will be required to demonstrate with substantial evidence through well- controlled** clinical trials ~~to demonstrate the safety and efficacy of such product candidate in humans. Clinical trials may fail to demonstrate~~ that ~~any product candidates we may develop are safe for humans and effective for indicated uses. For example, in April 2022 we discontinued development of tovinontrine in SCD and β- thalassemia based on the results of interim analyses of our Ardent and Forte Phase 2b clinical trial of tovinontrine in patients with SCD and β- thalassemia. Even if clinical trials are successful, changes in marketing approval policies during the development period, changes in or~~ **our** ~~the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned investigational new drug applications, or INDs, and other regulatory filings in the United States and abroad. We cannot be certain of the timely completion or outcome of our preclinical testing and studies, and cannot predict if the FDA or other regulatory agencies will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of any product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Furthermore,~~ product candidates are ~~subject to continued~~ **safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale.** ~~preclinical~~ **Preclinical and** ~~safety studies, which may be conducted concurrent with our~~ clinical testing **is** ~~. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials. Clinical trials are~~ expensive ~~, difficult to design~~ and ~~implement,~~ can take many years to complete **,** and ~~are~~ **our outcome is inherently** uncertain ~~as to outcome~~ . ~~We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. A failure~~ **Failure** ~~of one or more clinical trials~~ can occur at any **time during the preclinical study and clinical trial processes, and, because our product candidates are in early** ~~stage~~ **stages** of ~~testing~~ **developments** , ~~which~~ **there is a high risk of failure and we** may **never succeed in developing marketable products. The** ~~result~~ **results** ~~from a multitude~~ of **preclinical studies may** ~~factors, including, but~~ not **be predictive of the** ~~limited to, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. We may experience numerous unforeseen events during, or as a result~~ **results** of ~~,~~ clinical trials **of** ~~that could delay or~~ **our** ~~prevent our ability to receive marketing approval or commercialize any~~ product candidates **. Moreover** ~~we may develop , including: • regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; • regulators may decide~~ the ~~design~~ **results** of ~~our~~ **early** clinical trials **may** ~~is flawed, for example if our trial protocol does~~ not **be predictive** ~~evaluate treatment effects in trial subjects for a sufficient length~~ of **the** ~~time; • clinical trials of any product candidates we may develop may produce negative or inconclusive~~ results ~~, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities would consider likely to predict clinical benefit; • the number of patients required for clinical trials of any product candidates we may develop may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we may decide, or regulators or IRBs may require us, to suspend or terminate clinical trials of any product candidates we may develop for various reasons, including non- compliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; • regulators or IRBs may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post- marketing testing requirements to maintain regulatory approval; • regulators may revise the requirements for approving any product candidates we may develop, or such requirements may not be as we anticipate; • the cost of clinical trials of any product candidates we may develop may be greater than we anticipate; • the supply or quality of any product candidates we may develop or other materials necessary to conduct clinical trials of such product candidates may be insufficient or inadequate; • any product candidates we may develop may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the trials; and • regulators may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a risk evaluation and mitigation strategy, or REMS. If we are required to conduct additional clinical trials or other testing beyond those that we contemplate, if we are unable to successfully complete clinical trials or other testing of any product candidates we may develop, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • be delayed in obtaining marketing approval for any product candidates; • not obtain marketing approval at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling or a REMS that includes significant use or distribution restrictions or safety warnings; • be subject to additional post- marketing testing requirements; or • have the product removed from the market after obtaining marketing approval. Our product development costs will also increase if we experience delays in testing or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also change the design or protocol of one or more of our~~

~~clinical trials, including to add additional patients or arms, which could result in increased costs and expenses and / or delays. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize any product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize any product candidates and may harm our business and results of operations. The outcome of preclinical studies and earlier- stage clinical trials may not be predictive of the success~~ of later- stage clinical trials. ~~The outcome of~~ **Although product candidates may demonstrate promising results in** preclinical ~~testing~~ **studies** and **early** ~~earlier- stage~~ clinical trials **, they** may not **prove to** be **safe or effective in subsequent** ~~predictive of the success of later- stage~~ clinical trials. ~~Any~~ **Favorable results from certain animal studies may not accurately predict the results of other animal studies or of human trials, due to the inherent biologic differences in species, the differences between testing conditions in animal studies and human trials, and the particular goals, purposes, and designs of the relevant studies and trials. There is typically an extremely high rate of attrition from the failure of** product candidates ~~we may develop~~ **proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials** may fail to show the desired safety and efficacy **profile** ~~in clinical development~~ despite ~~positive results in~~ **having progressed through** preclinical studies **and** ~~or having successfully advanced through~~ initial clinical trials. **Likewise** ~~For example~~ , **early, smaller** ~~data from the interim analysis in our Ardent Phase 2b clinical trial of tovinontrine in SCD did not replicate our previously observed positive vaso- scale occlusive crisis data from our Phase 2a and OLE~~ clinical trials **may not be predictive** of **eventual safety** ~~tovinontrine in SCD. Similarly, data from the interim analysis in our~~ - **or effectiveness** ~~Forte Phase 2b clinical trial of tovinontrine~~ in ~~β~~ **large - scale pivotal** ~~thalassemia showed no meaningful benefit from treatment with tovinontrine as compared to placebo, despite previous positive preclinical data for tovinontrine in β- thalassemia. In April 2022, we discontinued the Ardent and Forte trials as well as the further development of tovinontrine in SCD and β- thalassemia. Several companies in the pharmaceutical and biotechnology industries have suffered similar setbacks in late- stage~~ clinical trials ~~even after achieving promising results in preclinical testing and earlier- stage clinical trials, and we cannot be certain that we will not face similar setbacks in any future product development we may pursue~~ . Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their **drugs. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as** products. ~~Furthermore~~ **The development of our product candidates and our stock price may also be impacted by inferences** , **whether correct or not, that are drawn between** the **success or** failure of **preclinical studies or clinical trials of our competitors or other companies in the biopharmaceutical industry, in addition to our own preclinical studies and clinical trials. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. Any preclinical studies or clinical trials that we conduct may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and 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 prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and 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. We do not know whether any preclinical studies or clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates. We are currently focusing our resources and efforts on ELVN- 001, ELVN- 002 and advancing our other research programs. Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forgo or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development activities for ELVN- 001, ELVN- 002 and our other research programs, including the development of any combination drug products or companion diagnostics, may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for ELVN- 001, ELVN- 002 and our other research programs, or the product candidates we are currently developing in these programs, we may relinquish valuable rights to our product candidates or programs through collaborations, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or program. Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates including ELVN- 001, ELVN- 002 and product candidates from our**

research programs, including the development of any combination drug products or companion diagnostics. A product candidate can unexpectedly fail at any stage of development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate. The success of ELVN- 001, ELVN- 002 and other product candidates we may develop will depend on many factors, including the following: • successful and timely completion of preclinical studies, including generating sufficient data to support the initiation or continuation of preclinical studies and clinical trials, including data that demonstrates improved efficacy, safety, and patient convenience compared to our competitors' products; • successful development of combination drug products; • successful development of a companion diagnostic, if required for regulatory approval of any product; • obtaining IRB approval at each clinical trial site; • approval of INDs for our planned clinical trials and future clinical trials; • the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; • successful initiation and completion of clinical trials; • successful and timely patient selection and enrollment in and completion of clinical trials; • maintaining and establishing relationships with CROs and clinical sites for the clinical development of our product candidates both in the United States and internationally; • the frequency and severity of adverse events in clinical trials; • demonstrating efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval; • the timely receipt of marketing approvals from applicable regulatory authorities; • the extent of any required post- marketing approval commitments to applicable regulatory authorities; • the maintenance of existing or the establishment of new supply arrangements with third- party drug product suppliers and manufacturers for clinical development, combination studies, and, if approved, commercialization of our product candidates; • obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally; • the protection of our rights in our intellectual property portfolio; • the successful launch of commercial sales following any marketing approval; • a continued acceptable safety profile following any marketing approval; • commercial acceptance by patients, the medical community and third- party payors; and • our ability to compete with other therapies. We do not have complete control over many of these factors, including certain aspects of preclinical and clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. 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 any product candidates from our lead programs, which would materially harm our business. If we do not receive marketing approvals for such product candidates, we may not be able to continue our operations. Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of our product candidates in our current pipeline, we expect to continue to innovate and potentially expand our portfolio. Research programs to identify product candidates may require substantial additional technical, financial and human resources, whether or not any new potential product candidates are ultimately identified. Our success may depend in part upon our ability to identify, select and develop promising product candidates and therapeutics. We may expend resources and ultimately fail to discover and generate additional product candidates suitable for further development. Even if we successfully advance any product candidates into preclinical and clinical development, their success will be subject to all of the preclinical, clinical, regulatory and commercial risks described elsewhere in this section. All product candidates are prone to risks of failure typical of biotechnology product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics indicating that it is unlikely to receive approval by the FDA, the EMA and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize ELVN- 001 or ELVN- 002, or successfully identify, develop and commercialize new product candidates, our business, prospects, financial condition and results of operations could be adversely affected. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. We do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any jurisdiction. Our product candidates may fail to demonstrate efficacy in humans, and particularly across tumor types. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk we face is the possibility that none of our product candidates under development will successfully gain market approval from the FDA, EMA or other comparable foreign regulatory authorities, resulting in us being unable to derive any commercial revenue from them after investing significant amounts of capital in their development. If the results of our ongoing or future preclinical studies and future clinical trials are inconclusive with respect to the safety and 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 prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial

protocols, differences in size and type of patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. As is typically the case with oncology drugs, there have been adverse events associated with the use of our product candidates and there could be adverse events caused by our product candidates in the future. Results of our future trials could reveal a high and unacceptable severity and prevalence of side effects, toxicities or adverse events when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences. For example, our trials could be suspended or terminated and the FDA, EMA or comparable foreign regulatory authorities or an IRB could order us to suspend clinical trials, cease further development of or deny approval of our product candidates for any or all targeted indications. This could require us to interrupt, delay or abandon their development or limit 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. Treatment- related side effects have resulted, and could result in additional patients dropping out of our trials, and could affect patient recruitment and the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly. In addition, our product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, our product candidates may be studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients to be enrolled in our future clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials for non- treatment related reasons. Further, our product candidates could cause undesirable side effects in clinical trials related to on- target toxicity. If on- target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to abandon our development or limit development to more narrow indications or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. Many compounds that initially showed promise in early- stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to the tolerability of our products versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label including " black box " warnings, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early- stage clinical trials. Our product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing. Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. For example, the FDA' s Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in early clinical settings, among other goals. How the FDA plans to implement these goals and their impact on specific clinical programs and the industry are unclear. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product candidate' s commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate **, ~~to demonstrate safety~~** and **~~efficacy in~~ it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and / or regulatory approval may be delayed for reasons beyond our control. Applications for our product candidates could fail to receive regulatory approval for ~~any~~ many reasons, including the following: • the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials; • the FDA,**

EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use; • the population studied in the clinical trial ~~could negatively impact~~ **may not be sufficiently broad or representative to assure efficacy and safety in** the ~~perception of any~~ **full population for which we seek approval; • the FDA, EMA or** other **comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that a product candidate' s risk-benefit ratio for our proposed indication is acceptable; • the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; • the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests required for our** product candidates **; and •** ~~then~~ **the approval policies** ~~under development and / or cause~~ **regulations of** the FDA **, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering** ~~or~~ **our clinical data insufficient for approval. This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in us failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third- party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. In addition, the FDA and** other regulatory authorities ~~to require~~ **may change their policies, issue** additional **regulations or revise** ~~testing~~ **existing** ~~before approving~~ **regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain** any **marketing authorizations we may have obtained. Additionally, if the Supreme Court reverses or curtails the Chevron doctrine, which gives deference to regulatory agencies in litigation against the FDA and** other ~~such~~ **agencies, more companies may bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA' s authority, lead to uncertainties in the industry, and disrupt the FDA' s normal operations, which could delay the FDA' s review of our marketing applications. If we are required by the FDA or comparable regulatory authorities to obtain approval of a companion diagnostic test in connection with approval of any of our** product candidates **or a group of therapeutic products, and we do not obtain or we face delays in obtaining approval of a diagnostic test, we will not be able to commercialize the product candidate and our ability to generate revenue will be materially impaired. We are a precision oncology company** . If we ~~decide~~ **are required by the FDA or comparable regulatory authorities** to ~~pursue~~ **obtain approval of a companion diagnostic test in connection with approval of** any **of our product candidates, such companion diagnostic test would be used during our more advanced phase clinical trials as well as in connection with the commercialization of our product candidates. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved. The approval of a companion diagnostic as part of the therapeutic product' s labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genomic alteration that the companion diagnostic was developed to detect. The FDA or a comparable regulatory authority may require approval of a companion diagnostic for any of our product candidates, whether before or concurrently with approval of the product candidate. We and / or** future **collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third- party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of our related** product **candidates. Further, in April 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. In June 2023, the FDA announced a new voluntary pilot program through which drug manufactures can provide to the FDA the diagnostic test performance information used to enroll patients into clinical trials for drug approval. Based on assessment of the performance information, the FDA will publish the minimum performance characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug to help laboratories identify specific biomarkers for their** development **of laboratory- developed tests (" LDTs") and to ensure more consistent performance of these tests for drug selection and improved cancer patient care. In September 2023, the FDA issued a proposed rule that, if finalized, will amend the FDA' s regulations to make explicit that in vitro diagnostics (" IVDs ") are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory, and will phase out its enforcement discretion for LDTs. These future issuances from the FDA and other regulatory developments in this area may impact our companion diagnostic development and strategy in connection with our product candidates and result in delays in regulatory approval. We may be required to conduct additional clinical trials to support a broader claim. Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that may require such tests. If**

we enter into such collaborative agreements, we will be dependent on the sustained cooperation and ~~efforts~~ effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity / specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of ~~or~~ our ~~difficulties in~~ product candidates may be adversely affected, our product candidates may not obtain marketing approval, and we may not realize the ~~enrollment~~ full commercial potential of ~~patients~~ any of our product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of product candidates or our relationship with such diagnostic company may otherwise terminate. In addition, such diagnostic company may not agree to commercialize the companion diagnostic test in all the countries in which we may sell our product candidates. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and / or delay the development or commercialization of our product candidates. We have limited experience as a company in designing and conducting clinical trials ~~, our receipt of necessary regulatory approvals could be delayed or prevented~~ . ~~Although we~~ The design and implementation of clinical trials is a complex process. We have limited experience as a company in designing and conducting clinical trials. We are currently evaluating ELVN- 001 in a Phase 1 clinical trial in adults with CML, and we are evaluating ELVN- 002 in a Phase 1 clinical trial in adults with solid tumors with HER2 alterations. We filed an IND and received FDA clearance in the first quarter of 2024 for an additional Phase 1 trial evaluating ELVN- 002 in combination with trastuzumab with and without chemotherapy in MBC and CRC with overexpressed or amplified HER2. We have nominated a development candidate for our third program and have completed IND- enabling studies for that product candidate. However, we have not initiated ~~currently developing our product candidates, if we decide to pursue any future product development efforts, identifying and qualifying patients to participate in~~ clinical trials for any other product ~~candidates~~ candidate and we may experience unexpected ~~develop will be critical to our~~ or ~~success~~ adverse results in the future . In part because ~~Successful and timely completion~~ of this lack of experience as a company and our limited infrastructure, we cannot be certain that our ongoing and planned preclinical studies and clinical trials will be completed on time, that we will successfully or cost-effectively design and implement clinical trials that achieve the desired clinical endpoints efficiently, or at all. Large-scale clinical trials would require significant additional financial and management resources and reliance on CROs and consultants. Relying on third- party clinical investigators, CROs and consultants may force us to encounter delays that ~~we enroll a~~ are outside of our control. We may be unable to identify and contract with sufficient investigators, CROs and consultants on a timely basis or at all. There can be no assurance that we will be able to negotiate and enter into any necessary services agreement with CROs on terms that are acceptable to it on a timely basis or at all. Any delays in the commencement or completion, or termination or suspension of our planned or future clinical trials could result in increased costs, delay or limit our ability to generate revenue and adversely affect our commercial prospects. We may not be able to file INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA, EMA or other comparable foreign regulatory authorities may not permit us to proceed. Before we can initiate clinical trials of a product candidate in any indication, we must submit the results of preclinical studies to the FDA, EMA or other comparable foreign regulatory authorities along with other information, including information about the product candidate' s chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission under which we must receive authorization to proceed with clinical development. Although we have received clearance of the IND for ELVN- 001 and ELVN- 002, the FDA, EMA or other comparable foreign regulatory authorities may require us to conduct additional studies before they allow us to initiate additional clinical trials or at any time during clinical testing, clinical trial authorization or comparable application, which may lead to additional delays and increase the costs of our preclinical development programs. Before obtaining marketing approval from the FDA of ELVN- 001, ELVN- 002 or any other programs, we must conduct extensive clinical trials to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by our CROs and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. We could encounter delays because we may need to relocate our corporate headquarters, which includes office and laboratory space. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase. We may not be able to file INDs for future product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND enabling studies. Moreover, we cannot be sure that submission of an

IND, such as the IND that was filed in the fourth quarter of 2023 for the evaluation of ELVN- 002 in combination with trastuzumab, will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that it will not change its requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our planned clinical trials may prevent us from initiating or completing our clinical trials or commercializing our product candidates on a timely basis, if at all. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or independent ethics committees of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or foreign regulatory authorities. Such authorities may impose such a suspension or termination 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 foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse events, failure to demonstrate a benefit from using a pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. For example, the Clinical Trials Regulation EU No 536 / 2014 entered into application on January 31, 2022, which aims to harmonize and streamline clinical trial authorization, simplify adverse event reporting procedures, and increase clinical trial transparency. Changes to regulatory requirements or the implementation of new requirements can increase the costs of compliance and expose us to great liabilities. Amendments may require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. From time to time, certain of our current or future scientific advisors or consultants who receive compensation from us may become investigators for our future clinical trials. Under certain circumstances, we may be required to report some of these relationships to the FDA. Although we expect any such relationships to be within the FDA' s guidelines, the FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates. If we experience delays in the completion of, or termination of, any clinical trial of any product candidate, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition, results of operations and prospects significantly. Interim, topline and preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials. These interim updates are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report responses in certain** patients ~~who~~ **that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow- up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline 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, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock. In addition, the information we choose to publicly disclose regarding a particular study or** trial ~~until its~~ **is typically selected from a more extensive amount of available information. Investors 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,** ~~conclusion~~ **conclusions , views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. If we experience delays or difficulties in the enrollment or maintenance of participants that meet the protocol criteria in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented** . We may not be able to initiate or continue clinical trials for ~~any~~ **our** product candidates ~~we may develop~~ if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials **to such trial' s conclusion** as required by the FDA **, EMA** or ~~similar~~ **other comparable foreign**

regulatory authorities ~~outside of the United States. We may not be able to identify, recruit, and enroll a sufficient number of patients to complete clinical trials of any product candidate we may develop because of the perceived risks and benefits of such product candidate, the availability of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective subjects and the subject referral practices of physicians, among other factors~~ . Patient enrollment is **a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited, and we have experienced minor delays in enrollment. Because there are effective, approved drugs and / or ongoing clinical trials being conducted for CML and for solid tumors with HER2 alterations, it may make it difficult for us to enroll patients in our trials for the same indications. For example, CML patient enrollment could have been and will likely be** affected by ~~a variety~~ **the recent approval** of **asciminib as well as our competitors that have ongoing clinical trials for programs that are under development for the same indications as our product candidates because patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Similarly, patient enrollment for our clinical trials directed to solid tumors with HER2 alterations may be impacted by competing therapeutics approved for NSCLC, MBC or CRC or for tumors with the same genetic mutation as the indications we may pursue for our product candidates, as well as clinical trials of other investigational products that may compete with our trials. Additionally, the CML patient population is relatively small and certain clinical trials for future product candidates may be focused on indications with relatively small patient populations, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate. In our ELVN- 001 and ELVN- 002 programs, we utilize genomic profiling of patients' tumors to identify suitable patients for recruitment into our clinical trials. We cannot be certain (1) how many patients will have the requisite alterations for inclusion in our clinical trials, (2) that the number of patients enrolled in each program will suffice for regulatory approval or (3) whether each specific BCR- ABL or HER2 mutation will be included in the approved drug label. If our strategies for patient identification and enrollment prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for our product candidates. Patient enrollment for our current or any future clinical trials has been and may continue to be affected by** other factors, including: • **size** ~~the prevalence~~ and **nature of the patient population; •** severity of the disease under investigation; • **availability and efficacy of approved drugs for** the **disease under investigation; • patient** eligibility criteria for the trial in question **as defined in the protocol, including biomarker- driven identification and / or certain highly specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker- driven patient eligibility criteria** ; • ~~the~~ perceived risks and benefits of the product candidate under ~~trial~~ **study** ; • **clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to** ~~the~~ **other** ~~requirements of~~ **available therapies, including any new products that may be approved or** ~~the~~ **other** ~~trial protocols~~ **product candidates being investigated for the indications we are investigating** ; • **clinicians' willingness to screen** ~~the~~ **their patients** ~~availability of existing commercially- available treatments~~ for ~~the indications~~ **biomarkers to indicate which patients may be eligible** for **enrollment in our** ~~which we are conducting~~ clinical trials; • ~~the ability to recruit clinical trial investigators with the appropriate competencies and experience; • efforts to facilitate timely enrollment in clinical trials; • the~~ patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; • ~~the~~ **treatment of patients at local facilities rather than central facilities; •** proximity and availability of clinical trial sites for prospective patients; **and** • the ~~conduct of~~ **risk that patients enrolled in** clinical trials ~~by~~ **will drop out of the trials before** ~~competitors~~ **completion** ~~for~~ **or, because** ~~product candidates that treat the~~ **they** ~~same indications as any product candidates we~~ may **be late** ~~develop; • the ability to identify specific patient populations for biomarker~~ **stage cancer** ~~defined trial cohort (s); and • the cost to, or lack of adequate compensation for, prospective~~ patients **, will not survive the full terms of the clinical trials** . Our inability to ~~locate and~~ enroll a sufficient number of patients for our clinical trials would result in significant delays ~~, could~~ **or may** require us to abandon one or more clinical trials altogether ~~and could delay or prevent our receipt of necessary regulatory approvals~~ . Enrollment delays in our clinical trials may result in increased development costs for ~~any~~ **our** product candidates **and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if** we **are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow- up periods. We face substantial competition which may result in others discovering, developing or commercializing products before or more successfully than we do. The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. In particular, precision oncology is a very competitive space and we have chosen to prioritize addressing well- validated biological targets, and therefore we expect to face competition from existing products and products in development for each of our product candidates. While we believe that our technology, the expertise of our team, and our development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from** ~~may~~ **many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully** develop **establish collaborative arrangements for research** ~~in obtaining approval from the FDA~~ , **development** ~~EMA or other comparable foreign regulatory authorities or in discovering~~ , ~~developing~~ **manufacturing** and ~~commercializing~~ **commercialization** ~~product candidates in our field before we do~~ .Our commercial ~~potential~~ **opportunity** could be reduced or eliminated if our competitors develop and commercialize products that are safer ~~or ,~~ more effective,have fewer or less severe side effects, ~~and~~ are more convenient or **are** less expensive than **any** products that we may develop.Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we ~~can~~ **may obtain approval for ours** ,which could result in our competitors establishing a strong market position before we are able to enter the market **.In addition,our ability to compete may be affected in many cases by insurers** or ~~could otherwise make~~ , which would **have** ~~cause the value~~

~~of our company to decline and~~ **an** ~~limit~~ **adverse effect on** our **business,** ~~ability to obtain additional financing~~ **financial condition, results of operations and prospects** . Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates ~~proceed~~ **progress** through preclinical **and** ~~studies to late- stage~~ clinical trials ~~towards potential~~ **to marketing** approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize ~~processes~~ **yield and manufacturing batch size, minimize costs and achieve consistent quality** and results **. For example, our plans to change the formulation, e. g., to a tablet form, for one or more of our product candidates during the course of our clinical trials could increase our costs and delay regulatory approval** . Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause ~~any~~ **our** product candidates ~~we may develop~~ to perform differently and affect the results of ~~planned clinical trials or other future~~ clinical trials conducted with the **altered** materials ~~manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval~~ . This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of **our** ~~the affected~~ product ~~candidate~~ **candidates** and jeopardize our ability to ~~commence sales~~ **commercialize our product candidates, if approved,** and generate revenue. If ~~serious adverse events~~ **we pursue alternative tablet formulations** or ~~unacceptable side effects are identified during the~~ **other** ~~development of~~ **changes to** any **of our** product candidates ~~we may develop~~ , ~~we~~ **the FDA and other regulatory authorities** may ~~need to abandon~~ **require additional studies, including bridging studies, which may significantly delay** ~~or~~ **our** ~~limit our development of those~~ **clinical trial timelines and regulatory approval. Our** product candidates ~~. Clinical trials by their nature utilize a sample of the potential patient population. Many product candidates that initially showed promise in early- stage testing have later been found to cause side effects that prevented their further development. If we decide to pursue any future product development efforts and any product candidates we develop are associated with undesirable side effects in clinical trials or have characteristics that are unexpected in clinical trials or preclinical testing, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. In pharmaceutical development, many~~ - **may** ~~compounds that initially show promise in early- stage or clinical testing are later found to cause side effects that delay or prevent further development of the compound. Additionally, if results of clinical trials reveal unacceptable side effects, we, the FDA or similar regulatory authorities outside of the United States, or the IRBs or Ethics Committees at the institutions in which our studies are conducted could suspend or terminate clinical trials or the FDA or similar foreign regulatory authorities could order us to cease clinical trials or deny approval of any product candidates we may develop for any or all targeted indications. Treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete any clinical trials. If we elect or are forced to suspend or terminate any clinical trial of any product candidates we may develop, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue from such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business. If any product candidate receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were~~ not ~~previously identified, our ability to market the drug could be compromised. If we decide to pursue any future product development efforts, the conduct of any clinical trials of product candidates is likely to be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If any product candidate receives regulatory approval, and we, or others, later discover that it is less effective than previously believed, or causes undesirable side effects, a number of potentially significant negative consequences could result, including: • withdrawal or limitation by regulatory authorities of approvals of such product; • seizure of the product by regulatory authorities; • recall of the product; • restrictions on the marketing of the product or the manufacturing process for any component thereof; • requirement by regulatory authorities of additional warnings on the label, such as a " black box " warning or contraindication; • decrease or elimination of third- party reimbursement; • requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients; • commitment to expensive post- marketing studies as a prerequisite of approval by regulatory authorities of such product; • the product may become less competitive; • initiation of regulatory investigations and government enforcement actions; • initiation of legal action against us to hold us liable for harm caused to patients; and • harm to our reputation and resulting harm to physician or patient acceptance of our products. Any of these events could prevent us from achieving~~ **achieve adequate** ~~or maintaining~~ market acceptance **among** ~~of a particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations. If we decide to pursue any future product development efforts, we may not be successful in our efforts to identify or discover product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success. If we decide to pursue any future product development efforts, there can be no assurance that we will be successful in our efforts to identify or acquire potential product candidates. Even if we identify or acquire additional product candidates, there can be no assurance that our development efforts will be successful. Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through a sale, strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. Even if any product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by~~ physicians, patients, **healthcare** ~~third- party~~ payors and others in the medical community

necessary for commercial success. ~~If any~~ **Even if our** product ~~candidate~~ **candidates** ~~receives~~ **receive** ~~marketing~~ **regulatory** approval, ~~it~~ **they** may **not** ~~nonetheless fail to~~ gain ~~sufficient~~ **adequate** market acceptance ~~by~~ **among** physicians, patients, third-party payors and others in the medical community. ~~Sales~~ **The degree** of ~~medical~~ **market acceptance of any of our approved product candidates will depend on a number of factors, including: • the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments; • the timing of market introduction of the product candidate as well as competitive** products ~~depend in part~~ **; • the clinical indications for which a product candidate is approved; • restrictions** on the ~~willingness~~ **use** of ~~physicians to prescribe~~ **product candidates in** the **labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products; • the potential and perceived advantages of our product candidates over alternative treatments; • the cost of** treatment **in relation** ~~, which is likely~~ to ~~be based on a determination~~ **alternative treatments; • the availability of coverage and adequate reimbursement** by ~~these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that any product we may develop is safe, therapeutically effective and cost effective as compared with competing treatments. Efforts to educate the medical community and~~ third- party payors ~~on~~ **, including government authorities; •** the ~~benefits~~ **availability** of ~~any~~ **an approved product candidate for use as a combination therapy; • relative convenience and ease of administration; • the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests; • the effectiveness of sales and marketing efforts; • unfavorable publicity relating to our** product candidates **;** ~~we may develop may require significant resources~~ and ~~may not be successful~~ **• the approval of other new therapies for the same indications** . If any **of our** product candidates ~~we may develop~~ **are approved but** do not achieve an adequate level of acceptance **by physicians, hospitals, healthcare payors and patients** , we may not generate ~~significant~~ **or derive sufficient revenue from that** product ~~revenues~~ **candidate** and ~~we may not become profitable~~ **our financial results could be negatively impacted** . The ~~degree of~~ market ~~acceptance of~~ **opportunities for** any product candidates we ~~may~~ develop, if approved **, may be limited to certain smaller patient subsets and may be smaller than we estimate them to be. When cancer is detected early (referred to as localized disease), conventional treatments which include chemotherapy, hormone therapy, surgery and radiation therapy and / or selected targeted therapies may be adequate to cure the patient in many cases. However, once cancer has spread to other areas (advanced or metastatic disease), cancer treatments may not be sufficient to provide a cure but often can significantly prolong life without curing the cancer. First- line (" 1L ") therapies designate treatments that are initially administered to patients with advanced or metastatic disease, while second- line (" 2L ") and third or later line therapies are administered to patients when the prior therapies lose their effectiveness. The FDA, EMA and other comparable foreign regulatory bodies often approve cancer therapies** for ~~commercial~~ **a particular line of treatment. Typically, drug approvals are initially granted for use in later lines of treatment, but with additional evidence of significant efficacy from clinical trials, biopharmaceutical companies can successfully seek and gain approval for use in earlier lines of treatment. We plan to initially seek approval of our product candidates in most instances at least as a second- or third- line therapy, for use in patients with advanced or metastatic cancer where at least one prior therapy has limited clinical benefit or has lost its effectiveness. For those product candidates that prove to be sufficiently** ~~safe~~ **safe and effective** , **if any, we would expect to seek approval as a 2L therapy and potentially ultimately as a 1L therapy. There is no guarantee that our product candidates, even if approved as a second, third or subsequent line of therapy would be approved for an earlier line of therapy, and prior to any such approvals we may have to conduct additional clinical trials that may be costly, time- consuming and subject to risk. Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the cancers that we are targeting. The potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Consequently, even if our product candidates are approved, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type. Even if we obtain significant market share for our products, if approved, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications. We face risks related to health epidemics and other outbreaks, such as COVID- 19, which could significantly disrupt our operations or otherwise result in material adverse impacts to us. Our business could be adversely impacted by the effects of health epidemics and other outbreaks, including: • delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; • difficulties interpreting data from our clinical trials due to the possible effects of health epidemics or other outbreaks on patients; • interruption of key preclinical and clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or due to restricted or limited operations of the CROs conducting such studies; • interruption or delays in the operations of the FDA, EMA or other regulatory authorities, which may impact review and approval timelines; • diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals**

serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials; • limitations in resources that would otherwise be focused on the conduct of our business, our preclinical studies or our clinical trials, including because of sickness or the desire to avoid contact with large groups of people or as a result of government- imposed " shelter in place " or similar working restrictions; • delays in receiving approval from regulatory authorities to initiate our clinical trials; • delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials; • interruption in global freight and shipping that may affect the transport of clinical trial materials, such as investigational drug product to be used in our clinical trials; • changes in regulations as part of a response to health epidemics or other outbreaks which may require us to change the ways in which our clinical trials are to be conducted, or to discontinue the clinical trials altogether, or which may result in unexpected costs; • delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and • refusal of the FDA, EMA or other regulatory authorities to accept data from clinical trials in affected geographies outside of their respective jurisdictions. The extent to which COVID- 19, including emergence of new variants or resurgence in COVID- 19 cases, or any other health epidemic, impacts our results will depend on ~~a number of factors~~ **future developments, which are highly uncertain and cannot be predicted** , including ~~:~~ ~~•~~ **new information which may emerge concerning** the **severity** ~~efficacy and potential advantages compared to alternative treatments; • the effectiveness~~ of ~~sales~~ **a particular virus** and **its variants and** ~~marketing efforts; •~~ the **actions** ~~cost of treatment in relation~~ to ~~alternative treatments~~ **contain it or treat its impact, among others. There can be no assurance that we will be able to avoid a material impact on our business, financial condition and operating results from the spread of COVID- 19 or its consequences** , including **disruption to our business and downturns in business sentiment generally or in our industry. To the extent a health epidemic or other outbreak adversely affects our business, financial condition and operating results, it may also have the effect of heightening** ~~any~~ **many of** ~~similar generic treatments; •~~ the ~~clinical indications for which the~~ **risks described in this section. Any** product **candidates we develop may become subject** ~~is approved; • the convenience and ease of administration compared~~ to **unfavorable** ~~alternative treatments; • the willingness of the target patient population to try new therapies and to continue treatment over time and of physicians to prescribe these therapies; • the strength of marketing and distribution support; • the timing of market introduction of competitive products; • the availability of~~ third- party coverage and **reimbursement practices, as well as pricing regulations. The availability and extent of coverage and** adequate reimbursement **by** ~~, and patients' willingness to pay out of pocket for required co- payments or in the absence of~~ third- party **payors, including government health administration authorities, private health** coverage **insurers** ~~or adequate reimbursement; • the prevalence and severity of any side effects; and • any restrictions on the use of our products~~ , **managed** ~~if approved, together with other medications. If we decide to pursue any future product development efforts and we are~~ **care** ~~unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing any product candidates if and when they are approved. We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties should we pursue developing and commercializing novel therapeutics. In the future, we expect that we would begin to build a sales and marketing infrastructure to market any product candidates we may develop, if and when approved by the applicable regulatory authority. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time- consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts would be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel; • the inability of sales personnel to educate adequate numbers of physicians on the benefits of any future products; • the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors; • the inability to price products at a sufficient price point to ensure an adequate and attractive level of profitability; • restricted or closed distribution channels that make it difficult to distribute products to segments of the patient population; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we are unable to establish our own sales, marketing and distribution capabilities and we enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we would develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute any product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new drug products is highly competitive. If we decide to pursue any future product development efforts, we will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and**

~~private research~~ organizations ~~that conduct research, seek patent protection~~ and establish collaborative arrangements for research, development..... affected in many cases by insurers or other third- party payors ~~seeking~~ **is essential for most patients** to ~~encourage the use of generic products~~ **be able to afford expensive treatments** . ~~If~~ **Sales of** any **of our** product candidates ~~achieve~~ **that receive** marketing approval **will depend substantially** , **both in** ~~we expect that they~~ -- **the United States and internationally, on** ~~would be priced at a significant premium over competitive generic products. Many of~~ the ~~companies against~~ **extent to** which ~~we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other~~ -- **the costs of such** ~~early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Even if we are able to commercialize any~~ product candidates ~~, the products may become subject to unfavorable pricing regulations, third- party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates obtain marketing approval. Our ability to commercialize any product candidates successfully~~ will **be** ~~depend in part on the extent to which coverage~~ -- **covered** and ~~adequate reimbursement~~ **reimbursed by** ~~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 **. If reimbursement is not available** , ~~such as~~ **or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. There is significant uncertainty related to third- party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the CMS, an agency within the U. S. Department of Health and Human Services (" HHS "). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and** private ~~health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and other~~ third- party payors ~~have attempted~~ **often follow CMS' s decisions regarding coverage and reimbursement** to ~~control~~ **a substantial degree. However, one third- party payor' s determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time- consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third- party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. As federal and state governments implement additional health care cost containment measures, including measures to lower prescription drug pricing, we cannot be sure that our products, if approved, will be covered by private or public payors, and if covered, whether the reimbursement will be adequate or competitive with other marketed products. Any actions by federal and state governments, such as the Inflation Reduction Act of 2022 (" IRA "), and health plans aimed at putting additional downward pressure on pharmaceutical pricing and health care** costs ~~by limiting~~ **could negatively impact** coverage and ~~the amount of~~ reimbursement for ~~particular medications~~ **our product candidates if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development** . **For further discussion, see " — We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations. "** Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. **Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining** ~~Coverage~~ **coverage** and reimbursement **for newly approved drugs. Third- party payors** may **limit coverage to specific product candidates on an approved list, known as a formulary, which might** not **include all FDA- approved drugs for a particular indication. We may need to conduct expensive pharmaco- economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will** be available for any product that we commercialize and, **if reimbursement is available, what the level of reimbursement will be. In addition, companion diagnostic tests require**

coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved. Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union (" EU "), medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third- party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third- party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition. Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management' s time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to advancing additional product candidates into clinical trials or marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is expensive and may increase over time. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition. Risks Related to Regulatory Approval and Other Legal Compliance Matters We may develop our current or future product candidates in combination with other therapies, which would expose us to additional risks. As part of our development strategy, we are seeking strategic collaborations to develop our current or future product candidates in combination with one or more currently approved cancer therapies or therapies in development. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially. We or our future third party collaborators may also evaluate our current or future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third- party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. We have never commercialized a product candidate as a company before and currently lack the necessary expertise, personnel

and resources to successfully commercialize any products on our own or together with suitable collaborators. We have never commercialized a product candidate as a company. We may license certain rights with respect to our product candidates to collaborators, and, if so, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party. Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws, and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time- consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability. The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction. We currently conduct our clinical trial for ELVN- 001 in the United States, Australia, France, Germany, South Korea, and Spain. In the future, we may conduct clinical trials for ELVN- 001 in other countries, including but not limited to Poland, Italy, Belgium, Netherlands, Canada, Hungary, Israel and Argentina. We are conducting our clinical trial for ELVN- 002 in the United States, Spain, France, Italy, Australia, Taiwan and South Korea. In the future, we may also conduct clinical trials for ELVN- 002 in other countries. We plan to conduct clinical trials for future candidates in the United States and internationally. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in the foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of our applicable jurisdiction. In some cases, the regulatory authority may require clinical trials to include patients in their jurisdiction to support regulatory approval. If the FDA, EMA 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 or clearance for commercialization in the applicable jurisdiction. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if **the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in** ~~these~~ **those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fails to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed. Even if our product candidates receive regulatory approval, they will be subject to significant post- marketing regulatory requirements and oversight. Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and on- going surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements and regulatory inspection. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and 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, EMA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as on- going compliance with cGMPs and GCPs for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities** are **subject to continual review and periodic, unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the**

manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including: • delays in or the rejection of product approvals; • suspension or restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; • restrictions on the products, manufacturers or manufacturing process; • warning or untitled letters; • fines, restitution, or disgorgement of profits or revenues; • consent decrees, injunctions or imposition of civil or criminal penalties; • suspension or withdrawal of regulatory approvals; • product seizures, detentions, or export or import bans; • voluntary or mandatory product recalls, withdrawals, and / or publicity requirements; • total or partial suspension of production; • imposition of restrictions on operations, including costly new manufacturing requirements; • restrictions or revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings; • imposition of a REMS, which may include distribution or use restrictions; and • requirements to conduct additional post- market clinical trials to assess the safety of the product. The FDA, EMA and other regulatory authorities' policies 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. Changes to existing policies and regulations can increase our compliance costs or delay our clinical plans. The FDA, EMA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If any of our product candidates are approved and we are found to have improperly promoted off- label uses of those products, we may become subject to significant liability. The FDA, EMA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted in the United States for uses that are not approved by the FDA as reflected in the product' s approved labeling, or in other jurisdictions for uses that differ from the labeling or uses approved by the applicable regulatory agencies. While physicians may prescribe products for off- label uses, the FDA, EMA and other regulatory agencies actively enforce laws and regulations that prohibit the promotion of off- label uses by companies, including promotional communications made by companies' sales forces with respect to off- label uses that are not consistent with the approved labeling, and a company that is found to have improperly promoted off- label uses may be subject to significant liability, including civil, criminal and administrative penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue. The United States federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Where appropriate, we plan to secure approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw accelerated approval. Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our product candidates from the FDA, EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA' s implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life- threatening condition that provides meaningful therapeutic benefit over available **therapies upon a determination that the product candidate has an effect on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease , such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or** ~~the~~ **other** ~~level of reimbursement may~~ **measure that is thought to predict clinical benefit but is** not ~~be satisfactory~~ **itself a measure of clinical benefit** . ~~Reimbursement may~~ **An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an** ~~affect~~ **effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or** ~~the~~ **other** ~~demand~~ **clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. However, because our product candidates are in early development, there can be no assurance that the FDA will permit us to utilize an expedited approval process** for ~~,~~ **any of** ~~or~~ **our product candidates. 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. Even if our product candidates are granted a designation or qualify for expedited development, it may not actually lead to faster development or expedited regulatory review and approval or increase the likelihood that** ~~the~~ **they** ~~price of~~ **will**

receive FDA approval. For example , if such post- approval studies fail to confirm the drug' s clinical benefit, the FDA may withdraw its approval of the drug. Prior to seeking accelerated approval, we will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that, after our evaluation of the feedback and other factors, we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e. g., Fast Track designation, Breakthrough Therapy designation or orphan drug designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all, because the FDA' s accelerated approval pathways do not guarantee an accelerated review by the FDA. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace. Where possible, we plan to seek Fast Track designation from the FDA for one or more of our product candidates. Even if one or more of our product candidates receive Fast Track designation, we may be unable to obtain or maintain the benefits associated with the Fast Track designation. Where possible, we plan to seek Fast Track designation for one or more of our current or future product candidates. Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA' s priority review procedures. Where possible, we plan to seek a Breakthrough Therapy designation from the FDA, which even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. Where possible, we plan to seek Breakthrough Therapy designation for one or more of our current or future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic 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 product candidates 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. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our 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 candidate products considered for approval under non- expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek Breakthrough Therapy designation for one or more of our current or future product candidates, there can be no assurance that it will receive Breakthrough Therapy designation. Where possible, we plan to pursue an orphan indication for our product candidates to treat CML and potentially others. However, we may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products. Where possible, we plan to pursue an orphan indication for our product candidates to treat CML and potentially others. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals 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. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for our product candidates. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product

candidate is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we **have obtained orphan drug designation for the orphan- designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review. In view of the court decision in Catalyst Pharms., Inc. v. Becerra, 14 F. 4th 1299 (11th Cir. 2021), the FDA published a notice in the Federal Register to clarify that while the agency complies with the court' s order in Catalyst, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the Catalyst order – that is, the agency will continue tying the scope of orphan- drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity. Existing regulatory policies 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. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the United States pharmaceutical industry. The ACA, which, among other things, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50 % (increased to 70 % pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government' s comparative effectiveness research. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Prior to the Supreme Court' s decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and healthcare measures initiated by the Biden administration will impact the ACA, our business, financial condition and results of operations. Complying with any new legislation or change in regulatory requirements could be time- intensive and expensive, resulting in a material adverse effect on our business. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032. In January 2013, the American Taxpayer Relief Act of 2012, among other things, increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the**

American Rescue Plan Act of 2021, a sunset provision, effective January 1, 2024, eliminated the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high- priced single- source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out- of- pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including pharmaceutical companies, the U. S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges as well as future legislative, executive, and administrative actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In 2021, many states passed or considered state drug price transparency and reporting laws that substantially increase the compliance burdens on pharmaceutical manufacturers. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time- intensive and expensive, resulting in a material adverse effect on our business, and expose us to greater liability. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: • the demand for our product candidates, if we obtain regulatory approval; • our ability to set a price that we believe is fair for our products; • our ability to obtain coverage and reimbursement approval for a product; • our ability to generate revenue and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. 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 product candidates. It is also possible that additional governmental action is taken in response to any future public health emergencies. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. The withdrawal of the United Kingdom (" UK ") from the EU, commonly referred to as " Brexit, " may adversely impact our ability to obtain regulatory approvals for our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU. Inadequate funding for the FDA, the SEC and other United States government agencies or the EMA or comparable foreign regulatory authorities 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, EMA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of 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, EMA 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 business. For example, in recent years, including in 2018 and 2019, the United States government

shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Our relationships with employees, independent contractors, consultants, commercial collaborators, healthcare professionals, clinical investigators, CROs, suppliers, vendors and third- party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings. We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, healthcare professionals, clinical investigators, CROs, suppliers, vendors and third- party payors may engage in misconduct or other improper activities. Healthcare providers and third- party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. **the federal Physician Payments Sunshine Act requires certain manufacturers of** drugs,devices,biologics **,** and medical supplies for which ~~reimbursement~~ **payment** is available under Medicare,Medicaid **,** or the Children' s Health Insurance Program (with ~~certain~~ **specific** exceptions) to report annually to ~~CMS in HHS~~ **the U.S.Department of Health and Human Services** information related to payments ~~or~~ **and** other transfers of value made **by that entity** to **physicians** ~~covered recipients~~ , **other** ~~including physicians (defined to include doctors,dentists,optometrists,podiatrists and chiropractors),certain non- physician~~ healthcare providers ~~(such as physician assistants and nurse practitioners),~~ and teaching hospitals **and** ~~,as well as~~ ownership and investment interests held by physicians **,other healthcare providers** and their ~~immediate~~ family members;and • analogous state **laws and regulations,such as state anti** ~~Obtaining~~ **obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of certain personal data breaches (including to supervisory authorities and potentially affected individuals), and taking certain measures when engaging third- party processors. The GDPR also imposes strict rules on the transfer of personal data outside the EEA to third- party countries that have not been found to provide adequate protection to such personal data, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to € 20 million or 4 % of annual global revenues, whichever is greater, for the most serious of violations. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. While the GDPR applies uniformly across the EU, each EU Member State is permitted to issue nation- specific data protection legislation, which has created inconsistencies on a country- by- country basis. Additionally, we could be subject to recently enacted UK data privacy and protection laws, regulations and standards, if we decide to enroll patients in the UK clinical trials. While the UK General Data Protection Regulation (the " UK GDPR ") largely mirrors the GDPR, Brexit and the subsequent implementation of the UK GDPR expose us to two parallel data protection regimes, each of which potentially authorizes similar significant fines and other potentially divergent enforcement actions for certain violations. In addition, on July 16, 2020, the European Court of Justice invalidated the EU- US Privacy Shield Framework, a mechanism under which personal data could be transferred from the EEA to entities in the United States that had self- certified under the Privacy Shield Framework. The Court also called into question the Standard Contractual Clauses (" SCCs "), noting adequate safeguards must be met for SCCs to be valid. Use of the SCCs must now be assessed on a case- by- case basis taking into account the legal regime applicable in the destination country, in particular, applicable surveillance laws and rights of individuals and additional measures and / or contractual provisions may need to be put in place. Additionally, the European Commission has adopted new SCCs that are required to be implemented. The UK also has issued new standard contractual clauses, similar to the SCCs, that also are required to be implemented. On March 25, 2022, the United States and EU announced ~~and~~ an " agreement in principle " to replace the EU- U. S. Privacy Shield transfer framework with the Trans- Atlantic Data Privacy Framework (" TADTF "). On July 10, 2023, the European Commission adopted an adequacy decision in relation to the TADTF, since renamed the EU- U. S. Data Privacy Framework (" EU- U. S. DPF "), allowing the EU- U. S. DPF to be utilized as a means of legitimizing EU- U. S. personal data transfers for participating entities. The UK and U. S. also established a UK Extension to the EU- U. S. DPF, effective as of October 12, 2023 (the " UK Extension "), whereby participants in the EU- U. S. DPF who participate in the UK Extension may rely upon the UK Extension as a means to legitimize personal data transfers from the UK to the U. S. The EU- U. S. DPF and UK Extension may be subject to legal challenges from privacy advocacy groups or others, and the European Commission' s adequacy decision regarding the EU- U. S. DPF provides that the EU- U. S. DPF will be subject to future reviews and may be subject to suspension, amendment, repeal, or limitations to its scope by the European Commission. We have encountered, and may continue to encounter, difficulties putting in place SCCs with certain personal data exporters. As supervisory authorities issue further guidance on personal data export mechanisms, including on the new SCCs, and / or start taking enforcement action, our compliance costs could increase. More generally, we may be subject to complaints and / or regulatory investigations or fines relating to cross- border personal data transfers, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we may conduct clinical trials, this could negatively impact our business. Furthermore, On June 28, 2021, the European Commission issued an adequacy decision under the GDPR and the Law Enforcement Directive, pursuant to which personal data generally may be transferred from the EU**

to the UK without restriction; however, this adequacy decision is subject to a four- year " sunset " period, after which the European Commission' s adequacy decision may be renewed. During that period, the European Commission will monitor the legal situation in the UK and may intervene at any time with respect to its adequacy decision. The UK' s adequacy determination therefore is subject to future uncertainty and may be subject to modification or revocation in the future, with the UK potentially being considered an inadequate third country under the GDPR, in which case transfers of personal data from the EEA to the UK will require a transfer mechanism, such as SCCs. Furthermore, there will be increasing scope for divergence in application, interpretation, and enforcement of the data protection law as between the UK and the EEA. This may increase the complexity of transferring personal data across borders. Similar laws have been proposed in other foreign jurisdictions. For example, on August 20, 2021, the Personal Information Protection Law (" PIPL ") of the People' s Republic of China (" PRC ") was adopted and went into effect on November 1, 2021. The PIPL shares similarities with the GDPR, including extraterritorial application, data minimization, data localization, and purpose limitation requirements, and obligations to provide certain notices and rights to citizens of the PRC. The PIPL allows for fines of up to 50 million renminbi or 5 % of a covered company' s revenue in the prior year. If additional laws are passed, such laws may have potentially conflicting requirements that would make compliance challenging. Such laws may require us to modify our operations, and may limit our ability to collect, retain, store, use, share, disclose, transfer, disseminate, and otherwise process personal data, may require additional investment of resources in compliance programs, impact strategies and could result in increased compliance costs and / or changes in our ongoing or planned business practices and policies. We may also be subject to federal and state privacy, data protection and data security laws and regulations in the United States including, without limitation, laws that regulate personal information, including health information. For example, California has enacted the California Consumer Privacy Act (" CCPA "), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy, data protection, and data security obligations on entities handling personal information of California consumers, devices, or households. The CCPA requires covered companies to provide new disclosures to California consumers about such companies' data collection, use and sharing practices and provide such consumers new ways to opt- out of certain sales of personal information. The CCPA also provides consumers with a private right of action in certain data breach situations. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations on July 1, 2020. Moreover, the California Privacy Rights Act (" CPRA "), which significantly modifies the CCPA, including by imposing additional obligations on covered companies and expanding consumers' rights with respect to certain sensitive personal information, became operative on January 1, 2023, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the United States. The CCPA has prompted a number of proposals for federal and state privacy legislation, some of which have been enacted. Many of these proposed and enacted laws are comprehensive privacy statutes that impose obligations similar to the CCPA. For example, Colorado enacted the Colorado Privacy Act (" CPA "), legislation similar to the CCPA that has taken effect in 2023; Connecticut and Virginia have also enacted legislation similar to the CCPA and CPA that have taken effect in 2023; Utah has enacted similar legislation that took effect on December 31, 2023; Florida, Montana, Oregon, and Texas have enacted similar legislation that takes effect in 2024; Delaware, Iowa, and Tennessee have enacted similar legislation that will take effect in 2025; and Indiana has enacted similar legislation that will take effect in 2026. With regard to the CPA, we are monitoring developments closely in view of our operations in Colorado. The CPA and its implementing rules, the final versions of which were issued by the Colorado Attorney General, became effective July 1, 2023. We may be required to modify our policies and practices and otherwise to incur additional costs and expenses in an effort to comply with the CPA and other new and evolving state privacy legislation. Collectively, these reflect a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. We may also publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal information. Although we endeavor to comply with our published policies and documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractors fail to comply with our published policies and documentation. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. The number and scope of obligations related to privacy, data protection and data security are changing, subject to differing applications and interpretations, and may be inconsistent between jurisdictions or in conflict with each other. As a result, compliance with United States and foreign privacy, data protection, and data security laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, retain, store, use, share, disclose, transfer, disseminate, and otherwise process data, or in some cases, impact our ability to operate in certain jurisdictions. Although we endeavor to comply with our published policies, other documentation, and all applicable privacy and security laws and regulations, we may at times fail to do so or may be perceived to have failed to do so. Any actual or alleged failure to comply with such obligations could result in governmental investigations, proceedings and enforcement actions (which could include civil or criminal fines or penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention and other processing of

information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. Our business activities may be subject to the U. S. Foreign Corrupt Practices Act (" FCPA ") and similar anti- bribery and anti- corruption laws and anti- money laundering laws, including laws of other countries in which we operate, as well as U. S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them. We are subject to the FCPA, the U. S. domestic public corruption and commercial bribery statutes contained in 18 U. S. C. § 201, the U. S. Travel Act and possibly other anti- bribery and anti- corruption laws and anti- money laundering laws in countries outside of the United States in which we conduct our activities. Anti- corruption and anti- bribery laws have been enforced aggressively in recent years and are interpreted broadly to generally prohibit companies, their employees, agents, representatives, business partners, and third- party intermediaries from authorizing, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may leverage third parties to sell our products and conduct our business abroad. We, our employees, agents, representatives, business partners and third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state- owned or affiliated entities and may be held liable for the corrupt or other illegal activities of these employees, agents, representatives, business partners or third- party intermediaries even if we do not explicitly authorize such activities. Our business activities may be subject to the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third- party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action or otherwise 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. Our business is heavily regulated and therefore may involve significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. We cannot assure you that all of our employees, agents, representatives, business partners or third- party intermediaries will not take actions in violation of applicable law for which we may be ultimately held responsible. As we commercialize our product candidates and increase our international sales and business, our risks under these laws may increase. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, 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 and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition. These laws also require that we keep accurate books and records and maintain internal controls and compliance procedures designed to prevent any such actions. While we have policies and procedures to address compliance with such laws, we cannot assure you that none of our employees, agents, representatives, business partners or third- party intermediaries will take actions in violation of our policies and applicable law, for which we may be ultimately held responsible. Any allegations or violation of the FCPA or other applicable anti- bribery and anti- corruption laws and anti- money laundering laws could result in whistleblower complaints, sanctions, settlements, prosecution, enforcement actions, fines, damages, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions, or suspension or debarment from government contracts, all of which may have an adverse effect on our reputation, business, results of operations, and prospects. Responding to any investigation or action will likely result in a materially significant diversion of management' s attention and resources and significant defense costs and other professional fees. In addition, our products may be subject to U. S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. 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, United States export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by United States sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and / or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including

those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our sublease for our corporate headquarters expires on December 30, 2024. We are assessing alternative spaces and, if we move our facility, such relocation, including our obligation to decontaminate our facility, may delay our product development, expose us to additional liabilities, and increase our costs. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. Any legal proceedings or claims against us could be costly and time- consuming to defend and could harm our reputation regardless of the outcome. We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, including intellectual property, product liability, employment, class action, whistleblower and other litigation claims, and governmental and other regulatory investigations and proceedings. We may incur liability under our agreements with third parties, and we are not always indemnified under such agreements. We may also be exposed to increased litigation from stockholders, suppliers and other third parties due to the combination of our business and Former Enliven' s business. For example, we were involved in a legal proceeding in connection with the Merger, which required the payment of a mootness fee and was voluntarily dismissed by the plaintiff in January 2023. Such matters can be time- consuming, divert management' s attention and resources, cause us to incur significant expenses or liability, or require us to change our business practices. In addition, the expense of litigation and the timing of this expense from period to period are difficult to estimate, subject to change, and could adversely affect our financial condition and results of operations. Because of the potential risks, expenses, and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Any of the foregoing could adversely affect our business, financial condition, and results of operations. Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business Our success is highly dependent on our ability to attract, hire and retain highly skilled executive officers and employees. We currently have a small team focused on research and development of small molecule kinase inhibitors. Our ability to discover and develop any product candidates is dependent on our chemists. To succeed, we must recruit, hire, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff, particularly Sam Kintz, our President, Chief Executive Officer and director and Joseph P. Lyssikatos, our Chief Scientific Officer and director. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We do not maintain " Key Person " insurance for any of our executives or other employees. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we have to offer. If we are unable to continue to attract and retain high- quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed. Our scientific and clinical advisors and consultants may enter into non- compete agreements with us and, given a shifting legal landscape, such agreements may or may not continue to be enforceable. Our scientific and clinical advisors and consultants typically will not enter into non- compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting or employment relationships with our scientific founders and other scientific and clinical advisors and consultants, or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed. Our reliance on a limited number of employees who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business. As of December 31, 2023, we had 46 full- time employees. Of these employees, 36 are engaged in research or product development and clinical activities. The small size of our centralized team may limit our ability to devote adequate personnel, time, and resources to support our operations or research and development activities, and the management of financial, accounting, and reporting matters. If our team fails to provide adequate administrative, research and development, or other services across our organization, our business, financial condition, and results of operations could be harmed. We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth. As of December 31, 2023, we had 46 full- time employees. Of these employees, 36 are engaged in research or product development and clinical activities. In order to successfully

implement our development and commercialization plans and strategies, we expect to need significant additional managerial, operational, sales, marketing, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining ~~adequate reimbursement~~ **, retaining and motivating our current and additional employees; • managing our internal development efforts effectively, including the preclinical, clinical, FDA, EMA and other comparable foreign regulatory agencies' review process** for ~~our~~ **ELVN- 001, ELVN- 002, and any other** ~~products~~ **product candidates while complying with any contractual obligations to contractors and other third parties; • managing increasing operational and managerial complexity; • complying with additional regulatory and compliance requirements related to advancing our product candidates and research programs; and • improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to successfully develop and, if approved, commercialize ELVN- 001, ELVN- 002 and other research programs will depend, in part, on our ability to effectively manage any future growth, and our management** may ~~be difficult~~ **also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of research, clinical development, regulatory functions and manufacturing. We also rely, and for the foreseeable future will continue to rely, on one or more employers of record to engage workers outside of the United States, which could expose the Company to liability for its employment practices outside of the United States and for liabilities associated with the employment practices of any such employer of record** . There can be no assurance that ~~any product candidates~~ **the services of independent organizations** , ~~even~~ **employers of record, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition,** if ~~they~~ **we** are **unable to** ~~approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication or cost- effective~~ **effectively manage our outsourced activities or if the quality or accuracy of the services provided** by third-party ~~payors. We may be required to conduct expensive pharmacoeconomic~~ **service providers is compromised for any reason, our preclinical** studies ~~to justify coverage~~ and ~~reimbursement~~ **clinical trials may be extended, delayed** or **terminated,** ~~the level of reimbursement relative to other therapies. If coverage~~ and **we may** ~~adequate reimbursement are~~ not ~~available, we may not~~ be able to ~~successfully commercialize any product candidate for which we~~ obtain marketing approval **for any of our product candidates or otherwise advance our business** . There ~~may~~ **can** be **no assurance that we will be able to manage our existing third- party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and / or engaging additional third- party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize ELVN- 001, ELVN- 002 and any other product candidates and, accordingly, may not achieve our research, development and commercialization goals. Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer actual or suspected security or data privacy incidents or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal information, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations, and potentially** significant delays in ~~obtaining coverage~~ **our clinical trials** and ~~reimbursement~~ **delivery of product to market. In the ordinary course of our business, we collect, store, process, and transmit large amounts of data, including intellectual property, proprietary** ~~for~~ **or confidential data** ~~newly approved drugs~~ , **employee data,** and ~~coverage may be more limited than the purposes for which the drug~~ **personal information. We also collect, store, process, and transmit health information, in connection with our clinical trials. It** is **critical** ~~approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply~~ that **we do so** ~~a drug will be paid for~~ in ~~all cases~~ **a secure manner to maintain the confidentiality, integrity, and availability of such data. Our obligations under applicable laws, regulations, contracts, industry standards, and other documentation may include maintaining the confidentiality, integrity, and availability of such data in** ~~or~~ **our possession** ~~at a rate that covers our~~ **or** ~~costs~~ **control** , **maintaining reasonable and appropriate security safeguards as part of an information security program, and restrictions on the use and disclosure of such data. These obligations create potential legal liability to regulators, business partners, clinical trial participants, employees, and other relevant stakeholders. We have outsourced certain elements of our operations (** including **elements** ~~research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use~~ of ~~the drug~~ **our information technology infrastructure) to third parties** and **have** ~~the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be~~ incorporated ~~into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States. Third~~ **third** - party ~~payors often~~ **technology into our information technology infrastructure, which collects, processes, transmits and stores intellectual property, proprietary or confidential data, employee data, and personal information. As a result, we manage a number of third- party providers who may or could have access to our information technology systems or to our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to additional third parties. Despite the implementation of security measures designed to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and external processing and storage**

systems (e. g., cloud), and those of our third- party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are from time to time vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, power outages, natural disasters, global pandemics (such as COVID-19), terrorism, acts of vandalism, war and telecommunication and electrical failures, as well as security breaches and incidents from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and / or other third parties (including nation- state and nation- state supported actors), or from cyber- attacks by malicious third parties (including the deployment of harmful malware, ransomware, viruses, denial- of- service attacks, phishing attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the unauthorized access to or acquisition, use, corruption, loss, destruction, alteration or dissemination of, or damage to, our data. For example, from time to time, we experience an increase in phishing and social engineering attacks from third parties in connection with the increase in remote work in recent years. As a result, we, as well as any of our CROs, clinical trial sites, manufacturers, other contractors or consultants who may be operating in remote work environments may have increased cyber security and data security risks, due to increased use of home wi- fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement information technology controls designed to reduce the risk of a cyber security or data security incident, there is no guarantee that these measures will be adequate to safeguard all systems, especially with an increased number of employees primarily working remotely. To the extent that any disruption or security incident were to result in any unauthorized, unlawful, or accidental access to, or acquisition, use, corruption, loss, destruction, unavailability, alteration or dissemination of, or damage to, our data (including confidential or personal information) or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. There can be no assurance that our data protection and security efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber security incidents that cause unauthorized, unlawful, or accidental access to or acquisition, use, corruption, loss, destruction, unavailability, alteration or dissemination of, or damage to, our data that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs (including clinical trials) and the development of our product candidates could be delayed. In addition, significant disruptions of our internal information technology systems or security incidents could result in the loss, misappropriation, and / or unauthorized access, use, acquisition, or disclosure of, or the prevention of access to, data (including trade secrets or other confidential data, intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized, unlawful, or accidental access, use, or disclosure of personal information, including personal information regarding our employees or business partners, could harm our reputation directly, compel us to comply with breach notification laws, subject us to financial exposure related to investigation of the incident (including cost of forensic examinations), subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. We may also be required to notify governmental authorities and / or affected individuals of breaches involving personal information. For example, all 50 states have laws including obligations to provide notification of security breaches of computer databases that contain personal information to affected individuals, state regulators, and / or others. These laws are not consistent, and compliance in the event of a widespread security breach or incident may be difficult and costly. We also may be contractually required to notify affected individuals or other relevant stakeholders of a security breach or incident. Regardless of our security measures and contractual protections, any actual or perceived security breach or incident or breach of our contractual obligations could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach or incident. Notifications and follow- up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or incident. We also rely ~~upon Medicare coverage policy~~ **on third parties to manufacture our product candidates,** and ~~payment limitations in setting~~ **similar events relating to** their **computer systems could** ~~own reimbursement policies, but~~ also ~~have their own methods and process apart from Medicare determinations. As a result, obtaining and maintaining coverage and adequate reimbursement is often time- consuming and costly. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any approved products that we develop could~~ have a material adverse effect on our ~~operating~~ **business. We and our third- party providers may not have the resources or technical sophistication to anticipate or prevent all such cyber- attacks. Techniques used to obtain unauthorized access to systems are increasingly sophisticated, change frequently and may not be known until launched against us or our third- party providers. While we have no reason to believe that we have experienced a data security incident that we have not discovered, attackers have become very sophisticated in the way they conceal their unauthorized access to systems, and many companies that have been attacked are not aware that they have been attacked. Any incident that leads to loss of or unauthorized access to, or use, alteration, or disclosure of information of**

individuals, including but not limited to personal information regarding our employees, could disrupt our business, harm our reputation, compel us to comply with applicable data breach notification laws, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us and result in significant legal and financial exposure and / or reputational harm. There have been and may continue to be significant supply chain attacks (such as the attacks resulting from vulnerabilities in SolarWinds Orion, Accellion FTA, Microsoft Exchange, Codecov, Kaseya VSA, MOVEit, Okta, and other widely- used software and technology infrastructure) and we cannot guarantee that our or our third- party providers' systems have not been breached or that they do not contain exploitable defects or bugs that could result in a security breach or incident of, or other disruption to, our systems and networks or the systems and networks of third parties that support us. Our ability to monitor our third- party providers' security measures is limited, and, in any event, malicious third parties may be able to circumvent those security measures, resulting in the unauthorized, unlawful, or accidental access to, misuse, disclosure, loss or destruction of our data, including employee personal information and other sensitive information. We have not experienced a cybersecurity incident that has been determined to be material, but our and our third- party providers' and partners' information technology systems have and may in the future experience cybersecurity incidents or vulnerabilities that could be exploited from inadvertent or intentional actions of our employees, third- party providers, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise, including organized criminal groups, " hacktivists, " nation states and others. Additionally, due to the geopolitical unrest associated with Russia' s invasion of Ukraine and the conflict in the Middle East, we and our CROs, contractors, and other third- party providers and collaborators may be vulnerable to heightened risks of cybersecurity incidents and security and privacy breaches. Security incidents that impact our information technology systems could result in breaches of our contracts (some of which may not have liability limitations and / or require us to indemnify affected parties) and could lead to litigation with collaborators, clinical trial participants, or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management' s time and attention, increase our costs of doing business, adversely affect our reputation or otherwise adversely affect our business. Similarly, security incidents could lead to regulatory investigations. We could be required to fundamentally change our business activities and practices in response to such litigation, which could have an adverse effect on our business. We may not have applicable or otherwise adequate insurance to protect us from, or adequately mitigate, liabilities or damages resulting from cyber or privacy incidents. The successful assertion of one or more large claims against us that exceeds any available insurance coverage that we might have, or results ~~,~~ **in changes to insurance policies (including premium increases** ~~our~~ **or the imposition of large deductible** ~~ability to raise capital needed to commercialize products and our~~ **or** ~~overall financial condition~~ **co- insurance requirements), could have an adverse effect on our business** . ~~If~~ **In addition,** we ~~decide~~ **cannot be sure that insurance coverage will be available on acceptable terms or that insurers will not deny coverage as** to ~~pursue~~ any future **claim. Further, any disruption or security incident that does or is perceived to result in unauthorized, unlawful, or accidental access to or acquisition, use, corruption, loss, destruction or alteration of, or damage to, our data, including our confidential or proprietary data, could expose us to litigation and governmental investigations, could delay the further development and commercialization of our** product **candidates** ~~development efforts~~ , **and** ~~our success may depend, in part, on our ability to penetrate foreign markets, where we would~~ **could** ~~be~~ subject **us** to ~~additional~~ **significant fines or penalties for any noncompliance with certain state, federal and / or international privacy and security laws. If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain** regulatory ~~burdens~~ **approval. We currently do not have** and **have never had a marketing** ~~other risks and uncertainties that, if they materialize, could harm our~~ **or** ~~business~~ **sales team** . **In order** ~~If we decide to pursue any future product development efforts, our future profitability may depend, in part, on our ability~~ to commercialize any product candidates **, if approved,** we ~~may develop~~ **must build marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services for each of the territories** in **which we may have approval to sell or** ~~markets~~ **market our product candidates. We may not be successful in accomplishing these required tasks. Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time- consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory- by- territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on our own. If we are unable to enter into such arrangements when needed, on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we**

may incur significant additional losses. A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business. We may seek regulatory approval of our product candidates outside of the United States and ~~the European Union. If we commercialize any product candidates we may develop in foreign markets~~ , **accordingly, we expect that** we will be subject to additional risks ~~and uncertainties~~ **related to operating in foreign countries if we obtain the necessary approvals** , including: • **differing regulatory requirements and reimbursement regimes in foreign countries, such as the lack of pathways for accelerated drug approval, may result in foreign regulatory approvals taking longer and being more costly than obtaining approval in the United States; • foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from nonclinical studies or clinical trials; • approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; • unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; •** economic weakness, including inflation, or political instability in particular **foreign** economies and markets; • **compliance** ~~the burden of complying~~ with ~~complex and changing foreign regulatory, tax, accounting and~~ legal requirements **applicable to privacy** , **data protection** ~~many of which vary between countries; • different medical practices and customs in foreign countries affecting acceptance in the marketplace; • tariffs and trade barriers~~ , ~~as well as~~ **information security and** other **matters** ~~governmental controls and trade restrictions; • other trade protection measures, import or export licensing requirements, economic sanctions or other restrictive actions by U. S. or foreign governments; • longer accounts receivable collection times; • longer lead times for shipping~~ ; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • **foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; • difficulties staffing and managing foreign operations; • complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries; •** workforce uncertainty in countries where labor unrest is **more** common **than in the United States** ; • ~~language barriers~~ **potential liability under the FCPA** ~~for~~ **or** ~~technical training~~ **comparable foreign regulations** ; • ~~reduced protection of~~ **challenges enforcing our contractual and** intellectual property rights **, especially** in ~~some~~ **those** foreign countries ~~,~~ **that do not respect** and **protect intellectual property rights** ~~related prevalence of generic alternatives~~ to ~~therapeutics~~ **the same extent as the United States** ; • ~~foreign currency exchange rate fluctuations and currency controls~~ **production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad** ; **and** • ~~differing foreign reimbursement landscapes; •~~ **business interruptions resulting from geo- political actions, including war and terrorism, trade policies, treaties and tariffs. These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations. Risks Related to Our Intellectual Property Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in- licensing relevant issued patents or pending applications from third parties. Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our future licensors will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our licensors' proprietary rights is** uncertain **. Only limited protection may be available** and ~~potentially~~ **may not** ~~inadequate~~ -- **adequately** ~~reimbursement of~~ **protect our rights** ~~our~~ -- **or permit us** ~~products; and • the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute. If risks related~~ to **gain or keep** any ~~of~~ **competitive advantage.** ~~these~~ **These** uncertainties ~~materializes, it~~ **and / or limitations in our ability to properly protect the intellectual property rights relating to our product candidates** could have a material adverse effect on our **financial condition and results of operations. We cannot be certain that the claims in our United States pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our future licensors, will be considered patentable by the United States Patent and Trademark Office (" USPTO "), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following: • the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction; • patent applications may not result in any patents being issued; • the FDA and its counterparts in other countries require detailed information of clinical trials to be included in certain public forums which may limit the patentability of certain disclosed inventions; • patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage; • our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already**

obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates; • there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and • countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates. The patent prosecution process is also expensive and time- consuming, and we and any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or any future licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising from, for example, conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. In addition, the laws of some countries may prohibit the contractual assignment of intellectual property prior to its creation. The assignment of intellectual property rights may not be self- executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority or entitlement disputes. 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. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Since patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we were in the past or will be in the future the first to file any patent application related to our product candidates. For example, some patent applications in the United States may be maintained in secrecy until the patents are issued. Further, publications in the scientific literature often lag behind actual discoveries. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in the public domain. In some cases, the work of certain academic researchers in the cancer therapeutics field has entered the public domain, which may preclude our ability to obtain patent protection for certain inventions relating to such work. Consequently, we cannot be certain that others have not filed patent applications for technology covered by our owned, and any of our future in- licensed, issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent or first to file an application for the technology. In addition, although we enter into non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third- party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. ~~Clinical trial and product liability lawsuits~~ **Even if we are successful in defending** against **such claims, litigation could result in substantial costs and distraction to management and other employees. In addition, the laws of some foreign countries, such as China where some of our CROs are based, may not protect our intellectual property rights to the same extent as do the laws of the United States and, even if they do, uneven enforcement and procedural barriers may exist in such countries. Damage awards resulting from successful litigation in foreign jurisdictions may not be in amounts commensurate with damage awards in the U. S. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not amenable to patent protection. Although we generally require all of our employees to assign their inventions to** us ~~could divert~~ **, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know- how, information,** ~~our~~ **or** ~~resources~~ **technology to enter into confidentiality agreements , we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. In addition, while we have undertaken reasonable efforts to ensure such agreements are enforceable and that employees and third parties comply with their obligations thereunder, these agreements may be found insufficient by a court of law or may be breached, or we may not enter into sufficient agreements with such individuals in the first instance, in either case potentially resulting in the unauthorized use or**

disclosure of our trade secrets and other intellectual property, including to our competitors, which could cause us to ~~incur substantial liabilities~~ **lose any competitive advantage resulting from this intellectual property. Individuals not subject to invention assignment agreements may make adverse ownership claims to our current** and **future intellectual property. Moreover, our competitors may independently develop knowledge, methods and know- how equivalent to our trade secrets. Competitors could purchase our products, if approved, and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Enforcing a claim that a third- party entity illegally obtained and is using any of our trade secrets is expensive and time- consuming, and the outcome is unpredictable, and we may not be able to obtain adequate remedies for such breaches. 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 intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our future licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates. In fact, patent applications may not issue as patents at all. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and our scope can be reinterpreted after issuance. Even if patent applications we own or in- license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in- license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our future licensors by developing similar or alternative technologies or products in a non- infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability, and our patents or the patents of our future licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third- party pre- issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post- grant review (" PGR ") and inter partes review (" IPR "), or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates 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. Moreover, our patents or the patents of our future licensors may become subject to post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our future licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which** could limit **our ability to stop others from using or** ~~commercialization~~ --- **commercializing similar or identical technology and products, or limit the duration** of ~~any~~ **the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to develop** products that **are similar to our product candidates but that are not covered by the claims of the patents that** we **own or license; • we or our future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license; • we or our future licensors or collaborators might not have been the first to file patent applications covering certain of our inventions; • others** may **independently** develop **similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that the pending patent applications we own or license will not lead to issued patents; • issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • we or our licensors may fail to meet**

obligations to the U. S. government with respect to any future in- licensed patents and patent applications funded by U. S. government grants, leading to the loss of patent rights; • we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs; • we may not successfully commercialize the product candidates, if approved, before our relevant patents expire; • the patents of others or pending or future applications of others may have an adverse effect on our business; and • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, it could significantly harm our business, results of operations and prospects. Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts. Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and / or corresponding foreign patent offices. Numerous third- party United States and foreign issued patents and pending patent applications exist in the fields in which we are developing 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 the use or manufacture of our product candidates. As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications can take many years to issue, there may be currently- pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third- party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Generative artificial intelligence resources that are publicly available present a risk that a company may inadvertently obtain, incorporate, or use a third party' s intellectual property. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could: • result in costly litigation that may cause negative publicity; • divert the time and attention of our technical personnel and management; • cause development delays; • prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law; • require us to develop non- infringing technology, which may not be possible on a cost- effective basis; • subject us to significant liability to third parties; or • require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non- exclusive, which could result in our competitors gaining access to the same technology. Although no third party has asserted a claim of patent infringement against us as of the date of this Annual Report on Form 10- K, others may hold proprietary rights that could prevent our product candidates from being marketed. It is possible that a third party may assert a claim of patent infringement directed at any of our product candidates. Any patent- related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market 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 . We ~~face~~ **cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary. Accordingly,** an ~~inherent~~ **adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and results of operations. In addition, intellectual property litigation, regardless of our outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a** risk **that some** of **our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Because our development programs may in the future 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 third- party proprietary rights. Because our development programs may in the future 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 third- party proprietary rights. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary for development and commercialization of our product candidates, either as a monotherapy or in combination with other drugs. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical ~~trial~~ development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make ~~and~~ an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product ~~liability exposure related~~ candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents or our future licensors' patents could be found invalid or unenforceable if challenged in court. Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in- license is not valid, is unenforceable and / or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our future licensors is invalid and / or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non- enablement, or obviousness- type double ~~testing~~ patenting . Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re- examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). The outcome following legal assertions of invalidity and / or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our future licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology, or any product candidates that we may develop . Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if resolved in ~~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 ~~United States~~ U.S. non- provisional filing date.Various extensions may be available,but the life of a patent,and the protection it affords,is limited.Even if patents covering ~~our~~ any product candidates are obtained,once the patent life has expired,we may be open to competition from competitive products ,including generics or biosimilars .Given the amount of time required for the development,testing and regulatory review of new product candidates,patents protecting such candidates might expire before or shortly after such candidates are commercialized.As a result,our owned and licensed patent portfolio may not provide us with sufficient rights ~~to exclude~~ clinical ~~trials,~~ and preclinical data and launch their product earlier than might otherwise be the case. We may not be able to protect our intellectual property rights throughout the world. Although we have pending patent applications in the United States and will ~~face~~ aspects of our ~~future licensors~~ business,could put our patents at risk of being invalidated or interpreted narrowly ~~and~~ ,could put our patent applications ~~or the patent applications of our future licensors~~ at risk of not issuing , and could provoke third parties to assert claims against us.We may not prevail in any lawsuits that we initiate,and the damages or other remedies awarded,if any,may not be commercially meaningful.Accordingly,our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.Many countries have compulsory licensing laws under which a patent owner may be compelled to ~~grant licenses~~ an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an ~~even~~ event ~~greater risk if we commercially sell any products that we may develop~~ were to occur, it could have a material adverse effect on our business . ~~While we currently~~ If our trademarks and trade names are not ~~developing~~ adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We

intend to use trademarks or trade names to brand our products. 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, which we need to build name recognition among potential partners or customers in our markets of interest. We have not registered any **of our trademarks, which could adversely affect our ability to defend our trademark rights. 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 trademarks that incorporate variations of our trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our 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 affect our financial condition or results of operations. We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets. We have entered into and may enter in the future into non- disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third- party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our** product candidates and **technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they** have **substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others. We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may ~~no~~ not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and** products **in the future. In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future product candidates that are the subject of such licensed rights could be adversely affected. Our future licensors may rely on third- party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in- license. If other third parties have ownership rights to our future in- licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. 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 redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to**

develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business. Disputes may arise between us and our future 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 patents and other rights to third parties; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • our right to transfer or assign the license; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and • the priority of invention of patented technology. In addition, the agreements under which we license intellectual property or technology from third parties 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. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. Despite our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in- licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors will have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Intellectual property discovered through government funded programs may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for United States- based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- United States manufacturers. Although we do not currently own issued patents or pending patent applications that have been ~~approved~~ generated through the use of United States government funding, we may acquire or license in the future intellectual property rights that have been generated through the use of United States government funding or grants. Pursuant to the Bayh- Dole Act of 1980, the United States government has certain rights in inventions developed with government funding. On December 8, 2023, the National Institute of Standards and Technology (" NIST") released the Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights (" Guidance ") to the public for comment. The Guidance represents the first federal framework specifying that price can be a factor in considering whether the government may exercise its march- in authority pursuant to 35 U. S. C. 200 et seq. (Bayh- Dole). These United States government march- in rights include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to ~~commercial~~ commercialize ~~sale,~~ the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations, also referred to as march- in rights. If the United States government exercised its march- in rights in our future intellectual property rights that are generated through the use of ~~product candidates~~ United States government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to ~~in clinical trials, and the sale of any approved products in the future, may expose~~ us , and there can ~~to liability claims. These claims might~~ be no assurance ~~made by patients~~ that ~~use~~ we would receive compensation from the United States government ~~product, healthcare providers, pharmaceutical companies or~~ for ~~others selling~~ the exercise of such ~~products~~ rights . ~~If we cannot successfully defend ourselves against claims~~ The United States government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for United States industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States industry may limit our ability to contract with non- United States product ~~candidates~~ manufacturers ~~or~~ for products ~~we may develop caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any~~

~~product candidates or products that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend any related litigation; • substantial monetary awards to trial participants or patients; • loss of revenue; • reduced resources of our management to pursue our business strategy; and • the inability to commercialize any products that we may develop. Although we currently hold clinical trial liability insurance coverage in amounts we believe to be adequate with respect to completed and discontinued clinical trials, we may need to increase our insurance coverage if we decide to pursue any future product development efforts and or if we commence commercialization of any product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover~~ **covered by** such **intellectual property** ~~claims and our business operations could be impaired~~ . Risks Related to Our Dependence on Third Parties **We rely on third parties to conduct preclinical studies and clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies. We currently utilize and depend upon, and plan to utilize and depend upon, independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners to conduct and support our preclinical studies and clinical trials under agreements with us. For example, we use Pharmaron to conduct preclinical studies and clinical trials and provide us with APIs. Since Pharmaron 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 of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs on the APIs we obtain from Pharmaron. Any of these matters could materially and adversely affect our business and results of operations. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In the future, we may also rely on third parties for the manufacture of any companion diagnostics we may develop. These third parties have had and will continue to have a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. Our third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our preclinical studies or clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. Some of these third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with CROs, clinical trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines. Our heavy reliance on these third parties for such drug development activities will reduce our control over these activities. As a result, we will have less direct control over the conduct, timing and completion of preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients, may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. We contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials and expect to do so ultimately for commercialization, and the loss of these third parties or their inability to supply us with sufficient quality and quantities of our product candidates or such quantities at an acceptable cost could delay, prevent or impair our development or commercialization efforts. We do not**

currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third- party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. Any supply interruption in limited or sole sourced materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. To date, we have obtained APIs and drug product for our product candidates from certain single- source CMOs. Any performance failures by such CMOs could materially harm our business. We do not have long- term supply agreements and may not be able to secure supply agreements, and we purchase our required drug product on a purchase order basis, which means that aside from any binding purchase orders we have from time to time, our supplier could cease supplying to us or change the terms on which it is willing to continue supplying to us at any time. If we were to experience an unexpected loss of supply of any of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing preclinical studies or clinical trials. We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third- party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on third-party manufacturers entails additional risks, including: • the failure of the third party to manufacture our product candidates according to our schedule and specifications, or at all, including if our third- party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them; • the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms; • the termination or nonrenewal of arrangements or agreements by our third- party contractors at a time that is costly or inconvenient for us; • the breach by the third- party contractors of our agreements with them; • the failure of third- party contractors to comply with applicable regulatory requirements, including cGMPs; • the failure of the third party to manufacture our product candidates according to our specifications; • the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified; • the inability of our third- party contractors to import or export our product candidates internationally; • clinical supplies not being delivered to clinical sites on time, or at all, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, or at all, resulting in lost sales; and • the misappropriation of our proprietary information, including our trade secrets and know-how. We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for compliance with cGMP regulations for manufacturing both APIs and finished drug products. Our CMOs are also subject to import and export rules and restrictions, which may impact their ability to acquire materials used in the manufacturing of our product candidates or export our manufactured investigational products to the countries where our clinical trials are conducted. To date, we have obtained most of our APIs and drug product for our product candidates, from single- source third- party CMOs. We are in the process of developing our supply chain for each of our product candidates and intend to put in place framework agreements under which third- party CMOs will generally provide us with necessary quantities of APIs and drug product on a project- by- project basis based on our development needs. As we advance our product candidates through development, we are considering our lack of redundant supply for the APIs and drug product for each of our product candidates to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities, they will not be able to secure and / or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by FDA, EMA or comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third- party manufacturers, 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 our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis. Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals. In order to commercially produce our products, if approved, either at a third party' s facility or in any of our facilities, we will need to comply with the FDA' s cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may

experience shortages of qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our precision medicines for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non- compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business. If our third- party manufacturers use hazardous materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third- party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations. If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, product candidates, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: • increased operating expenses and cash requirements; • the assumption of additional indebtedness or contingent liabilities; • the issuance of our equity securities; • assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel; • the diversion of our management' s attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition; • retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products, product candidates and marketing approvals; and • our inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions or pursues partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. If we decide to establish collaborations but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans. Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. We may also seek strategic collaborations to develop combination therapy strategies for our portfolio products, and / or maximize portfolio value globally through selective co- development and / or commercialization collaborations. Any of these relationships may require us to incur non- recurring and other charges, increase our near- and long- term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. We face significant competition in seeking appropriate collaborators and the negotiation process is time- consuming and complex. Whether we reach a definitive agreement for a collaboration depends, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of preclinical studies or clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative efforts and third parties may not view them as having the requisite potential to demonstrate safety and efficacy. In addition, there have been a significant number of business combinations among large pharmaceutical companies, and business combinations could result in a reduced number of potential future

collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators. If and when we seek to enter into collaborations, 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 a product candidate, reduce or delay our development program or one or more of our other research programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may 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 our product candidates or bring them to market and generate product revenue. We may enter into collaborations with third parties for the development ~~or~~ **and** commercialization of product candidates. If ~~our~~ **those** collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates ~~and our business could be adversely affected~~. **If** ~~We are not currently party to any sales, marketing, distribution, development, licensing or broader collaboration arrangements with ongoing activities. However, if~~ we ~~do~~ enter into any ~~such~~ **collaboration** arrangements with any third parties ~~in~~ **for** the ~~future~~ **development and commercialization of our product candidates**, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of ~~any~~ **our** product candidates ~~we may develop~~. Our ability to generate ~~revenues~~ **revenue** from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations **involving our product candidates would** ~~that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations~~ pose **numerous** ~~a number of~~ risks **to us**, including the following: • collaborators have significant discretion in determining the ~~amount and timing of~~ efforts and resources that they will apply to these collaborations **and** ~~; • collaborators~~ may not perform their obligations as expected; • collaborators may **deemphasize or** not pursue **development and** commercialization of ~~any~~ **our** product candidates ~~we may develop that achieve regulatory approval~~ or may elect not to continue or renew **development or** commercialization programs based on **clinical trial** results ~~of clinical trials or other studies~~, changes in the collaborators' strategic focus **, including as a result of a business combination or sale or disposition of a business unit or development function,** or available funding ~~,~~ or external factors ~~,~~ such as an acquisition ~~,~~ that ~~may divert~~ **diverts** resources or ~~create~~ **creates** competing priorities **; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing**; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with ~~any~~ **our** product candidates ~~and products~~ if the collaborators believe that ~~the~~ competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • **a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products; • we may grant exclusive rights to our collaborators that would prevent us from collaborating with others; • collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings; • disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our** product candidates ~~discovered in collaboration with us may be viewed by our~~ **or that result in costly litigation** ~~collaborators as competitive with their own product candidates~~ or **arbitration that diverts management attention and** ~~products, which may cause collaborators to cease to devote~~ resources **; • collaborations may be terminated and, if terminated, may result in a need for additional capital** to ~~the~~ **pursue further development or** commercialization of ~~any~~ **the applicable** product candidates; • ~~a collaborator~~ **collaboration** ~~may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product; • disagreements~~ **agreements may not lead to** ~~with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research,~~ development or commercialization of product candidates **in the most efficient manner** ~~, might lead to additional responsibilities for~~ **or at all** ~~us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive~~; • collaborators ~~may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability; and • collaborations may be terminated for the convenience of the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of any product candidates could be delayed and we may need additional resources to develop any product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10- K also apply to the activities of our collaborators. Additionally, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination, the collaborator might**

deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected. If we are not able to establish or maintain collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected. In connection with any future product development efforts, we may decide to collaborate with pharmaceutical or biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third- party intellectual property rights that we consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical and biotechnology companies that have resulted in a reduced number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop any product candidates or bring them to market. If we decide to pursue any future product development efforts, we expect to rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may harm our business. We historically have relied on third-party clinical research organizations to conduct our clinical trials, including our discontinued Ardent and Forte Phase 2b clinical trials in SCD and in β- thalassemia. If we decide to pursue any future product development efforts, we do not expect to independently conduct clinical trials of any such product candidates. We expect we would rely on third parties, such as clinical research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct any such clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities, should we pursue them, might be delayed. Our reliance on these third parties for research and development activities would reduce our control over these activities but will not relieve us of our responsibilities. For example, we would remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize any product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. We also expect to rely on other third parties to store and distribute drug supplies for any clinical trials we may conduct. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may successfully develop and commercialization of our products, producing additional losses and depriving us of potential product revenue. If we decide to pursue any future product development efforts, we expect to contract with third parties for the manufacture of any product candidates we may develop for preclinical and clinical testing and would expect to continue to do so for commercialization. This reliance on third parties entails risks, including that such third parties may not be able to comply with applicable regulatory requirements. Any performance failure on the part of our manufacturers could delay clinical development or marketing approval. We do not have any manufacturing facilities and if we decide to pursue any future product development efforts, we expect to rely on third parties for the manufacture of any product candidates for preclinical and clinical testing. Reliance on third- party manufacturers entails additional risks, including: • reliance on the third- party for regulatory compliance and quality assurance; • the possible breach of the manufacturing agreement by the third- party; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; and • the possible termination or nonrenewal of the agreement by the third- party at a time that is costly or inconvenient for us. Third- party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements

outside of the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Any product candidates or products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. Historically, we relied on a single manufacturer of active pharmaceutical ingredient and a different single manufacturer for finished drug product in the development of our product candidates. If we decide to pursue any future product development efforts, we expect we may similarly rely on a single or limited number of manufacturers at each stage of the manufacturing process. If any of our future contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture any product candidates we may develop, we may incur added costs and delays in identifying and qualifying any such replacement. Our current and anticipated future dependence upon others for the manufacture of any product candidates or products we may develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. Risks Related to our Intellectual Property If we are unable to obtain, maintain, enforce and protect patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected. If we decide to pursue any future product development efforts, our success will depend in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others or may license from others, particularly patents, in the United States and other countries with respect to any proprietary technology and product candidates we develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to any product candidates we may develop that are important to our business and by in- licensing intellectual property related to our technologies and product candidates. If we are unable to obtain or maintain patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed. The patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. Therefore, these in- licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business. The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the scope of patent protection outside of the United States is uncertain and laws of non- U. S. countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. With respect to both owned and in- licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Further, we may not be aware of all third- party intellectual property rights potentially relating to any product candidates we may develop. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing of the priority application, or in some cases not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in- license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and in- licensed patent rights are highly uncertain. Moreover, our owned and in- licensed pending and future patent applications may not result in patents being issued that protect our technology and product candidates, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value of, or narrow the scope of, our patent rights. Moreover, we or our licensors may be subject to a third- party pre- issuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third- party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Patents may never issue from our patent applications, or the scope of any patent may not be sufficient to provide a competitive advantage. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in- licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection,

prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in- licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our owned or in- licensed patents by developing similar or alternative technologies or products in a non- infringing manner. As a result, our owned and in- licensed patent portfolio may not provide us with **timely** sufficient rights to exclude others from commercializing technology and products similar or identical to any of **accurate information regarding development progress and activities under the collaboration** our - **or** technology **may limit our ability to share such information, which could adversely impact our ability to report progress to our investors** and **otherwise plan our own development of our** product candidates . Patent terms **; • collaborators** may be inadequate to protect our competitive position on **own** any **or co- own intellectual property covering our products or** product candidates for **that result from our collaborating with them,** an **and** adequate amount of time. Patents **in such cases, we would not** have a limited lifespan. In the **exclusive** United States, if all maintenance fees..... may not provide us with sufficient rights - **right** to exclude others from commercializing products similar or identical to ours. Given the expected expiration date of these patents, and the fact that safe harbor protections in many jurisdictions permit third parties to engage in development ---- **develop** , including clinical trials, these patents may not provide us with a meaningful competitive advantage. If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our - **or** obligations under such agreements, our business could be harmed. If we decide to pursue any future product development efforts, it may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property **;** rights could seek either an **and •** injunction prohibiting our sales or an obligation on our part to pay royalties and / or other forms of compensation. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly. Additionally, if we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. If we do not obtain patent term extension in the United States under the Hatch- Waxman Act and in non- U. S. countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed. In the United States, the patent term of a patent that covers an FDA- approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non- United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when any product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any non- U. S. country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed. It is

possible that we will not obtain patent term extension under the Hatch- Waxman Act for a U. S. patent covering any product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO a petition for patent term extension under the Hatch- Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch- Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO. Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering any product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If a product candidate is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate. Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy- Smith America Invents Act, or the Leahy- Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in- licensed patent applications and the maintenance, enforcement or defense of our owned and in- licensed issued patents. The Leahy- Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost- effective avenues for competitors to challenge the validity of patents, and enable third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO- administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith Act, the United States transitioned to a first- to- file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third- party was the first to invent the claimed invention. As such, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. We and our licensors, and any future licensors, may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Competitors and other third parties may infringe, misappropriate or otherwise violate our or our current and future licensors' issued patents or other intellectual property. As a result, we or any current or future licensor may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time- consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post- grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in non- U. S. jurisdictions (e. g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any such proceeding could put one or more of our owned or in- licensed patents at risk of being invalidated or interpreted narrowly and could put any of our owned or in- licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third- party from using the technology at issue in a proceeding on the grounds that our owned or in- licensed patents do not cover such technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and prospects. Interference or derivation proceedings provoked by third parties, or brought by us or by our licensors, or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non- exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and,

even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring any product candidates to market. Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. If we decide to pursue any future product development efforts, our commercial success depends upon our ability and the ability of our collaborators - **collaborator** to develop, manufacture, market and sell any product candidates we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in non- U. S. jurisdictions such as oppositions before the European Patent Office. Numerous U. S. and non- U. S. issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties. The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time- consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as any product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third- party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third- party - ' s **sales and marketing activities or** intellectual property. Third parties may assert that we are employing their - **other operations** proprietary technology without authorization. There may **not** be **in compliance** third- party patents or patent applications with **applicable laws resulting in civil** claims to materials, formulations or methods, such as methods of manufacture or methods for - **or criminal proceedings** treatment, related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies . **Our operating results** Because patent applications can take many - **may fluctuate significantly** years to issue , there may be currently pending patent applications which **makes our** may later result in issued patents that the product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third- party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, be forced to indemnify our customers or collaborators or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third- party' s intellectual property rights, we could also be required to obtain a license from such third- party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. A finding of infringement could prevent us from commercializing any product candidates or force us to cease some of our business operations - **operating** , which could materially harm our business. In addition, we may be forced to redesign any product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results **difficult** of operations and prospects. Intellectual property litigation or other legal proceedings relating to intellectual property **predict and** could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or **our operating** 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 **to fall below expectations or** or **our guidance. Our quarterly** other interim proceedings or developments and **annual operating** if securities analysts or

~~investors perceive these~~ results **may fluctuate significantly in** ~~to be negative, it could have a substantial adverse effect on~~ the ~~price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any~~ future ~~sales~~, ~~marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and non- U. S. patent agencies in several stages or annually over the lifetime of our owned and in- licensed patents and patent applications. The USPTO and various non- U. S. governmental patent agencies also require compliance with a number of procedural, documentary and other similar provisions during the patent application process. In certain circumstances, we may rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service, outside firms and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in~~ which ~~non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our current or future licensors fail to maintain the patents and patent applications covering any product candidates, it may have a material adverse effect on our business, financial condition, results of operations and prospects. We may not be able to protect our intellectual property and proprietary rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of non- U. S. countries may not protect our rights to the same extent as the laws of the United States. In addition, the laws of some non- U. S. countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in non- U. S. jurisdictions. The legal systems of certain countries do not favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to biotechnology products, which could make~~ **makes** it difficult for us to **predict** ~~stop the infringement of our patents or~~ **our future** ~~marketing of competing~~ -- **operating** ~~products in violation of~~ **results. From time to time, we may enter into license** ~~our~~ - **or** ~~intellectual property~~ **collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and / or royalties, which may become** ~~and~~ - **an** ~~proprietary rights generally~~ **important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next**. In addition, **we measure compensation cost** ~~certain jurisdictions do not protect to the same extent or~~ **for stock- based awards made to employees** at ~~all inventions that constitute new methods of treatment. Proceedings to enforce our intellectual property and proprietary rights in non- U. S. jurisdictions could result in substantial costs and divert our efforts and attention from other~~ -- **the** aspects of our business, could put..... a patent owner may be compelled to grant **date** ~~licenses to third parties. In addition, many countries limit the enforceability~~ of ~~patents against government agencies or government contractors. In these~~ -- **the** ~~countries~~ **award** , **based on** the **fair** ~~patent owner may have limited remedies, which could materially diminish the~~ value of ~~such patent. If we~~ **the award as determined by** ~~or~~ **our** ~~any~~ **board** of **directors** ~~our current or future licensors is forced to grant a license to third parties with respect to any patents relevant to our business~~, ~~our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an~~ **and recognize** ~~interest in our owned or in- licensed patents, trade secrets or other~~ -- **the cost** ~~intellectual property~~ as an ~~inventor~~ **expense over the employee' s requisite service period. As the variables that we use as a basis** ~~or~~ **for** ~~eo~~ **valuing these awards change over time, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following: • the timing and cost of, and level of investment in, research and development activities relating to our programs, which will change from time to time; • our ability to enroll patients in clinical trials and the timing of enrollment; • the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with**

manufacturers; • expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets; • the timing and outcomes of preclinical studies and clinical trials for ELVN - 001 ~~inventor. For example~~ , **ELVN- 002 and** ~~we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing~~ any product candidates ~~. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in- licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to any product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, or we have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Certain of our employees, consultants and contractors were previously employed at universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and contractors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer. Litigation may be necessary to defend against these claims. In addition, while it is our policy to require that our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations and prospects. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third- party, and we could be required to obtain a license~~ from ~~such third- party to commercialize our technology or~~ **our** ~~products, which license may not be available on commercially reasonable terms, or at all, or such license may be non- exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed. In addition to seeking patents for any product candidates we may seek to develop, we also rely on trade secrets and confidentiality agreements to protect our unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract~~ research ~~organizations~~ **programs** , ~~contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our~~ - **or** ~~employees and consultants, but we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third- party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete~~ **competing** ~~with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third- party, our competitive position may be materially and adversely harmed. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own; • we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future; • we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in- licensed intellectual property rights; • it is possible that our owned and in- licensed pending patent applications or those we may own or in- license in the future will not lead to issued patents; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect any~~ product candidates; • ~~we cannot ensure~~ **the need to conduct unanticipated clinical trials or trials** that **are larger or more complex than anticipated; • our ability to develop combination drug products or companion diagnostics; • our ability to acquire drug product for combination trials; • competition from existing and**

potential future products that compete with ELVN- 001, ELVN- 002 or any **of** ~~patents issued to us or~~ **our** ~~our current~~ **research programs, and changes in the competitive landscape of** ~~or~~ **our** ~~future licensors will provide a basis~~ **industry, including consolidation among our competitors or partners; • any delays in regulatory review or approval of ELVN- 001, ELVN- 002 or any of our other research programs; • the level of demand** for ~~an~~ **any of** ~~exclusive market for~~ our ~~commercially viable~~ product candidates ~~or will provide us with any competitive advantages~~ **, if approved, which may fluctuate significantly and be difficult to predict** ; • ~~we cannot ensure that our commercial activities~~ **the risk / benefit profile, cost and reimbursement policies with respect to** ~~or~~ **our** product candidates ~~will not infringe upon the patents~~ **, if approved, and existing and potential future products that compete with ELVN- 001, ELVN- 002 or any** of **our** ~~others~~ **other research programs** ; • ~~we cannot ensure~~ **our ability to commercialize ELVN- 001, ELVN- 002 or any of our research programs, if approved, inside and outside of the United States, either independently or working with third parties; • our ability to establish and maintain collaborations, licensing or other arrangements; • our ability to adequately support future growth; • potential unforeseen business disruptions** that ~~we will be able~~ **increase our costs or expenses; • future accounting pronouncements or changes in our accounting policies; and • the changing and volatile global economic and political environment. The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-** to ~~successfully commercialize~~ **- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for** any **period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. Risks Related to Our Common Stock The market price of our common stock has been and is likely to continue to be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include: • timing and results of INDs, preclinical studies and clinical trials of our** product candidates ~~on a substantial scale~~ , **or** ~~if approved, before the~~ **those of** ~~relevant patents that we own or~~ **our** ~~license expire~~ **competitors or our existing or future collaborators** ; • ~~we may not~~ **failure to meet or exceed financial and** ~~develop~~ **development** ~~additional proprietary technologies that are patentable~~ **projections we may provide to the public** ; • **failure to meet** ~~the patents of others may harm our~~ **or** ~~business~~ **exceed the financial and development projections of the investment community** ; ~~and~~ • **announcements** ~~we may choose not to file a patent in order to maintain certain technology as a trade secrets or know- how, and a third- party may subsequently file a patent application covering such technology. Should any~~ of **significant acquisitions** ~~these events occur~~ , **strategic collaborations, joint ventures** ~~they could have a material adverse effect on our~~ **or capital commitments by us or our competitors; • actions taken by** ~~business, financial condition, results of operations and prospects. Risks Related to Regulatory~~ **regulatory agencies with respect** ~~Approval of Our Product Candidates and Other Legal Compliance Matters If we decide~~ to **our** ~~pursue any future~~ product **candidates** ~~development efforts~~ , ~~even if we complete the necessary preclinical studies and~~ clinical trials, ~~the~~ **manufacturing process or sales and** marketing ~~approval process is expensive~~ **terms; • disputes or other developments relating to proprietary rights** , ~~time~~ **including patents, litigation matters, and our ability to obtain patent protection for our technologies; • additions or departures of key personnel; • significant lawsuits, including patent or stockholder litigation; • 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; • geo** - ~~consuming~~ **political developments, general market or macroeconomic conditions including inflation and interest rates; • market conditions in the pharmaceutical and biotechnology sectors; • expiration of market** ~~and~~ **stand** ~~uncertain and may prevent~~ **- off or lock- up agreements; • changes in the structure of healthcare payment systems; • announcement of expectation of additional financing efforts; • sales of securities by** us ~~from obtaining approvals for~~ **or our securityholders in** the ~~commercialization of~~ **future; • if we fail to raise** ~~any~~ **an adequate amount of capital to fund our operations and continued development of our** product candidates **; • trading volume of** ~~. If we are not able to obtain, or~~ **our common stock; • publicity** ~~if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize any product candidates, and our~~ **or announcements** ~~ability to generate revenue will be materially impaired. If we decide to pursue any future product development efforts, any product candidates we may develop and the activities associated with their development and commercialization, including design, testing, manufacture, packaging, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export, import and adverse event reporting, are subject to comprehensive regulation~~ by **competitors** ~~the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside~~ of ~~the United States. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of any such product candidates. Marketing approval of drugs in the United States requires the submission of a~~ new ~~drug application, or NDA, to the FDA and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the NDA for that product. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, toxicology, and chemistry, manufacturing and controls. We have not submitted an application for or received marketing approval for any product candidates we may develop in the United States or in any other jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third- party clinical research organizations or other third- party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing processes to, and inspection of manufacturing facilities by, the regulatory~~

authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of any product candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product. The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate in various countries. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for any product candidates may be harmed and our ability to generate revenues will be materially impaired. We may not be able to obtain or maintain orphan drug designation or exclusivity for any product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products . If we decide to pursue any future product development efforts, we may seek orphan drug designation in indications or for **or success** any product candidates we develop. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because competing drugs containing a different active ingredient can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. On August 3, 2017, the U. S. Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA' s pre- existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term " same disease or condition " means the designated " rare disease or condition " and could not be interpreted by the FDA to mean the " indication or use. " We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process. If we decide to pursue any future product development efforts, we may seek Fast Track designation for product candidates we may develop. If a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot be certain that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Accelerated approval by the FDA, even if granted for any product candidates does not increase the likelihood that any product candidates will ultimately receive full approval. If we decide to pursue any future product development efforts, we may seek approval of any other product candidates we may develop using the FDA' s accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life- threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. The FDA makes the determination regarding whether to accept a biomarker as a proposed surrogate endpoint. Prior to seeking such accelerated approval, we will request feedback from the FDA regarding the eligibility of the drug product candidate for accelerated approval and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of accelerated approval, the FDA will require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well- controlled post- marketing clinical trials. These confirmatory trials must be

completed with due diligence and we may be required to evaluate different or additional endpoints in these post- marketing confirmatory trials. In addition, the FDA currently requires as a condition for accelerated approval pre- clearance of promotional materials prior to use, which could adversely impact the timing of the commercial launch of the product. There can be no assurance that the FDA will agree with our surrogate endpoints or intermediate clinical endpoints, or that we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all. Moreover, as noted above, for drugs granted accelerated approval, the FDA requires post- marketing trials to confirm the benefit of the drug. These confirmatory trials must be completed with due diligence. We may be required to evaluate additional or different clinical endpoints in these post- marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for any product candidates we may develop, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace. Even if we do receive accelerated approval, we may not ultimately be able to obtain full FDA approval. If we decide to pursue any future product development efforts, a failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates from being marketed abroad. If we decide to pursue any future product development efforts, in order to market and sell our products in the European Union and many other foreign jurisdictions, we or our potential third- party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the product be approved for reimbursement before the product can be made available for sale in that country. We or our potential third- party collaborators may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and European Union Customs Union. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to European Union rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012 / 1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law of the United Kingdom the body of European Union law governing medicinal products that pre- existed prior to the United Kingdom' s withdrawal from the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business. We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States. Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development

activities, is subject to the political process, which is inherently fluid and unpredictable. For example, over the last several years the U. S. government has shut down several times and certain regulatory agencies, such as **asciminib)** the FDA and the SEC , have had to furlough critical **clinical** FDA **progress or lack thereof** , SEC and **significant contracts, commercial relationships or capital commitments; • the impact of any natural disasters, public health emergencies, health epidemics or** other **outbreaks** government employees and stop critical activities. If a prolonged government shutdown occurs , **such as** it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Separately, in response to the COVID- 19 pandemic , a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. As of May 26, 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID- 19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre- approval inspection or an inspection of clinical sites is required and due to the COVID- 19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic and may experience delays in their regulatory activities. Accordingly, if a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets If we decide to pursue any future product development efforts, any product candidate for which we obtain marketing approval could be subject to post- marketing restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved. If we decide to pursue any future product development efforts, any product candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS. If any product candidate receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, including the adoption and implementation of REMS. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post- approval marketing and promotion of drugs to ensure, among other things, that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies impose and enforce stringent restrictions on manufacturers' communications regarding off- label use, and if we promote our products beyond their approved indications, we may be subject to enforcement action or prosecution arising from off- label promotion. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product. Violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, and other statutes and regulations relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, including the False Claims Act, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have various consequences, including: • suspension of or restrictions on such products, manufacturers or manufacturing processes ; • restrictions and warnings on the **introduction** labeling or marketing of a **technological innovations or new** product **candidates that compete with** ; • restrictions on product distribution or **our** use; • requirements to conduct post- marketing studies or clinical trials; • warning letters or untitled letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenues; • suspension of any ongoing clinical trials; • suspension or withdrawal of marketing approvals; • damage to relationships with any potential collaborators; • unfavorable press coverage and damage to our reputation; • refusal to permit the import or export of our products; • product seizure or detention; • injunctions or the imposition of civil or criminal penalties; or • litigation involving patients using our products. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post- marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping, and costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a REMS. Similar restrictions apply to the approval of our products in the

European Union. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the European Union' s stringent pharmacovigilance or safety reporting rules, which can impose post- authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer' s license is mandatory; and the marketing and promotion of authorized drugs, which are strictly regulated in the European Union and are also subject to European Union Member State laws. The failure to comply with these and other European Union requirements can also lead to significant penalties and sanctions. We may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings. Healthcare providers, third- party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with healthcare providers and third- party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Potentially applicable U. S. federal and state healthcare laws and regulations include the following: • the federal Anti- Kickback Statute, prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an **and** individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare programs such as Medicare and Medicaid; • The federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions against individuals or entities for knowingly presenting, or causing to be presented to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; **and** • **period** the federal Physician Payments Sunshine Act requires..... and regulations, such as state anti - kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non - **period fluctuations** governmental third party payors, including private insurers and some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or **our financial results** marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. Payments made to physicians in certain European Union Member States must be publicly disclosed . Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization and / or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they - **the stock markets** may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant lawsuits or fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations. The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding data subjects in the European Union, including personal health data, is subject to the European Union General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or EEA, in May 2018. The GDPR is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the

individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third- party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that such rules should apply to transfers of personal data from clinical trial sites located in the EEA to the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and / or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. Given the breadth and depth of changes in data protection obligations, complying with the GDPR' s requirements is rigorous and time intensive and requires significant resources and an ongoing review of our technologies, systems and practices, as well as those of any third- party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. Similar privacy and data security requirements are either in place or underway in the United States. There are a broad variety of data protection laws that may be applicable to our activities, and a range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act, or CCPA, which became effective on January 1, 2020, is creating similar risks and obligations as those created by GDPR, although the CCPA does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). Many other states have passed similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with current and any future federal and state laws regarding privacy and security of personal information could expose us to fines and penalties. We also face a threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business. Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain reimbursement for any of our candidate products that do receive marketing approval and our ability to generate revenue will be materially impaired. In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the CARES Act. These Medicare sequester reductions were suspended through the end of March 2022. From April 2022 through June 2022 a 1 % sequester cut will be in effect, with the full 2 % cut resuming thereafter. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Since enactment of the ACA, there have been and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the TCJA in 2017, Congress repealed the " individual mandate. " The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018, a U. S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The U. S. Supreme Court heard this case on November 10, 2020 and on June 17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA.

Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re- examine: policies that undermine protections for people with pre- existing conditions, including complications related to COVID- 19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. Current and future legislative efforts may limit the costs for our products, if and when they are licensed for marketing, and that could materially impact our ability to generate revenues. The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U. S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician- administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule to rescind it. With the issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence- based care. In addition, in October 2020, the Department of Health and Human Services, or HHS, and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule was implemented on January 1, 2023. The rule also creates a new safe harbor for price reductions reflected at the point- of- sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, which was implemented on January 1, 2023. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for any product candidates or additional pricing pressures. Finally, outside the United States, in some nations, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost- effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed. If we or any third- party manufacturers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could harm our business. If we decide to pursue any future product development efforts, we and any third- party manufacturers we may engage will be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. If we decide to pursue any future product development efforts, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We expect we would contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Liability under certain environmental laws governing the release and cleanup of hazardous materials is joint and several and could be imposed without regard to fault. We also could incur significant costs associated with civil or criminal fines and penalties or become subject to injunctions limiting or prohibiting our activities for failure to comply with such laws and regulations. Although we currently maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We currently do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future

laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Further, with respect to the operations of any third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of any product candidates or products. In addition, our supply chain could be adversely impacted if any of our third- party contract manufacturers become subject to injunctions or other sanctions as a result of their non- compliance with environmental, health and safety laws and regulations. We are subject to anti- corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition. Our operations are subject to anti- corruption laws, including the U. K. Bribery Act 2010, or Bribery Act, the U. S. Foreign Corrupt Practices Act, or FCPA, and other anti- corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti- corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti- corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti- corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti- corruption laws or Trade Control laws by United Kingdom, U. S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. Our employees, independent contractors, consultants and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading, which could cause significant liability for us and harm our reputation. We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants and vendors. Misconduct by these partners could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or similar foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U. S. federal and state law, and requirements of non- U. S. jurisdictions, including the European Union Data Protection Directive. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs. Our internal computer systems and those of any collaborators, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and

~~telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third- party vendors and / or business partners, or from cyberattacks by malicious third parties. Cyber incidents are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. For example, we~~ have experienced ~~attempts at phishing and e- mail fraud with the goal of causing payments to be transmitted to an unintended recipient. Cyber incidents could also include the deployment of harmful malware, ransomware, denial- of- service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The risk of cyber incidents could also be increased by cyberwarfare in connection with the ongoing conflict between Russia and Ukraine, including potential proliferation of malware from the conflict into systems unrelated to the conflict. While we have not experienced any material system failure, accident, cyber incidents or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position and reputation could be harmed and the further development and commercialization of any product candidates we may develop could be delayed. Risks Related to Our Common Stock and Our Status as a Public Company An active trading market for our common stock may not continue to develop or be sustained. Our shares began trading on the Nasdaq Global Select Market on March 12, 2020. Prior to March 12, 2020, there was no public market for our common stock, and we cannot be certain that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or at all. If securities analysts do not publish or cease publishing research or reports or publish misleading, inaccurate or unfavorable research about our business or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline. The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not have control over these analysts. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analyst will provide favorable coverage. If one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline. The price of our common stock may be volatile and fluctuate substantially, which could result in~~ substantial ~~losses for our stockholders. Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme~~ volatility that has often been unrelated to the operating performance of ~~particular~~ **individual** companies. **These broad market fluctuations** ~~As a result of this volatility, our stockholders~~ may **also adversely affect** ~~not be able to sell their~~ -- **the trading price of our** common stock ~~at or above the price paid~~ **. In addition, macroeconomic conditions, a recession, depression** ~~for~~ -- **or** ~~their~~ - **other sustained adverse** ~~shares. The~~ market **event** ~~price for our common stock may be influenced by many factors, including: • results~~ **resulting from** ~~of or developments in preclinical studies and clinical trials of any product candidates we may develop or those~~ -- **the spread** of ~~our competitors or potential collaborators; • timing of the results of our preclinical studies and clinical trials or those of our competitors; • our success in commercializing any product candidates, if and when approved; • the success of competitive products or technologies; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to any product candidates we may develop; • the results of our efforts to discover, develop, acquire or in- license products, product candidates, technologies or data referencing rights, the costs of commercializing any such products and the costs of development of any such product candidates or technologies; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • variations in our financial results or the financial results of companies that are perceived to be similar to us; • sales of common stock by us, our executive officers, directors or principal stockholders, or others; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical and biotechnology sectors; • general economic, industry and market conditions, including, without limitation, the current adverse impact of the~~ COVID- 19 ~~pandemic~~ **, the Russia- Ukraine and Israel- Hamas conflicts, or otherwise could materially and adversely affect our business and the value of our 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. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have** ~~and~~ - **an** ~~political~~ **adverse effect on our operating results** and ~~economic instability caused~~ **financial condition. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We have not generated any revenues from the commercial sale of products and will not be able to generate any product revenues until, and only if, we receive approval to sell our product candidates from the FDA or other regulatory authorities. The cash from both us and Former Enliven at closing, including the net proceeds of the Former Enliven pre-closing financing, are expected to fund operations into early 2026. However, as we have not generated any revenue from commercial sales to date and do not expect to generate any revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our general corporate activities and to fund our research and**

development, including our currently planned clinical trials and plans for new clinical trials and product development. We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations or, if such funds are available, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by **issuing equity securities, our stockholders may experience additional significant dilution and new investors could gain rights, preferences and privileges senior to** the **holders of common stock. On June 23, 2023, we filed a shelf registration statement on Form S- 3 with the SEC, which was declared effective by the SEC on July 3, 2023, which allows us to undertake various equity and debt offerings up to $ 400. 0 million (the " Shelf Registration "). On June 23, 2023, we also entered into an Open Market Sale AgreementSM (the " Sales Agreement ") with Jefferies LLC (the " Sales Agent "), pursuant to which we may offer and sell shares of our common stock, from time to time through an " at- the- market " program under the Securities Act, having an aggregate offering price of up to $ 200. 0 million through the Sales Agent. We do not have any committed external source of funds. Debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that may not be favorable. Given our capital constraints, we will need to prioritize spending on our clinical and preclinical programs. If we are unable to raise sufficient funds to support our** current ~~conflict between Russia~~ and ~~Ukraine and~~ **planned operations, we may elect to discontinue certain of our ongoing activities or programs. Our inability to raise additional funds could also prevent us from taking advantage of opportunities to pursue promising new or existing programs in the future. In the event that we would need to obtain additional funding, our ability to raise or access capital may be affected by** ~~economic~~ **macroeconomic events** ~~sanctions adopted in response to the conflict;~~ and ~~•~~ **disruptions to** the **banking and financial sectors. Failures of banks and** other **financial institutions, such as Silicon Valley Bank in March 2023, or issues in the broader U. S. financial system, including the federal government' s potential failure to raise the debt ceiling, may impact the broader capital markets, and in turn, may impact our ability to access those markets or negatively impact our investments. Further, a tightening of credit markets and lending standards could make it more difficult for us to raise capital through either debt or equity offerings on commercially reasonable terms or at all. Our forecasts regarding our beliefs in the sufficiency of our financial resources to support our current and planned operations are forward- looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of** factors ~~described~~ **, including the factors discussed elsewhere** in this " Risk Factors " section. **These estimates are based on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than currently expected. Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and marketable securities and to timely pay key vendors and others. Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and marketable securities and to timely pay key vendors and others. If banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future, we may be unable to access, and we may lose, some or all of our existing cash, cash equivalents and marketable securities to the extent those funds are not insured or otherwise protected by the FDIC.** In **addition** ~~the past~~ , ~~following periods of volatility~~ in ~~the market price~~ **such circumstances we might not be able to timely pay key vendors and others. We regularly maintain cash balances that are not insured or are in excess** of ~~a company~~ **the FDIC** ' s **insurance limit. Any delay in our ability to access our cash, cash equivalents and marketable** securities **(or the loss of some or all of such funds) or** ~~, securities class- action litigation has often been instituted against that company. Any lawsuit~~ to **timely** ~~which we are a party~~ -- **pay key vendors** ~~, with or without merit, may result in an~~ **and others could have a material adverse effect** ~~unfavorable judgment. We also may decide to settle lawsuits~~ on ~~unfavorable terms. Any such negative outcome could result in payments of substantial damages or~~ **our operations and** ~~fines, damage to our reputation or adverse changes to our offerings or business practices. Such litigation may also~~ cause us to **need to seek additional capital sooner than planned. We have incurred and will continue to** incur **significant legal, accounting and** other ~~substantial~~ **expenses as a public company that Former Enliven did not incur as a private company, including** costs **associated with public company reporting obligations under the Exchange Act** ~~to defend such claims and divert management' s attention and resources~~ . Our executive officers ~~, directors~~ and ~~principal stockholders, if they choose to act together~~ --- **other** ~~,~~ **personnel** have ~~the ability~~ **devoted and will continue** to ~~control~~ **devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with** all ~~matters submitted to stockholders for approval. As~~ of ~~December 31, 2022, our executive officers and directors and our stockholders who owned more than 5 % of our outstanding common stock, in the aggregate, beneficially owned shares representing approximately 39 % of our common stock. As a result, if~~ these ~~stockholders were~~ **requirements. Any changes we make** to ~~choose~~ **comply with these obligations may not be sufficient** to **allow us to satisfy our obligations as a public company on a timely basis, or** ~~act~~ - **at** ~~together, they would be able to significantly influence~~ all ~~matters submitted to our stockholders for approval, as well as our management and affairs~~ . ~~For example, these~~ **These** ~~persons~~ **reporting requirements** , ~~if~~ **rules and regulations, coupled with** ~~they~~ - **the** ~~choose to act together~~ **potential litigation exposure associated with being a public company** , ~~would~~ **could** ~~have significant influence over the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may: • delay, defer or prevent a change in control; • entrench our management and board of directors; or • delay or prevent a merger, consolidation, takeover or other business combination involving us that other stockholders may desire. This concentration of ownership may~~ also ~~adversely affect the market price of our common stock. We have broad discretion in the use of our cash, cash equivalents and investments and may not use them effectively. Our management has broad~~

~~discretion in the application of our cash, cash equivalents and investments and could use such funds in ways that do not, despite the exercise of reasonable judgement, improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of any product candidates we may develop. Pending their use, we may invest our cash, cash equivalents and investments in a manner that does not produce income or that loses value. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders. We have never declared or paid cash dividends on our capital stock and we have no current plans to pay cash dividends on our common stock. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock, impair our ability to raise capital through the sale of additional equity securities, and~~ make it more difficult for **us** ~~our stockholders~~ to **attract** ~~sell their common stock at a time~~ and **retain qualified** ~~price that they deem appropriate. Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such~~ persons ~~sell,~~ **to serve on the board of directors** or ~~indicate~~ **on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms. Once we are no longer** an ~~intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We currently have on file with the SEC a universal shelf registration statement which allows us to offer and sell registered common stock, preferred stock, debt securities, warrants and / or units from time to time pursuant to one or more offerings up to an aggregate of $ 200 million, at prices and terms to be determined at the time of sale. In July 2021, we issued and sold 8, 333, 333 shares of common stock with aggregate gross proceeds of approximately $ 50 million under this universal shelf registration statement. Moreover, holders of an aggregate of 11, 005, 600 shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all 4, 654, 296 shares of common stock that we may issue under our equity compensation plans and such shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates, vesting arrangements and exercise of options. We are an "~~ emerging growth company~~ **,** "~~ and~~ a "~~ smaller~~ reporting company **or otherwise no longer qualify for** ,"~~ and the reduced disclosure requirements~~ applicable **exemptions, we will be subject** to ~~emerging growth~~ **additional laws and regulations affecting public** companies **that will increase** ~~and smaller reporting companies may make~~ our ~~common stock less attractive to investors~~ **costs and the demands on management and could harm our operating results** . 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. However, as** an "~~ emerging growth company, "~~ ~~or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until December 31, 2025, although if the market value of our common stock that is held by non- affiliates exceeds $ 700. 0 million as of any June 30 before that time or if~~ we **may take advantage** ~~have annual gross revenues~~ of ~~$ 1. 235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $ 1. 0 billion of non- convertible debt over a three- year period. For so long as we remain an EGC, we are permitted and intend to rely on~~ exemptions from **various** ~~certain disclosure~~ requirements **such as an** ~~that are applicable to other public companies that are not EGCs. These exemptions~~ - **exemption from** ~~include: • being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure; • not being required to comply with~~ the ~~auditor attestation requirements~~ - **requirement** ~~in the assessment of~~ **to have our independent auditors attest to** our internal control over financial reporting ~~; •~~ **under Section 404 of the Sarbanes- Oxley Act of 2002 as well as an exemption from the " say on pay " voting requirements pursuant to the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010. After we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company " which may allow us to take advantage of some of the same exemptions from disclosure requirements including** not being required to comply with ~~any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to~~ the auditor **attestation requirements of Section 404 of** ~~' s report providing additional information about~~ the ~~audit~~ **Sarbanes- Oxley Act** and ~~the financial statements; •~~ reduced disclosure obligations regarding executive compensation **in** ~~; and • exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may choose to take advantage of some or~~ **our** ~~all of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, the JOBS Act permits an EGC to take advantage of an extended transition period~~ **periodic reports** ~~to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to take advantage of such extended transition period, which means that when a standard is issued or revised~~ and **proxy statements. Even after** ~~it has different application dates for public or private companies,~~ we ~~will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (1) irrevocably elect to " opt out " of such extended transition period or (2)~~ no longer qualify as an ~~EGC. We are also~~ **emerging growth company, we expect to still qualify as** a **"** smaller reporting company, ~~and we~~ **" as such term is defined in Rule 12b- 2 under the Exchange Act, in at least the near term, which** will

~~remain a smaller reporting~~ **allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to** ~~company~~ **comply** ~~until~~ **with** the ~~fiscal year following~~ **auditor attestation requirements of Section 404 of** the **Sarbanes** ~~determination that either (i) our voting and non-~~ **Oxley Act** ~~voting common shares held by non-affiliates is more than $ 250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenues are less than $ 100 million during the most recently completed fiscal year~~ and ~~our voting and non- voting common shares held by non- affiliates is more than $ 700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies have~~ reduced disclosure obligations **regarding** ~~, such as an exemption from providing selected financial data and an ability to provide simplified~~ executive compensation ~~information~~ **in the definitive proxy statement / prospectus** and ~~only two years of audited financial~~ **in our periodic reports and proxy** statements. **Once** ~~We have incurred and will continue to incur costs as a result of operating as a public company, and our management has devoted and will continued to be required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, and particularly after~~ we are no longer an ~~EGC~~ **emerging growth company** , **a smaller reporting company or otherwise 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 ~~that~~ **to do so. If** we ~~did~~ **are** not **able to** ~~incur as a private company~~ **comply with** ~~. The Sarbanes- Oxley Act of 2002,~~ the ~~Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing~~ requirements **in a timely manner or at all** ~~of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies~~ , **our** ~~including establishment and maintenance of effective disclosure and~~ financial **condition** ~~controls and corporate governance practices. Our management will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our~~ - **or** ~~legal and financial compliance costs~~ **the market price of our common stock may be harmed. For example** , **if** ~~particularly as~~ we **or our independent auditor identify deficiencies in our** ~~hire additional financial and accounting employees to meet public company~~ internal control ~~and financial reporting requirements, and will make some activities more time- consuming and costly. We continuously evaluate these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting with our Annual Reports on Form 10- K. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To comply with Section 404, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes- Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls~~ over financial reporting that are deemed to be material weaknesses **we could face additional costs to remedy those deficiencies, the market price of** ~~or~~ **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. Our issuance of additional capital stock pursuant to our equity incentive plan and employee stock purchase plan, or in connection with financings, acquisitions, or otherwise will dilute the interests of other security holders and may depress the price of our common stock. We expect to grant equity awards to employees, directors and consultants under our equity incentive plan and employee stock purchase plan. We will need substantial additional funding before we can complete the development of our product candidates. We may also raise capital through equity financings in the future. As part of our growth strategy, we may seek to acquire companies and issue equity securities to pay for any such acquisition. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline. Provisions** that **are in** ~~may require prospective or~~ **our** ~~retroactive changes to our financial statements~~ **certificate of incorporation and bylaws and provisions under Delaware law could make an acquisition of** ~~or~~ **our** ~~identify~~ **company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our management. Provisions that are included in our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or** other ~~areas~~ **change in control of us that stockholders may consider favorable, including transactions in which our common stockholders might otherwise receive a premium price** for **their shares**

~~further attention or improvement~~ . **These provisions** ~~Inferior internal controls~~ could also ~~cause~~ **limit the price that** investors **might be willing** to **pay** ~~lose confidence~~ in **the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors will be responsible for appointing the members of our management team, these provisions may frustrate** ~~our~~ **or** ~~reported financial information~~ **prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: • continue the use of a classified board of directors such that not all members of our board of directors are elected at one time; • allow the authorized number of our directors to be changed only by resolution of our board of directors; • limit the manner in which stockholders can remove directors from our board of directors; • provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our board of directors; • limit who may call stockholder meetings; • prohibit actions by our stockholders by written consent; • require that stockholder actions be effected at a duly called stockholders meeting; • authorize our board of directors to issue preferred stock without stockholder approval** , which could **be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that** have **not been approved by our board of directors; and • require the approval of the holders of at least 75 percent of the votes that all of our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or for our stockholders to amend our bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the " DGCL "), which generally prohibits** a ~~negative effect which generally prohibits a~~ person who,together with their affiliates and associates,owns 15 % or more of ~~a~~ **the** company' s outstanding voting stock from,among other things,merging or combining with the company for a period of three years after the date of the transaction in which the person acquired ownership of 15 % or more of the company' s outstanding voting stock,unless the merger or combination is approved in a prescribed manner.Our ~~restated~~ certificate of incorporation ~~designates~~ **generally provides that** the ~~state courts in~~ **Court of Chancery of** the State of Delaware ~~as~~ **is** the ~~sole~~ **exclusive forum for substantially all disputes between us** and ~~exclusive forum for certain types of actions and proceedings that may be initiated by~~ our stockholders,which could ~~discourage lawsuits against the company and~~ **limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or** our directors,officers ~~and~~ **or other** employees.Our ~~restated~~ certificate of incorporation provides that,unless ~~we~~ **the company** ~~consent~~ **consents** in writing to the selection of an alternative forum,the Court of Chancery of the State of Delaware (or,if the Court of Chancery of the State of Delaware does not have jurisdiction,the federal district court for the District of Delaware) **is** ~~will be~~ the sole and exclusive forum for the following types of proceedings:(1) any derivative action or proceeding brought ~~on~~ on **our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to the company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our restated certificate of incorporation or amended and restated bylaws (in each case, as** ~~the~~ **they** ~~trading price of~~ **may be amended from time to time)** ~~our~~ **or** ~~stock~~ **governed by the internal affairs doctrine** . ~~We~~ **This** ~~asserting a claim arising pursuant to any provision of our restated certificate of incorporation or amended and restated bylaws (in each case,as they may be amended from time to time) or governed by the internal affairs doctrine.These~~ choice of forum ~~provisions~~ **provision** will not apply to suits brought to enforce a duty or liability created by the Securities Act,the Exchange Act or any other claim for which federal courts have exclusive jurisdiction. ~~These~~ **This** exclusive forum ~~provisions~~ **provision** may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and may limit ~~the~~ **a stockholder' s** ability ~~of our stockholders~~ to bring a claim in a judicial forum that **it** ~~such stockholders find~~ **finds** favorable for disputes with us or our directors,officers or **other** employees **or stockholders** ,which may discourage such lawsuits against us and our directors,officers and **other** employees **and stockholders** .Alternatively,if a court were to find the choice of forum ~~provisions~~ **provision** contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action,we may incur additional costs associated with resolving such action in other jurisdictions,which **could materially and adversely affect our business,financial condition and results of operations.Our ability to utilize our NOLs and tax credit carryforwards may be subject to limitations.Following the Merger,our NOLs** are ~~required~~ **attributable** to ~~disclose changes made in our internal controls~~ **current year losses, as well as both the historic pre- Merger NOLs of Former Enliven** and ~~procedures on a quarterly basis and~~ our ~~management~~ **historic pre- Merger NOLs, subject to applicable limitations. As of December 31, 2023, the Company had federal NOLs of approximately $ 185. 3 million, of which approximately $ 177. 3 million do not expire and approximately $ 8. 0 million will begin to expire in 2037 for U. S. federal tax purposes. As of December 31, 2023, the Company also had California, Colorado and Massachusetts NOLs of approximately $ 126. 7 million, $ 4, 000 and $ 124. 2 million, respectively, which will expire at various dates through 2043 for state tax purposes. As of December 31, 2023, the Company had federal tax credit carryforwards of approximately $ 10. 5 million, which will begin to expire in 2036 for U. S. federal tax purposes. The Company also had state tax credit carryforwards of approximately $ 1. 3 million, of which approximately $ 0. 5 million will not expire. The remaining state tax credit carryforwards will expire at various dates through 2038. In general, our ability to use our NOLs and tax credit carryforwards to offset potential future taxable income and related income taxes that would otherwise be due** is **dependent upon our generation** ~~required to assess the effectiveness~~ of **future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs and tax credit carryforwards. For U. S. federal income tax purposes, under** ~~these~~ -- **the** ~~controls annually. However~~ **Tax Cuts and Jobs Act of 2017 (" TCJA")** , **as amended by the Coronavirus Aid, Relief, and Economic Security Act (" CARES Act "), NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but** for **taxable years beginning after December 31, 2020, the**

deductibility of federal NOLs is limited to 80 % of current year taxable income. It is uncertain whether and to what extent various states will conform to the federal tax laws. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state income taxes owed. In addition, under Internal Revenue Code of 1986, as ~~long as we are~~ **amended (" IRC") Section 382 and Section 383 of the Code, and corresponding provisions of state law, if a corporation undergoes** an " ~~emerging growth~~ **ownership change, " its ability to use its pre- change NOLs and other pre- change tax attributes (such as tax credit carryforwards) to offset its post- change income may be limited, including as a result of ownership changes that are beyond its control. A Section 382 " ownership change " is generally defined as a greater than 50 percentage point change (by value) in the** company ~~" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an " emerging growth company " for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management~~ ' s **equity ownership by certain " 5- percent shareholders "** ~~assessment might not. Undetected material weaknesses in our internal controls~~ over ~~financial reporting~~ **a rolling three- year period. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, existing NOLs** could ~~lead~~ **expire or otherwise be unavailable** to ~~financial statement restatements~~ **offset future income tax liabilities. The Company has completed** ~~and~~ **an** ~~require us to incur~~ **analysis and determined that ownership changes have occurred under Section 382 in** the ~~expense of remediation~~ **past, as well as in 2023 due to the Merger** . ~~Our disclosure~~ **The Company' s deferred tax assets have been reduced by the amount of NOLs and tax credit carryforwards expected to expire unused due to the Section 382 limitation. We may experience subsequent shifts in our stock ownership, some of which are outside of our** ~~controls~~ **control** ~~and procedures may not prevent or detect all errors or acts of fraud~~ . As a **result** ~~public company~~ , **if** we **earn net taxable income and determine that an ownership change has occurred and our ability to use our historical NOLs and tax credit carryforwards** are **materially limited, it will adversely affect our future operating results** ~~subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed~~ by **effectively increasing** ~~us in reports we file or~~ **our future income tax obligations** ~~submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected~~ . Changes in tax laws or in their implementation ~~or interpretation~~ may adversely affect our business ~~and~~ **, operating results, or** financial condition. Changes in tax law **, including changes to tax rates, tax treaties, and regulations or their interpretation, may cause us to experience fluctuations in our tax obligations and effective tax rates and otherwise** may adversely affect our business **, operating results,** or financial condition. ~~On~~ **For example, on** December 22, 2017, the **United States** ~~U. S.~~ government enacted the TCJA, which significantly reformed the Code. The TCJA, as amended by the CARES Act, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 %, the limitation of the tax deduction for net interest expense to 30 % of adjusted taxable income (except for certain small businesses), the limitation of the deduction for NOLs to 80 % of current year taxable income and the elimination of NOL carrybacks, in each case, for NOLs arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely **), the requirement for research** and ~~such NOLs arising in taxable~~ **experimental (" R & E ") expenditures to be capitalized for tax** years beginning ~~before January 1~~ **after December 31** , 2021 **, and the modification or repeal of many other business deductions and credits. In accordance with the TCJA, R & E expenditures under Internal Revenue Code Section 174** are **required** ~~generally eligible~~ to be ~~carried back up to~~ **amortized over a period of** five years ~~)~~ **for domestic expenses and 15 years for foreign expenses beginning in 2022. As a result** , **we have capitalized R & E expenditures in our current tax provision. However, recently proposed tax legislation, if enacted, would restore the ability to deduct currently domestic R & E expenditures through 2025 and would retroactively restore this benefit for 2022 and 2023. Any of** ~~the~~ **these** ~~imposition~~ **developments or future changes in federal, state, or international tax laws or tax rulings, including the release** of **regulatory guidance, could adversely affect our effective tax rate and otherwise affect our business, operating results, or financial condition. We do not anticipate that we will pay any cash dividends in the foreseeable future. The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As** a ~~one~~ **result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future. There may not be an active trading market for our common stock and our stockholders may not be able to resell their shares of common stock for a profit, if at all. Prior to the Merger, there had been no public market for shares of Former Enliven capital stock. An active trading market for our shares of common stock may not be sustained. If an active market for our common stock is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all. Future sales of shares by existing stockholders could cause our stock price to decline. Sales of a substantial number of shares of our common stock in the public market could occur at any time, including under the Shelf Registration or the Sales Agreement. Further, if our existing securityholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. Approximately 18 million shares became available for sale in the public market 180 days after the closing of the Merger as a result of the expiration of lock** - ~~time taxation~~ **up agreements. All other outstanding shares** of ~~offshore~~

~~earnings at reduced rates regardless of whether they~~ **common stock, other than shares held by our affiliates,** are ~~repatriated~~ **freely tradable** , **without restriction** ~~the elimination of U. S. tax on foreign earnings (subject to certain important exceptions)~~ , **in** the **public market** ~~allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits~~ . In addition **, shares of common stock that are subject** to **outstanding options of** the ~~CARES~~ **Company will 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 these shares are sold, the trading price of our common stock could decline. Our executive officers, directors and principal stockholders will have the ability to control or significantly influence all matters submitted to our stockholders for approval. As of December 31, 2023, our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially owned approximately 87. 3 % of our voting 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 ~~part~~ **well as our management and affairs, for example, the election** of ~~Congress' response to~~ **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** ~~the~~ **other** ~~COVID~~ **stockholders may desire. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to 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 the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline. We have broad discretion in the use of our cash, cash equivalents and marketable securities and the proceeds from the Former Enliven pre** - **closing financing** ~~19 pandemic, economic relief legislation has been enacted in 2020~~ and ~~2021 containing tax provisions~~ **may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment** . ~~In addition~~ **We have broad discretion over the use of our cash** , **cash equivalents and marketable securities and the proceeds from the Former Enliven pre- closing financing. 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** ~~the~~ **these** ~~Inflation~~ **resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our cash resources. Our internal control over financial reporting may not meet the standards required by** ~~Reduction --~~ **Section 404 of the Sarbanes- Oxley** Act, **and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act, could have a material adverse effect on** ~~or~~ **our** ~~the IRA~~ **business and share price. As a privately held company** , **Former Enliven** was ~~signed into law~~ **not required to evaluate its internal control over financial reporting** in ~~August 2022. The IRA introduced new tax provisions, including~~ a **manner that meets the standards of** ~~1 % excise tax imposed on certain stock repurchases by~~ publicly traded companies **required** ~~. In the absence of regulatory guidance, the 1 % excise tax generally applies to certain acquisitions of stock~~ by **Section 404 of** the ~~publicly traded company~~ **Sarbanes- Oxley Act** (**" Section 404 "** ~~or certain of its affiliates~~) ~~from a stockholder of~~ **. Our management is required to report on** the ~~company in exchange~~ **effectiveness of our internal control over financial reporting. The rules governing the standards that must be met** for ~~money or~~ **our management** ~~other property (other than stock of the company itself), subject~~ to ~~a de minimis exception. Thus~~ **assess our internal control over financial reporting are complex and require significant documentation** , ~~the excise tax~~ **testing and possible remediation. Any failure to maintain effective internal control over financial reporting** could **severely inhibit** ~~apply to certain transactions that are not traditional stock repurchases. Regulatory guidance under the TCJA and such additional legislation, is and continues to be forthcoming, and such guidance could ultimately increase or~~ **our ability to accurately report** ~~lessen the impact of these laws on~~ our ~~business and~~ financial condition **, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. General Risk Factors Our operations are vulnerable to interruption by flood, fire, earthquakes, power loss, telecommunications failure, terrorist activity, pandemics and other events beyond our control, which could harm our business. Our office facilities are located in Colorado. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major blizzard, flood, fire, earthquake, power loss, telecommunications failure, terrorist activity, pandemics or other disasters and do not have a recovery plan for such disasters** . In addition, ~~it is uncertain if and~~ **we do not carry sufficient insurance** to **compensate us for actual losses from interruption of our business** ~~what~~ **that may occur,** ~~extent various states will conform to the TCJA~~ and **any losses** ~~additional tax legislation. Provisions in our~~ - **or damages incurred by us** ~~corporate charter documents and under Delaware law~~ could ~~make~~ **harm our business. Also, our CROs** ~~an~~ **and** ~~acquisition of~~ **suppliers' facilities are located in multiple locations where other natural disasters** ~~our~~ - **or** ~~company,~~ **similar events** which ~~may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or~~

~~remove our current directors and members of management. Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions~~ could **severely disrupt** ~~also limit the price that investors might be willing to pay in the future for shares of~~ our **operations** ~~common stock~~, ~~thereby depressing the market price of~~ **could expose us to liability and could have a material adverse effect on** our **business** ~~common stock~~. In addition, ~~because~~ **telecommunication system failures** ~~our~~ **or disruptions could significantly disrupt** ~~board of directors is responsible for appointing the members of~~ our ~~management team,~~ **operations since our employees are primarily working remotely. The occurrence of any of** these ~~provisions may frustrate~~ **business disruptions could seriously harm** ~~or~~ **our operations and financial condition and increase** ~~prevent any attempts by our stockholders to replace or~~ **our** ~~remove~~ **costs and expenses. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil** ~~our~~ **or** ~~current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: • establish a classified board of directors such that only one of three classes of directors is elected each year; • allow the authorized number of our directors to be changed only by resolution of our board of directors; • limit the manner in which stockholders can~~ **an epidemic outbreak could have a negative effect** ~~remove directors from our board of directors; • establish advance notice requirements for stockholder proposals that can be acted~~ on ~~at stockholder meetings and nominations to~~ our **operations** ~~board of directors; • require that stockholder actions must be effected at a duly called stockholder meeting~~ and **the operations** ~~prohibit actions by our stockholders by written consent; • limit who may call stockholder meetings; • authorize our board~~ of **our suppliers** ~~directors to issue preferred stock without stockholder approval~~, which could **harm** be used to institute a " poison..... jurisdictions, which could materially adversely affect our business, financial condition and ~~operating~~ results **of operations** .